Ciba Specialty Chemicals Corporation
North America

Ciba

September 13, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Resources
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Via Next Day Courier
Return Receipt Requested

Subject: Citizen Petition: OTC Docket 75N-183H (triclosan)

Ciba Specialty Chemicals Corporation ("Ciba"), Home and Personal Care Segment and the Triclosan Industry Alliance (TIA)[1] submits this petition under 21 CFR § 10.30 requesting the Commissioner of Food and Drugs to re-open the administrative record to allow for the submission and evaluation of additional safety data supporting the Category I safety and long-term use status of triclosan in the proposed 21 CFR Part 333, the OTC Tentative Final Monograph for Health-Care Antiseptic Drug Products:

Triclosan, (2,4,4'-trichloro-2'-hydroxydiphenyl ether), has broad-spectrum antimicrobial activity against gram-positive and gram-negative bacteria. It has been safely utilized in health-care professional and consumer products including deodorants, soaps and dentifrices for over 30 years. The favorable safety profile of triclosan has been well established in numerous laboratory and clinical studies and through extensive human experience.

Ciba and the Triclosan Industry Alliance believe that all data necessary to support the Category I status of triclosan are currently available. These data have either been already submitted to the FDA or are included with this petition and are described herein.

Further, we believe the existing database on the carcinogenic potential of triclosan is adequate and that a dermal carcinogenicity study in rats is not necessary. Triclosan does not have the profile of either a human or a rat dermal carcinogen or of a rodent skin tumor promoter. The available database is adequate to support the conclusion that triclosan is not a dermal carcinogen. The conduct of a dermal carcinogenicity evaluation of triclosan in rats is unnecessary and is unlikely to add significant additional information to the assessment of the safety of this chemical.

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[1] Members of the Triclosan Industry Alliance include: Ciba Specialty Chemicals Corporation, Colgate-Palmolive, Dial Corporation, GlaxoSmithKline Consumer Healthcare, Procter & Gamble Company, Unilever United States Incorporated.

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P.O. Box 2444
High Point, NC 27261-2444

Tel. 888 396 2422

Action Requested

Under this Citizen's Petition, Ciba and the Triclosan Industry Alliance formally request that FDA:

- Re-open the administrative record to allow for the submission and evaluation of additional safety data (contained herein) supporting the Category I safety and long-term use status of triclosan;

- Waive the request for a chronic dermal carcinogincity study on triclosan based on information contained in the studies and position paper being submitted which demonstrates that the existing database on the carcinogenic potential of triclosan is adequate and that a dermal carcinogenicity study in rats is not necessary;

- Utilize the data referenced in this petition in support of the Category I status for triclosan in both the final Monograph for topical antimicrobial health-care products (comprised of products commonly described as pre-operative skin preparations, surgical scrubs and healthcare personnel hand products) and the planned Monograph for topical antimicrobial food handler, consumer hand, and consumer body products ; and

- Make a provision in the final Monograph or rulemaking for the continued use of triclosan until any additional studies deemed further necessary by the Agency to support the Category I status are completed and submitted.

Background

On June 17, 1994, FDA issued an amended "tentative final monograph (TFM)" which established the conditions under which (OTC) topical health-care antiseptic drug products are generally recognized as safe and effective and not misbranded (59 FR 31402). It also established a new subpart E under 21 CFR part 333 which covers health-care antiseptic products. Such products include products for personal use in the home and products used by health-care professionals.

This notice also amended the previous notice of proposed rulemaking on topical antimicrobial drug products which was issued on January 6, 1978 (43 FR 1210). The June 17, 1994 TFM was further amended by FDA on November 15, 1994 (59 FR 58799) to extend the comment period until December 15, 1995. Ciba submitted specific comments on this rulemaking (Docket No. 75N-183H) on June 19, 1995 and December 14, 1995.

FDA stated in the June 17, 1994 TFM that data previously submitted on a two-year chronic oral toxicity study in rats were unacceptable as the sole evidence of the safety of the long-term use of triclosan as a health-care personnel handwash or surgical

handscrub. FDA further stated that "data from another chronic exposure study" were necessary to assess the safety of the long-term use of triclosan.

In its comments of December 14, 1995, Ciba stated that it would perform a chronic study via the dermal route to support the long-term safety of triclosan, but that the data from these studies would not be available prior to FDA's December 15, 1995 deadline for further safety data submission. Ciba further requested that FDA not finalize the TFM with regard to triclosan unless it believed that the current data were sufficient to classify triclosan as a Category I ingredient or until ongoing and planned studies were completed and reviewed by the Agency. Ciba and the TIA have been working with the FDA since the issuance of the June 17, 1994 TFM to develop the data needed to support the long-term use of triclosan as a Category I ingredient.

Current Situation

Since the publication of the June 17, 1994 TFM, Ciba and members of the TIA have maintained a healthy dialogue with key officials at FDA regarding the need for a chronic dermal carcinogencity study on triclosan and have made several submissions to the OTC Docket (75N-183H) in support of the long-term use of triclosan as a Category I ingredient. The most relevant of these submittals include the following:

- A 16 volume submission on September 12, 1994 which included various metabolism, mutagencity, and genotoxicity studies; selected excerpts from an independent expert panel report on the safety of triclosan; a summary of the current safety data available on triclosan; a pathology working group report of a triclosan 90-day oral subchronic study in Sprague-Dawley rats; a 13-week subchronic oral toxicity study of triclosan in CD-1® mice; and a 90-day subchronic dermal toxicity study in the rat with satellite group;
- A TIA report entitled "Species Selection for Chronic Dermal Testing with Triclosan" on June 23, 1997;
- Submission of a study protocol (13-week dermal subchronic study of triclosan in rats) on March 6, 1998; and
- A chronic exposure study submitted on September 15, 1999 on the potential tumorigenic and chronic toxicity effects of triclosan following prolonged dietary administration to hamsters

During 1997, Ciba and the TIA had several communications with FDA regarding study species selection for the dermal study and agreed that the rat was the appropriate species for conducting the dermal carcinogenicity study. On June 23, 1997 a study protocol for a dermal subchronic study in rats was submitted for Agency review. Following this submission, several communications were made with the Agency regarding test (control) vehicle (i.e., acetone) and measurable end-points. However, difficulties were encountered in finding a test vehicle that would be representative of those used in liquid carriers used for final formulations. All test vehicles tested (acetone, propylene glycol) were too harsh (regardless of species) for conducting a long-term

dermal carcinogenicity study. Following this exercise, the results of three different repeated dose studies were discussed with FDA. However, these reports were not submitted to the docket. These reports (identified below) are now enclosed with this Petition for inclusion (and FDA review) into OTC Docket 75N-183H.

- Burns, J.M., et. al, *14-Day Repeated Dose Dermal Study of Triclosan in Rats*, CHV 6718-102, Corning Hazelton, Inc., April 28, 1997
- Burns, J.M., et. al, *14-Day Repeated Dose Dermal Study of Triclosan in Mice*, CHV 6718-101, Corning Hazelton, Inc., April 28, 1997
- Burns, J.M., et. al, *14-Day Repeated Dose Dermal Study of Triclosan in CD-1 Mice*, CHV 2763-100, Corning Hazelton, Inc., April 29, 1997

Following the generation of this data, members of the TIA had a conversation with Dr. Robert Osterberg of FDA on August 12, 1998 questioning the need for conducting a chronic dermal carcinogencity study on triclosan, given that the results of a new two year bioassay in hamsters would be available soon and sufficient safety data already exist that preclude the need for a chronic dermal carcinogencity study on triclosan. As part of this discourse, consideration was given to the possibility of eliminating the need for conducting a two-year dermal carcinogencity study via submission of the two-year hamster study and reasonable findings from the 90-day dermal study submitted on September 12, 1994. FDA suggested that if data regarding the potential issue of dermal irritation were submitted together with data from the two-year hamster study, such data might be sufficient to remove the lifetime dermal study requirement.

Following the completion and submission of the long-term hamster study and in follow-up to FDA's suggestion of August 12, 1998, the TIA prepared a position paper titled: *"Triclosan: Adequacy of Data to Support the Lack of Potential for Dermal Carcinogencity"* in August, 2001. The main premise of this paper is that the TIA believes that the existing database on the carcinogenic potential of triclosan is adequate and that a dermal carcinogenicity study in rats is not necessary. Key issues raised in this paper include the following:

- Triclosan does <u>not</u> have the profile of biological activities of any known human skin carcinogen or skin cancer risk factor;
- Triclosan is nongenotoxic and is unlikely to be a rat skin carcinogen since these agents appear to be predominantly genotoxic;
- Triclosan does not cause skin hyperproliferative changes such as acanthosis at typical use levels;
- Dermal carcinogenicity studies with other compounds demonstrate that there is no simple association between chronic skin irritation and skin carcinogenesis;

- The available data from the rat, hamster and mouse cancer bioassays with oral dosing of triclosan are adequate to assess the carcinogenic potential of triclosan;

- Extensive human experience with triclosan through both controlled clinical studies and over 30 years of safe product use support the dermal safety of this material; and

- The conduct of a dermal carcinogenicity evaluation of triclosan in rats is unnecessary and is unlikely to add significant additional information to the assessment of the safety of this chemical.

On August 8, 2001, members of the TIA contacted FDA regarding this position paper and it was suggested that Ciba and the TIA submit a Citizen's Petition to the docket to reopen the administrative record and amend the TFM to include triclosan. Copies of this position paper are included with this Petition. Ciba and the TIA formally request that FDA review the information contained in and submitted with this Citizen Petition in support of the long-term use and safety of triclosan at concentrations of up to 1 percent.

Ciba and the TIA are aware that the Agency is currently developing a Monograph for topical antimicrobial healthcare professional products which will be comprised of products commonly described as pre-operative skin preparations, surgical scrubs and healthcare personnel hand products. Ciba also understands that the FDA will address the remaining product categories (i.e., food handler products, consumer hand products and consumer body products) sometime in the future under a separate monograph. If the Agency feels that additional studies are needed to support the Category I status of triclosan, Ciba formally requests that the FDA not finalize triclosan in the Monograph or make a provision in the final Monograph or rulemaking for the continued use of triclosan until those studies are completed and submitted to the Agency.

Environmental impact

According to 21 CFR 25.31(c), this petition qualifies for a categorical exclusion from the requirement for submission of an environmental assessment.

Economic impact

According to 21 CFR 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of the petition.

Certification

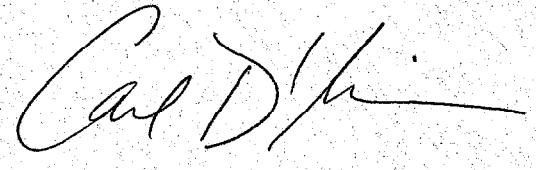
The undersigned certifies that, to the best of his/her knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data known to the petitioner which are unfavorable to the petition.

Conclusion

Ciba and the TIA concludes that the available data are sufficient to support the safety of both short- and long-term uses of triclosan in topical applications containing up to 1 percent active ingredient. As such, we believe triclosan should be granted Category I status for long-term use and safety under FDA's Monograph for antimicrobial health-care and consumer/food-handler products.

At this time, Ciba also wishes to notify the Agency that additional data supporting the Category I efficacy status of triclosan will be submitted under a separate petition shortly. Ciba and the TIA are open to discussing this further with the FDA if necessary. Please contact the undersigned at (336) 801-2493 if there are any further questions or comments regarding this petition.

Sincerely,



Carl David D'Ruiz, MPH

Chair TIA Regulatory Task Force and
Head, Product Stewardship & Regulatory Affairs
Home and Personal Care Segment

Attachments

Desk copy:

Charles J. Ganley, MD
Dr. Robert Osterberg
Dr. Norman See
Debbie Lumpkins
Dr. Jonathan Wilkin
OTC Docket No. 78N-0038

Cc:

K. Hostetler
C. Ehrenberger
M. Bernheim
J. Plautz
TIA Regulatory Task Force

Ciba Specialty Chemicals Corporation
North America

Volume 118

Ciba

OTC Docket No. 75N-183H

(triclosan)

Burns, J.M., et. al, *14-Day Repeated Dose Dermal Study of Triclosan in Rats*, CHV 6718-102, Corning Hazelton, Inc., April 28, 1997

Ciba Specialty Chemicals Corporation
Home & Personal Care Segment
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September 13, 2001

This Submission: Volume 1 of 1 Volume

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RAT/Acetone

SPONSOR: Triclosan Industry Alliance DATE: April 28, 1997

MATERIAL: Triclosan

SUBJECT: AMENDMENT 2 TO FINAL REPORT
14-Day Repeated Dose Dermal Study of Triclosan in Rats
Study No. 6718-102

This report, with the exception of Attachment 1 (photographs), supersedes the report dated November 15, 1996, in response to changes requested by the Sponsor.

Study Director:

John M. Burns, M.S., D.V.M., M.B.A., M.A.
Department of Toxicology

4/28/97
Date

CORNING Hazleton

Sponsor:

Triclosan Industry Alliance
Contact: Ciba-Geigy Corporation, Chemicals Division
P.O. Box 18300
Greensboro, North Carolina 27419-8300

AMENDMENT 2 TO FINAL REPORT

Study Title:

14-Day Repeated Dose Dermal Study of Triclosan in Rats

Author:

John M. Burns, M.S., D.V.M., M.B.A., M.A.

Amendment Completion Date:

April 28, 1997

Performing Laboratory:

Corning Hazleton Inc. (CHV)
9200 Leesburg Pike
Vienna, Virginia 22182-1699

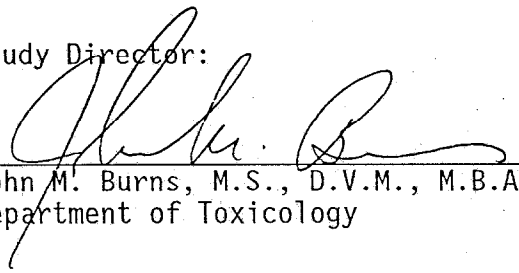
Laboratory Study Identification:

CHV 6718-102

COMPLIANCE STATEMENT
14-Day Repeated Dose Dermal Study of Triclosan in Rats

This study, as performed by Corning Hazleton Inc., was conducted in compliance with the Good Laboratory Practice Regulations as set forth in Title 21 of the U.S. Code of Federal Regulations Part 58, issued December 22, 1978 (effective June 20, 1979), and with any applicable amendments, with the exception that the protocol did not contain the date of approval of the protocol by the Sponsor. Deviations from the protocol are listed in Appendix 9. There were no deviations from the aforementioned regulations which affected the quality or integrity of the study or the interpretation of the results in the report.

Study Director:



John M. Burns, M.S., D.V.M., M.B.A., M.A.
Department of Toxicology

4/28/97
Date

QUALITY ASSURANCE STATEMENT
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Quality Assurance inspections and reviews of this study were conducted according to the standard operating procedures of the Quality Assurance Unit and according to the Good Laboratory Practice regulations of the Food and Drug Administration (FDA), Title 21 of the U.S. Code of Federal Regulations Part 58, issued December 22, 1978 (effective June 20, 1979), and with any applicable amendments. These inspections and reviews were performed and findings were reported to the Study Director and management as follows:

Dates of Inspection/Review	Dates Findings Reported	Inspector/Reviewer
Protocol Review:		
4/15,23/96	4/23/96	L. Cassell
Inspection and/or Data Review:		
4/24/96	4/24/96	L. Cassell
5/9/96	5/9/96	L. Cassell
5/16,17,20/96	5/20/96	D. Bland
Report and Data Review:		
8/13-21/96	8/21/96	D. Kuhn
8/25-27/96	8/27/96	D. Kuhn
11/15/96	11/15/96	K. Maloid
Amendment #1:		
11/21/96	11/21/96	K. Maloid
Amendment #2:		
4/24/97	4/24/97	K. Maloid

Kim Maloid 4/28/97

Kim Maloid
Quality Assurance Unit

Date Released

STUDY IDENTIFICATION
14-Day Repeated Dose Dermal Study of Triclosan in Rats

CHV Study No.:	6718-102
Test Material:	Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether)[a]
Study Monitor:	Keith Hostetler, Ph.D., D.A.B.T. Chemicals Division Ciba-Geigy Corporation P.O. Box 18300 Greensboro, North Carolina 27419-8300 (910) 632-7237
Sponsor:	Triclosan Industry Alliance Contact: Ciba-Geigy Corporation,Chemicals Division P.O. Box 18300 Greensboro, North Carolina 27419-8300
Study Director:	John M. Burns, M.S., D.V.M., M.B.A., M.A. Corning Hazleton Inc. (CHV) 9200 Leesburg Pike Vienna, Virginia 22182-1699 (703) 893-5400
Study Timetable	
Study Initiation	April 22, 1996
Initiation of Dosing:	April 24, 1996
Necropsy:	May 9 and 10, 1996

[a] Also identified in the raw data as IRGASAN DP 300. For reporting purposes, the test material will be identified as Triclosan.

STUDY PERSONNEL
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Study Director:	John M. Burns, M.S., D.V.M., M.B.A., M.A.
Scientific Director:	Michael R. Moore, Ph.D., D.A.B.T.
Toxicologist:	David Dehler, M.A.
Study Coordinator:	J. F. Arrington, Jr., B.S.
Veterinarian:	William E. Ridder, D.V.M., M.S., Ph.D.
Pathologist:	John M. Burns, M.S., D.V.M., M.B.A., M.A.
Biostatistician:	Ajit K. Thakur, Ph.D.
Formulations/Analytical Chemistry Supervisor:	Mark Smyth, B.S.
Laboratory Supervisor:	Nancy M. Centanni, M.S., LATg
Laboratory Group Leader:	Magdaline F. Palmer, B.S.
Laboratory Head Technician:	Abdullah S. Hassan, B.S.

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SUMMARY

This study was designed to evaluate the dermal toxicity of Triclosan in acetone when applied to the skin of rats 7 times a week for at least 14 days and to provide a scientific basis for dose selection for a possible subsequent 90-day dermal study.

One hundred forty Crl:CD®BR rats (70 males and 70 females) were randomized by weight into seven groups with equal sex populations. Until the day before scheduled sacrifice, each animal in Groups 2-7 received Triclosan as a dermal solution in acetone at levels of 0, 0.3, 0.6, 1.5, 3.0, or 6.0 mg/animal/day respectively. Group 1 was held as an untreated control but, with the exception of application of an acetone solution, was handled in the same manner as animals in the other groups. At necropsy, blood was collected to determine plasma levels of Triclosan.

Acetone solutions of Triclosan were prepared daily. Solutions prepared on Study Days 1 and 8 were analyzed.

Criteria used to evaluate compound effects were mortality, appearance and behavior, clinical changes at the site of application (graded prior to treatment on Study Days 1, 4, 8, 11 and 15), food consumption, body weight gain, body weight, liver and brain weights, macroscopic organ changes, and histologic changes in liver and at the site of application.

There were no unscheduled deaths during the course of this study. Appearance and behavior, were comparable among the various groups.

Test-material related clinical changes consisting of erythema in 6.0 mg/day females and scaling in 6.0 mg/day animals of both sexes were observed at the site of application. The occasional observation of these or other changes in other sex-groups was considered incidental.

Food consumption was comparable between animals treated with Triclosan in acetone and animals treated with acetone alone. No

INTRODUCTION

This study was designed to evaluate the dermal toxicity of Triclosan in acetone when applied to the skin of rats seven times a week for at least 14 days, and to provide a scientific basis for dose selection in a possible subsequent 90-day dermal study. Dosing began on April 24, 1996, and terminal sacrifices were conducted on May 9 and 10, 1996.

The study, as performed by CHV, was conducted in compliance with the Good Laboratory Practice Regulations as set forth in Title 21 of the U.S. Code of Federal Regulations Part 58, issued December 22, 1978 (effective June 20, 1979), and with any applicable amendments.

The protocol was reviewed and approved by the Institutional Animal Care and Use Committee at CHV and is presented in Appendix 7. Deviations from the protocol are presented in Appendix 8.

TEST AND VEHICLE/CONTROL MATERIALS

The test material, Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether), batch No. P409198, was received from Ciba-Geigy Corporation on June 6, 1996, and stored at room temperature and protected from light in brown glass bottles. It was described as a white powder with a reported purity of 99.3%. Methods of synthesis and stability, composition, or other characteristics which define the test material are on file with the Sponsor.

The vehicle/control material, acetone (lot No. 13A139), was received from Baxter Health Care on November 2, 1995 (expiration date: November 2, 1996), and stored at room temperature. It was described as a clear, colorless liquid with an assumed purity of 100%.

Archive samples of the test article (5 g) and vehicle/control material (10 mL) were taken at initiation and stored at room temerature, protected from light.

Unused test article will be used in subsequent studies.

TEST ANIMALS AND HUSBANDRY

A total of 168 (84/sex) approximately 4-week-old Crl:CD®BR rats was received on April 9, 1996, from Charles River Laboratories, Raleigh, North Carolina. Animals were assigned temporary numbers, acclimated to laboratory conditions for approximately 2 weeks, and released for study use by a staff veterinarian.

Caging Conditions - Upon receipt, animals of the same sex were housed two/cage in suspended stainless-steel, wire-mesh cages measuring 24.2 x 22.0 x 17.3 cm (d x w x h). Beginning 1 week prior to dosing (at initiation of the prestudy food consumption data collection), they were individually housed. Cages were rotated weekly to ensure similar exposure to light.

Feed and Water - PMI® Certified Rodent Diet® #5002 and tap water, via an automatic watering system, were available ad libitum during the acclimation and study periods, unless otherwise noted. The feed was analyzed by the manufacturer for concentrations of specified heavy metals and nutrients, aflatoxin, chlorinated hydrocarbons, and organophosphates. Water samples are routinely analyzed for specified microorganisms, pesticides, heavy metals, alkalinity, and halogens. The water meets the criteria specified for human drinking water in Fairfax County, Virginia. Results of the feed and water analyses are reviewed by the Department of Laboratory Animal Medicine for compliance to specified limits and are on file at CHV.

No contaminants were known to be present in the diet or water at levels which might interfere with this study.

Environmental Conditions - The temperature and relative humidity in the animal room were monitored at least once daily and ranged from 19.4 to 24.3°C (66.9 to 75.7°F) and 40.0 to 53.5%, respectively. Ten or

greater air changes/hour and a 12-hour light/12-hour dark cycle (approximately 0600 to 1800 hours) were maintained.

Justification for Number of Animals on Study - This study was designed to use the fewest number of animals possible, consistent with the objective of the study, the scientific needs of the Sponsor, contemporary scientific standards, and in consideration of applicable regulatory requirements.

Justification of Species - Rats may be used in subsequent subchronic and chronic oncogenicity studies. Rats historically have been used in dermal carcinogenicity evaluations and are recommended by appropriate regulatory agencies. A large database on longevity and the incidence of spontaneous pathologic lesions exists for the rat.

METHODS

Group Assignment and Dosage Levels

Animals were initially accepted into the randomization pool based upon physical examinations and food consumption; animals with findings were eliminated from the randomization pool. A total of 140 rats (70/sex) was assigned to study using a computerized weight-randomization program, which first eliminated the animals with extreme body weights, then selected the random assignment that produced homogeneity of variance and means by Bartlett's Test (1937) and One-Way Analysis of Variance (ANOVA). At randomization, the weight variation of the animals selected did not exceed ±2 standard deviations of the mean body weight for each sex, and the mean body weight for each group of each sex was not statistically different. Animals were assigned to study groups as follows:

Group	Dosage Level mg/animal/day	Concentration mg/mL	Number of Animals Male	Number of Animals Female	Animal Numbers Male	Animal Numbers Female
1 (Untreated Control)	0	-	10	10	B75770-B75779	B75780-B75789
2 (Vehicle Control)	0	-	10	10	B75790-B75799	B75800-B75809
3	0.3	1.00	10	10	B75810-B75819	B75820-B75829
4	0.6	2.00	10	10	B75830-B75839	B75840-B75849
5	1.5	5.00	10	10	B75850-B75859	B75860-B75869
6	3.0	10.00	10	10	B75870-B75879	B75880-B75889
7	6.0	20.00	10	10	B75890-B75899	B75900-B75909

During the randomization process, each study animal was assigned a unique number. A microidentification device implanted subcutaneously was used to permanently identify each animal.

At initiation of dosing, the animals were approximately 6-7 weeks of age with body weights ranging from 200 to 241 g for the males and 140 to 180 g for the females.

Animals not used on study were removed from the study room.

Application Site

The site of application was an approximate 2- x 3-cm area on the dorsal skin of the back. At least 24 hours prior to the first dose and during the next 18 days as needed, the whole back region, including the application site, was clipped free of hair to allow uniform application of doses and clear observation of the application site. (The location of any skin nicks was noted and mapped on a diagram.) Untreated and vehicle/control rats were clipped at the same frequency as the treated rats.

Application Method

Dosing solutions were applied at a fixed volume of 300 μL per application. The treated animals were dosed at approximately the same

time each day through the day prior to the scheduled necropsy. The application started at the nape of the neck and extended approximately 3 cm down the back and approximately 1 cm on each side of the midline. Templates were used to aid in defining the test site and to help ensure that the test article was reproducibly applied to approximately the same area on the dorsal skin.

Appropriate micropipetting devices (dedicated for each dose level) were used and the dose was evenly distributed over the application site. A new disposable pipette tip was used for each animal. The Group 1 animals served as the untreated control group. The Group 2 animals were treated with the vehicle, acetone, in the same manner as the treated animals.

Other than control at the time of actual application, no additional procedures were implemented to prevent spread of the compound beyond the intended site of application or to prevent incidental ingestion due to normal grooming behavior.

The dermal route was chosen because it is an expected route of human exposure and is the route to be used on subsequent subchronic and chronic studies of Triclosan in rats.

Compound Formulation

Dosing formulations were mixed daily and components were assumed to be 100% pure for the purpose of dosage preparation. To prepare the dosing formulation, a stock solution for Group 7 was formulated using the following steps: (1) the required amount of Triclosan was weighed on an mg balance and transferred into a volumetrically precalibrated beaker, (2) acetone was added until the final volume was achieved, and (3) the mixture was stirred on a magnetic stirrer for approximately 15 minutes. To prepare the dosing formulation for Groups 3-6, the required amount of the Group 7 stock solution was measured into a volumetrically precalibrated beaker and the solution was diluted with the appropriate amount of acetone

(following Steps 2 and 3 as previously described). The dosing solutions were transferred into brown glass vials for dosing. To prevent the compound from evaporating, each dose group's vial was opened immediately prior to dosing of the first animal of that group.

On Days 1 and 8, samples (5 mL each) from Group 2-7 dose preparations were taken and transferred to the analytical chemistry laboratory for analysis.

Analysis of Prepared Formulations

Routine Concentration - The samples taken on Days 1 and 8 from the Group 2-7 dose preparation mixes were analyzed in duplicate for concentration of the test material.

Analytical Method - Routine concentration analyses were performed using high-performance liquid chromatography. The method is fully outlined in Appendix 1.

Observations and Records

Mortality and Clinical Observations - The rats were observed for mortality and moribundity twice daily, with at least 6 hours between each observation period. A careful cageside observation for obvious indications of toxic effects was performed once daily. Subsequently, these signs were recorded during the prescheduled daily clinical observations or physical examinations, as appropriate. Physical examinations were performed at least once prior to initiation of dosing and weekly thereafter (examinations were done prior to daily dosing). This examination included pharmacological and toxicological findings.

Dermal Irritation - The treated skin was graded for irritation prior to treatment (Day 1) and on Days 4, 8, 11, and 15 according to the following scale:

Scale for Evaluation of Skin Reactions

Erythema (not including eschar area)
0 - None
1 - Slight (barely perceptible)
2 - Moderate (well-defined)
3 - Marked (beet red)

Edema (not including eschar area)
0 - None
1 - Slight (barely perceptible)
2 - Moderate (raised approximately 1 mm)
3 - Marked (raised more than 1 mm)

Scaling (not including eschar area)
0 - None
1 - Slight (slight scaling without evidence of peeling)
2 - Moderate (large flakes with sloughing)
3 - Marked (pronounced flaking denuded areas)

Fissuring (not including eschar area)
0 - None
1 - Slight (definite cracks in epidermis)
2 - Moderate (cracks in dermis)
3 - Marked (cracks with bleeding)

Eschar** (exudate, crust)
N - No
Y - Yes

Exfoliation** (sloughing of the eschar tissue)
N - No
Y - Yes

Ulcer** (loss of epidermis)
N - No
Y - Yes

Scale for Evaluation of Skin Reactions - continued

Alopecia***
N - No
Y - Yes

Nonviable (dead) tissue**
N - No
Y - Yes

Thickening (not including eschar area)
N - No
Y - Yes

* Grades assigned were based on the most severely affected area except where area was judged to be <20% of the treatment site. Severe reactions occurring on <20% of a site were described in a footnote.

** Scoring discontinued on portion of test site with eschar, exfoliation, ulcer or nonviable (dead) tissue. The dimensions of the individual lesions or the approximate percentage of the treated area affected were noted.

*** The approximate percentage of the treatment area affected was noted.

Body Weight and Food Consumption - Body weights were recorded at randomization, prior to treatment, weekly thereafter and at study termination. Food consumption was measured and recorded 1 week prior to treatment and weekly thereafter.

Blood Sampling at Termination

On the day of scheduled necropsy, blood was taken from each rat by puncture of the orbital plexus (following carbon dioxide/oxygen inhalation anesthesia), collected in a lithium-heparinized container, and processed for plasma. Animals were fasted overnight (with water available) prior to the blood collection. Individual samples were

maintained at approximately -20°C. Residual plasma samples will be stored at approximately -20°C until report finalization and then discarded.

Terminal Studies

Sacrifice and Gross Pathology - All animals were weighed the day of scheduled necropsy, given an intraperitoneal injection of sodium pentobarbital, and exsanguinated. Necropsies were performed on all animals by appropriately trained personnel using procedures approved by board-certified pathologists, and all findings were recorded. Each necropsy was performed under the direct supervision of a veterinary pathologist. Necropsies included examination of the following:

all orifices
carcass
cervical tissues and organs
cranial cavity
external surface of the body
external surface of the brain
nasal cavity and paranasal sinuses
thoracic, abdominal, and pelvic cavities/viscera
application site

Photographs (taken with color slide film) of gross lesions representative of the findings were taken for each dose level.

Organ Weights - The brain (including brain stem) and liver were weighed after careful dissection and trimming of fat and other contiguous tissue. Liver- and brain-to-terminal-body-weight and liver-to-brain-weight ratios were calculated.

Tissue Preservation - The following tissues (when present) from each animal were preserved in 10% neutral-buffered formalin: lesions, liver, and skin (treated and untreated sites, including subcutis and muscular layers).

Histopathology - The following tissues were embedded in paraffin, sectioned, stained with hematoxylin and eosin, and examined microscopically: skin from the application site, untreated skin from the lateral side, liver, and macroscopic lesions. Skin sections were oriented to permit evaluation of epidermal, dermal, and folliculosebaceous units.

Statistical Analyses

The mean values in the summary tables for body weights, body weight changes, food consumption (excluding pretreatment values), fasted terminal body weights, and organ weight data of the treated groups (Groups 3-7) were compared statistically to the data from the same sex of the vehicle control group (Group 2).

Initially, Levene's test (at the 5.0% probability level) was performed to determine if the groups demonstrated equal variances. If no significant difference was revealed by this test, parametric analyses was conducted. If unequal variances were detected by Levene's test, rank transformation of the data was conducted. In those cases, all succeeding analyses was conducted on the rank-transformed data. It should be noted that analysis of variance and related procedures on ranked data are statistically identical to nonparametric tests such as Kruskal-Wallis and Wilcoxon-Mann-Whitney tests.

Tests included one-way ANOVA (at the 5.0% probability level) to assess differences across all groups. When significant differences were observed, Dunnett's test was applied for pairwise comparisons of each treatment group against the vehicle control group (at 5.0% and 1.0% probability levels). If Dunnett's test revealed significant differences, linear regression/Terpstra-Jonckheere test was performed to evaluate whether a dose-related trend exists.

Irritancy scores were analyzed by categorical methods including exact tests for heterogeneity and association when the tables were sparse using StatXact Turbo (Cytel, 1994).

Statistical significance is designated throughout the text of this report by the term *significant*.

Record Retention

All paper raw data, documentation, records, protocol, specimens (wet tissues, paraffin blocks, and slides), archive samples of test

article and vehicle, and final report generated as a result of this study will be archived in the storage facilities of Corning Hazleton for a period of 10 years following submission of the final report (final report completion date). Ten years after submission of the final report, all of the aforementioned materials will be sent to the Sponsor or the Sponsor may elect to have the materials retained in the Corning Hazleton Archives for an additional period of time. All raw data stored on magnetic media will be retained by Corning Hazleton.

RESULTS

Analytical Chemistry

Results of analyses for routine concentration are presented in Table 1.

Results of routine concentration analyses indicated that all formulations were within 8% of target.

In-life Observations

Clinical Observations - No clinical observations or tumors were noted during the course of this study.

Dermal Irritation Scores - A summary of the incidence of dermal irritation scores are presented in Table 2 and presented individually in Appendix 2.

Dose-related clinical changes consisting of erythema for Group 7 females and scaling for Group 7 males and females were observed at the site of application, as summarized in Text Table 1. Statistical evaluation of affected animals revealed increased means compared to Group 2 in all groups examined; p-values are presented in Text Table 2.

Text Table 1
Incidence of Dermal Irritation

Sex:	Male			Female		
Group:	5	6	7	5	6	7
Dose Level: (mg/animal/day)	1.5	3.0	6.0	1.5	3.0	6.0
Type of Skin Reaction						
Erythema		1/40	2/40	1/40		11/40
Scaling			14/40		1/40	32/40
Eschar			7/40	1/40	2/40	12/40
Thickening						2/40

Gradings were collected on Days 4, 8, 11, and 15. Maximum occurrence is 40/sex/group.

Text Table 2
Results of Statistical Evaluation of Dermal Irritation

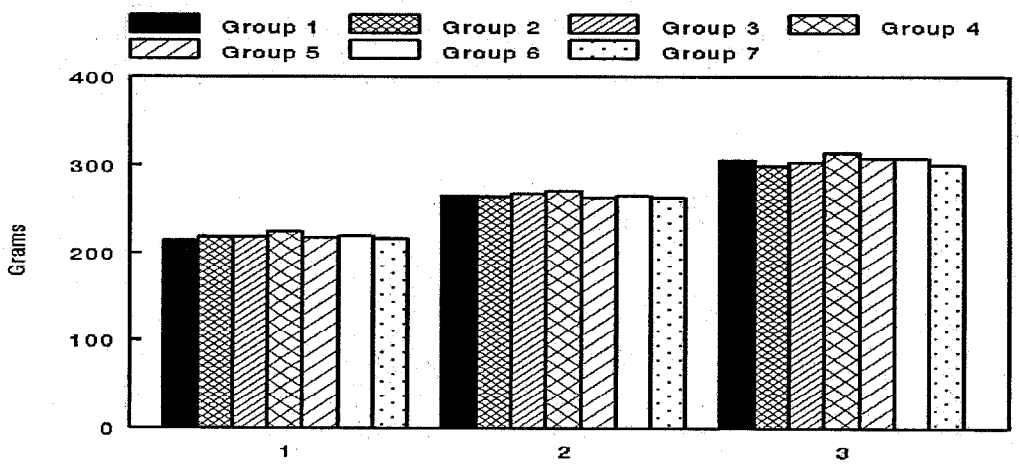
Observation	Group Analyzed	Male p-value	Female p-value
Erythema			
Day 4	2 vs. 7	a	.5000
Day 8	2 vs. 7	a	.0433 *
Day 11	2 vs. 7	a	.0433 *
Day 15	2 vs. 3-7		.0298 *
	2 vs. 3	a	a
	2 vs. 4	a	a
	2 vs. 5	a	.5000
	2 vs. 6	a	a
	2 vs. 7	a	.2368
Eschar			
Day 4	2 vs. 7	.5000	.5000
Day 8	2 vs. 3-7		.0004 **
	2 vs. 3	a	a
	2 vs. 4	a	a
	2 vs. 5	a	a
	2 vs. 6	a	.5000
	2 vs. 7	.2368	.0433 *
Day 11	2 vs. 3-7		<0.0001 **
	2 vs. 3	a	a
	2 vs. 4	a	a
	2 vs. 5	a	a
	2 vs. 6	a	.5000
	2 vs. 7	.2368	.0163 *
Day 15	2 vs. 3-7		.0298 *
	2 vs. 3	a	a
	2 vs. 4	a	a
	2 vs. 5	a	.5000
	2 vs. 6	a	a
	2 vs. 7	.2368	.2368
Scaling			
Day 4	2 vs. 7	a	.0433 *
Day 8	2 vs. 3-7		<0.0001 **
	2 vs. 3	a	a
	2 vs. 4	a	a
	2 vs. 5	a	a
	2 vs. 6	a	.5000
	2 vs. 7	.0054 **	<0.0001 **
Day 11	2 vs. 7	.0163 *	<0.0001 **
Day 15	2 vs. 7	a	.0004 **

Note: p-values are shown only for groups that warranted statistical evaluation.
a = No evaluation performed; response pattern in the treated group is the same as in Group 2.
* = Significant at $p \leq 0.05$
** = Significant at $p \leq 0.01$

Body Weight and Food Consumption - Mean body weight data are presented in Table 3A and depicted graphically in Figure 1; body weight change data are presented in Table 3B. Individual body weight and body weight change data are presented in Appendices 3A and 3B, respectively. Mean food consumption data are presented in Table 4 and depicted graphically in Figure 2. Individual data are presented in Appendix 4.

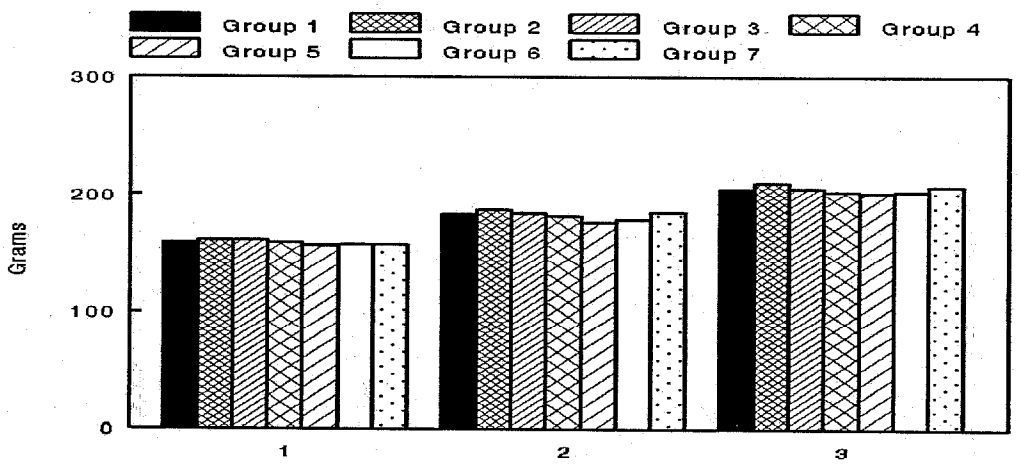
There were no significant differences in the mean weekly or total body weight or food consumption values when compared to control Group 2. Mean body weight changes were significantly higher than control Group 2 for the Group 4 and 5 males at Week 2.

Figure 1
Mean Body Weights
Males



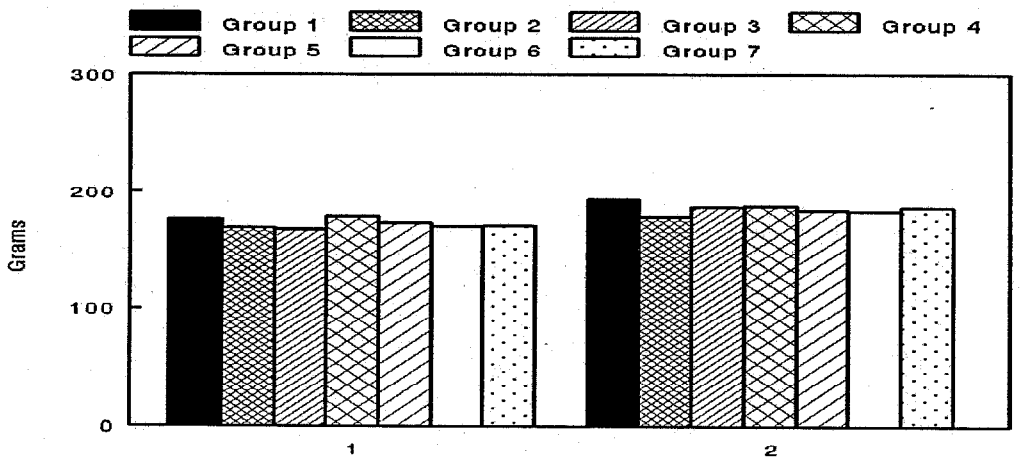
Week

Females



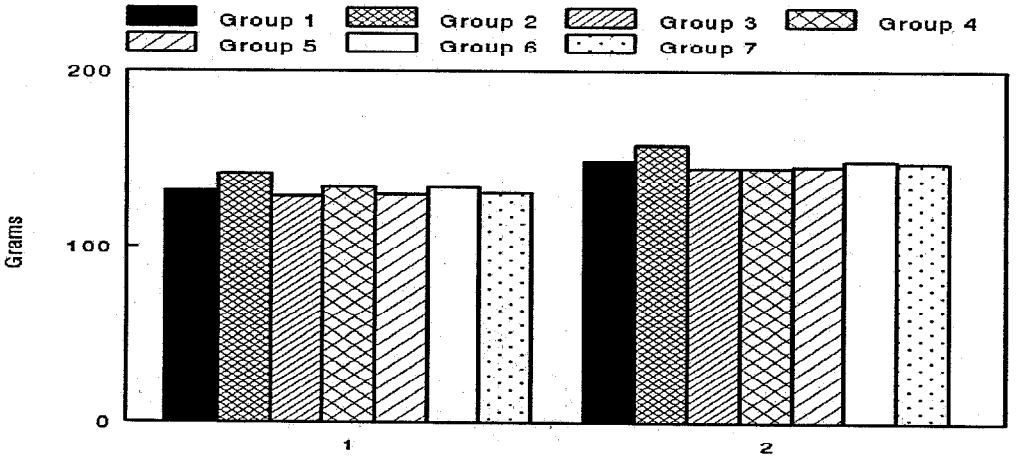
Week

Figure 2
Mean Food Consumption
Males



Week

Females



Week

Plasma Analyses

The results of the plasma analyses are presented in Text Table 3. A plasma analysis report is presented in Appendix 6.

Text Table 3
Sample Analysis Summary

Group	Sex	Dose Level mg/rat/day	Mean Concentration µg/mL	SD	CV %
1	M	0	ND	NA	NA
1	F	0	ND	NA	NA
2	M	0	ND	NA	NA
2	F	0	ND	NA	NA
3	M	0.3	1.015	0.692	68.2
3	F	0.3	1.221	0.793	64.9
4	M	0.6	2.066	1.03	49.9
4	F	0.6	2.402	0.930	38.7
5	M	1.5	6.634	3.02	45.5
5	F	1.5	5.234	3.21	61.3
6	M	3.0	14.13	4.13	29.3
6	F	3.0	9.173	3.78	41.2
7	M	6.0	31.55	13.2	41.8
7	F	6.0	18.11	7.16	39.6

ND - Not detectable
NA - Not applicable

Terminal Studies

Gross Pathology - Gross pathology findings are summarized in Table 5. Individual gross pathology findings are presented in Appendix 5.

Photographs of the treated areas taken at necropsy are presented in Attachment 1.

Findings noted included dark areas of the liver in one Group 2 female, one Group 4 male and two Group 5 males; calculus in the urinary bladder and a thickened urinary bladder wall in one Group 4 male; calculus in the kidney of one Group 4 male; dilated pelvises in the kidneys of one male and one female in Group 4 and one male in Group 7; pelvic fluid in the kidney in one Group 4 female; one enlarged mandibular lymph node in a Group 4 female, one incidence each of fluid in the uterus and distended uteri in Group 3 females; and a thickened uterus wall in one Group 7 female. Findings at the application site included eschar in two males and two females in Group 7 and one female in Group 5; erythema in one Group 6 male and one Group 5 and 7 female; and scaling in seven Group 7 females.

Organ Weights - Organ weight data are presented in Table 6. Individual data are presented in Appendix 5.

Evaluation of the data revealed no statistically significant change in mean values of absolute liver or brain weight, liver-to-body-weight, brain-to-body-weight or liver-to-brain-weight ratios compared to Group 2 animals.

Histopathology - Microscopic findings are summarized in Table 7. Individual histopathology findings are presented in Appendix 5. The findings are further discussed in the Pathology Report.

Biologically meaningful microscopic changes were observed in the 6.0 mg/animal/day group (Group 7) at the site of topical administration. In both sexes, an acanthosis corresponding to the macroscopic observation of eschar formation was observed. This correspondence was also true in the single 1.5 mg/animal/day (Group 5) female with observable eschar formation at necropsy. An increased incidence of hyperkeratosis corresponding to scaling was observed in the 6.0 mg/animal/day females.

DISCUSSION AND CONCLUSION

Changes related to Triclosan were restricted to the application site. These changes were detectable clinically, at necropsy, and microscopically. Based on these changes, 6.0 mg/animal/day is considered an effect level for Triclosan when administered dermally to rats in acetone for at least 14 days. Although possible Triclosan-related changes were observed in a single 1.5 mg/day animal, a level of 3.0 mg/animal/day is considered a no-effect level under the same conditions. Triclosan enters the systemic circulation in a dose-related manner when applied dermally in acetone.

Study Director:

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Department of Toxicology

4/28/97
Date

Study Coordinator:

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Department of Toxicology

4/28/97
Date

PATHOLOGY REPORT

Methods

Seventy Crl:CD®BR rats of each sex were divided into seven groups and dosed with Triclosan in acetone as a vehicle or the vehicle alone as a control as follows:

Group	Number of Rats		Dosage Level
	Males	Females	mg/animal/day
1 (Untreated Control)	10	10	0
2 (Vehicle Control)	10	10	0
3	10	10	0.3
4	10	10	0.6
5	10	10	1.5
6	10	10	3.0
7	10	10	6.0

Exposure was by topical application to the dorsal skin, once daily, for at least 14 consecutive days before sacrifice.

At sacrifice, each animal was subjected to a complete necropsy. Clinical observations were reviewed at necropsy. Representative samples of treated skin, untreated skin, liver, and macroscopic changes were preserved in 10% neutral-buffered formalin. Tissues from all animals were embedded in paraffin, sectioned at 5 μm, stained with hematoxylin and eosin, and examined microscopically.

Results

Macroscopic - Biologically meaningful macroscopic changes consisting primarily of eschar formation in two animals of each sex in the 6.0 mg/animal/day group and scaling in seven females in the 6.0 mg/animal/day group were observed at the site of topical administration. The eschar formation in a single 1.5 mg/animal/day female was possibly related to Triclosan administration.

Organ Weight - No statistical differences in liver weights were noted in comparison to the vehicle control group.

Microscopic - Biologically meaningful microscopic changes were observed in the 6.0 mg/animal/day group at the site of topical administration. In both sexes, an acanthosis corresponding to the macroscopic observation of eschar formation was observed. This correspondence was also true in the single 1.5 mg/animal/day female with observable eschar formation at necropsy. An increased incidence of hyperkeratosis corresponding to scaling was observed in the 6.0 mg/animal/day females. No microscopic liver changes were considered related to dermal Triclosan administration.

Conclusion

The application of Triclosan in acetone to the skin of Crl:CD®BR rats for at least 14 consecutive days resulted in changes at the application site characterized by acanthosis (both sexes) and hyperkeratosis (females). Although the changes were primarily observed in the 6.0 mg/animal/day group, those observed in a single 1.5 mg/animal/day female were probably related to Triclosan application.

Pathologist:

John M. Burns

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Department of Pathology

4/24/97
Date

STATISTICAL REPORT

Methods

Graded skin irritation scores (Erythema, Eschar, and Scaling) in this study were analyzed by exact linear-by-linear association test (StatXact-Turbo, 1992) to test for association (trend) between the dose levels and the various degrees of toxicity. In the case of significant association observed for Groups 2-7, vehicle (Group 2) versus each treated group (Groups 3-7) comparisons were performed, where it was necessary, to investigate the nature of any treatment effect.

Exact one-tail p-values were used and compared against 0.05 significance level. Males and females were analyzed separately in this study.

Results

According to Text Table 2 which presents the statistical results based on linear-by-linear association test, there was no toxicity observed in the male Groups 2-7 for Erythema and in Groups 2-6 for Eschar and Scaling in this study; as a result, no dose-response test and group comparisons were performed for those cases of this sex. Group 7 showed a slightly increased Eschar (but not statistically significant so) when compared against Group 2 on any day. A significant number of Group 7 male animals showed increased Scaling on Days 8 ($p = 0.0054$) and 11 ($p = 0.0163$) when compared against Group 2, but not on Days 4 and 15. In the females, there was a significant ($p < 0.05$ for Groups 2 vs. 3-7) positive dose-response relationship between the dose levels and the degrees of Erythema, Eschar, and Scaling. However, the significant trend in each case may not be very informative since both Groups 3 and 4 exhibited no

finding. Nevertheless, female Groups 5 and 6, and particularly Group 7, showed some increase in the above parameters when compared against Group 2.

Biostatistician:

akthakur 4/24/97

Ajit K. Thakur, Ph.D. Date

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StatXact-Turbo

StatXact-Turbo, Cytel Software Gorp., Cambridge, Massachusetts, 1992.

Table 1
Analytical Chemistry Results
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Analytical Method No. 629 states that the determination of Triclosan in acetone will be conducted for a concentration range given in units of % and/or ppm. Analytical Chemistry results were reported during the analyses in mg/mL, in order to reflect the same concentration units which were used by the Formulations department. Given below is a conversion factor which can be used to convert concentrations given in mg/mL to ppm.

concentration of a liquid in ppm = concentration of that liquid in μg/mL

1.0 mg/mL x 1000 μg/mg = 1000 μg/mL

Therefore,

concentration of liquid in mg/mL x 1000 = concentration in ppm

Table 1
Analytical Chemistry Results
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Routine Concentration Analyses

		Assayed Level (mg/mL)						Percent of Target					
Group:		2	3	4	5	6	7	2	3	4	5	6	7
Dose Level (mg/animal/day):		0	.3	.6	1.5	3.0	6.0	0	.3	.6	1.5	3.0	6.0
Target Concentration (mg/mL):		0	1.0	2.0	5.0	10.0	20.0	0	1.0	2.0	5.0	10.0	20.0
Day 1	A	ND	1.079	2.126	5.336	10.65	20.05	ND	108	106	107	107	100
	B	ND	1.063	2.115	5.262	10.58	20.24	ND	106	106	105	106	101
Day 8	A	ND	0.9807	1.941	5.135	9.972	19.27	ND	98.1	97.0	103	99.7	96.3
	B	ND	1.008	1.967	5.035	9.947	19.29	ND	101	98.4	101	99.5	96.4

Note: A and B are duplicate analyses of a single sample.
ND = None detected.

Table 2
Summary Incidence of Dermal Irritation Scores
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day. On Day 1 of dermal scoring, all animals were normal.

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 4

CATEGORY / KEYWORD / QUALIFIER	SEX:	NUMBER OF ANIMALS AFFECTED						
		MALE						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	0	.3	.6	1.5	3	6
	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	10	10	10
SLIGHT		0	0	0	0	0	0	0
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	10	7
SLIGHT		0	0	0	0	0	0	3
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	10	10	9
YES (1% TO 20% OF TEST SITE)		0	0	0	0	0	0	1
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	10
*** END OF LIST ***								

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 4

CATEGORY / KEYWORD / QUALIFIER	SEX:	NUMBER OF ANIMALS AFFECTED						
		FEMALE						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	0	.3	.6	1.5	3	6
	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	10	10	9
SLIGHT		0	0	0	0	0	0	1
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	10	6
SLIGHT		0	0	0	0	0	0	4
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	10	10	9
YES (1% TO 20% OF TEST SITE)		0	0	0	0	0	0	1
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	10
*** END OF LIST ***								

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 8

		NUMBER OF ANIMALS AFFECTED						
	SEX:	MALE						
CATEGORY	GROUP:	1	2	3	4	5	6	7
KEYWORD	DOSE:	0	0	.3	.6	1.5	3	6
QUALIFIER	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	10	10	9
SLIGHT		0	0	0	0	0	0	0
MODERATE		0	0	0	0	0	0	1
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	10	4
SLIGHT		0	0	0	0	0	0	2
MODERATE		0	0	0	0	0	0	4
MARKED		0	0	0	0	0	0	0
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	10	10	8
YES (1% TO 20% OF TEST SITE)		0	0	0	0	0	0	2
YES (21% TO 40% OF TEST SITE)		0	0	0	0	0	0	0
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	10
YES		0	0	0	0	0	0	0
*** END OF LIST ***								

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 8

CATEGORY / KEYWORD / QUALIFIER	SEX:	NUMBER OF ANIMALS AFFECTED						
		FEMALE						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	0	.3	.6	1.5	3	6
	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	10	10	6
SLIGHT		0	0	0	0	0	0	4
MODERATE		0	0	0	0	0	0	0
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	9	0
SLIGHT		0	0	0	0	0	1	5
MODERATE		0	0	0	0	0	0	4
MARKED		0	0	0	0	0	0	1
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	10	9	6
YES (1% TO 20% OF TEST SITE)		0	0	0	0	0	1	3
YES (21% TO 40% OF TEST SITE)		0	0	0	0	0	0	1
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	9
YES		0	0	0	0	0	0	1
*** END OF LIST ***								

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 11

		NUMBER OF ANIMALS AFFECTED						
	SEX:	MALE						
CATEGORY	GROUP:	1	2	3	4	5	6	7
KEYWORD	DOSE:	0	0	.3	.6	1.5	3	6
QUALIFIER	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	10	10	9
SLIGHT		0	0	0	0	0	0	0
MODERATE		0	0	0	0	0	0	1
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	10	5
SLIGHT		0	0	0	0	0	0	1
MODERATE		0	0	0	0	0	0	4
MARKED		0	0	0	0	0	0	0
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	10	10	8
YES (1% TO 20% OF TEST SITE)		0	0	0	0	0	0	2
YES (21% TO 40% OF TEST SITE)		0	0	0	0	0	0	0
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	10
YES		0	0	0	0	0	0	0
*** END OF LIST ***								

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 11

		NUMBER OF ANIMALS AFFECTED						
	SEX:	FEMALE						
CATEGORY	GROUP:	1	2	3	4	5	6	7
KEYWORD	DOSE:	0	0	.3	.6	1.5	3	6
QUALIFIER	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	10	10	6
SLIGHT		0	0	0	0	0	0	4
MODERATE		0	0	0	0	0	0	0
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	10	0
SLIGHT		0	0	0	0	0	0	5
MODERATE		0	0	0	0	0	0	4
MARKED		0	0	0	0	0	0	1
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	10	9	5
YES (1% TO 20% OF TEST SITE)		0	0	0	0	0	1	4
YES (21% TO 40% OF TEST SITE)		0	0	0	0	0	0	1
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	9
YES		0	0	0	0	0	0	1
*** END OF LIST ***								

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 15

NUMBER OF ANIMALS AFFECTED

CATEGORY / KEYWORD / QUALIFIER	SEX:	MALE						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	0	.3	.6	1.5	3	6
	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	10	9	10
SLIGHT		0	0	0	0	0	1	0
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	10	10
SLIGHT		0	0	0	0	0	0	0
MODERATE		0	0	0	0	0	0	0
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	10	10	8
YES (1% TO 20% OF TEST SITE)		0	0	0	0	0	0	2
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	10
*** END OF LIST ***								

TABLE 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
SUMMARY INCIDENCE OF DERMAL IRRITATION SCORES

DAY 15

NUMBER OF ANIMALS AFFECTED

CATEGORY / KEYWORD / QUALIFIER	SEX:	FEMALE						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	0	.3	.6	1.5	3	6
	NUMBER:	10	10	10	10	10	10	10
*** TOP OF LIST ***								
EVALUATION OF SKIN REACTIONS								
ERYTHEMA								
NONE		10	10	10	10	9	10	8
SLIGHT		0	0	0	0	1	0	2
EDEMA								
NONE		10	10	10	10	10	10	10
SCALING								
NONE		10	10	10	10	10	10	2
SLIGHT		0	0	0	0	0	0	6
MODERATE		0	0	0	0	0	0	2
FISSURING								
NONE		10	10	10	10	10	10	10
ESCHAR								
NO		10	10	10	10	9	10	8
YES (1% TO 20% OF TEST SITE)		0	0	0	0	1	0	2
EXFOLIATION								
NO		10	10	10	10	10	10	10
ULCER								
NO		10	10	10	10	10	10	10
ALOPECIA								
NO		10	10	10	10	10	10	10
NONVIABLE (DEAD) TISSUE								
NO		10	10	10	10	10	10	10
THICKENING								
NO		10	10	10	10	10	10	10
*** END OF LIST ***								

Table 3A
Body Weight Means and Standard Deviations
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day.

TABLE 3A
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
BODY WEIGHT MEANS AND STANDARD DEVIATIONS (G)

	SEX:	MALE						
	GROUP:	1	2	3	4	5	6	7
WEEK	DOSE:	0	0	.3	.6	1.5	3	6
1	N	10	10	10	10	10	10	10
	MEAN	214	219	219	225	218	220	217
	S.D.	10.6	7.6	9.6	8.6	6.1	11.7	6.7
2	N	10	10	10	10	10	10	10
	MEAN	266	265	268	271	264	266	264
	S.D.	16.5	13.6	13.6	10.5	8.4	14.1	10.4
3	N	10	10	10	10	10	10	10
	MEAN	305	299	303	314	307	307	300
	S.D.	19.1	16.6	18.9	14.5	10.7	17.0	17.9

TABLE 3A
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
BODY WEIGHT MEANS AND STANDARD DEVIATIONS (G)

	SEX:	FEMALE						
	GROUP:	1	2	3	4	5	6	7
WEEK	DOSE:	0	0	.3	.6	1.5	3	6
1	N	10	10	10	10	10	10	10
	MEAN	159	162	162	159	157	158	158
	S.D.	8.6	11.1	8.4	7.6	11.0	7.1	12.4
2	N	10	10	10	10	10	10	10
	MEAN	183	187	184	182	176	179	185
	S.D.	11.9	15.0	10.6	10.1	14.4	10.8	15.1
3	N	10	10	10	10	10	10	10
	MEAN	205	210	206	203	202	203	207
	S.D.	13.2	13.2	7.7	13.1	17.2	12.2	19.2

Table 3B
Body Weight Change Means and Standard Deviations
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day.

TABLE 3B
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
BODY WEIGHT CHANGE MEANS AND STANDARD DEVIATIONS (G)

	SEX:	MALE						
	GROUP:	1	2	3	4	5	6	7
WEEK	DOSE:	0	0	.3	.6	1.5	3	6
1	N	10	10	10	10	10	10	10
	MEAN	52	47	49	46	47	46	47
	S.D.	6.3	9.1	5.5	3.2	6.6	7.4	6.9
2	N	10	10	10	10	10	10	10
	MEAN	39	34	35	43*	43*	41	36
	S.D.	6.4	5.6	8.9	6.3	4.7	6.8	8.7
1-2	N	10	10	10	10	10	10	10
RT	MEAN	91	80	84	89	90	87	83
	S.D.	10.7	13.1	13.0	8.5	10.4	11.3	15.3

* Significantly different from control value, $p \leq 0.05$.
RT - Rank transformation used in analysis of data.

TABLE 3B
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
BODY WEIGHT CHANGE MEANS AND STANDARD DEVIATIONS (G)

	SEX:	FEMALE						
	GROUP:	1	2	3	4	5	6	7
WEEK	DOSE:	0	0	.3	.6	1.5	3	6
1	N	10	10	10	10	10	10	10
	MEAN	25	26	22	23	19	21	26
	S.D.	7.7	10.8	7.8	6.1	8.7	7.4	7.1
2	N	10	10	10	10	10	10	10
	MEAN	21	23	22	21	26	24	23
	S.D.	11.5	9.3	9.2	8.8	9.2	7.5	8.3
1-2 RT	N	10	10	10	10	10	10	10
	MEAN	46	49	44	44	45	45	49
	S.D.	7.5	3.1	8.5	10.1	10.0	9.5	11.6

RT - Data analyzed following rank transformation.

Table 4
Food Consumption Means and Standard Deviations
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day.

TABLE 4
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
FOOD CONSUMPTION MEANS AND STANDARD DEVIATIONS (G)

	SEX:	MALE						
	GROUP:	1	2	3	4	5	6	7
WEEK	DOSE:	0	0	.3	.6	1.5	3	6
-1	N	10	10	10	10	10	10	10
	MEAN	151	154	155	160	152	152	155
	S.D.	9.6	5.1	9.6	9.1	14.6	11.6	8.9
1	N	10	10	9	10	10	10	10
	MEAN	176	169	168	179	173	170	171
	S.D.	14.5	9.8	11.5	9.0	9.8	17.1	6.2
2	N	10	10	10	10	10	10	10
	MEAN	193	179	187	188	184	183	186
	S.D.	18.0	11.8	11.6	7.7	11.7	20.4	9.7
1-2	N	10	10	9	10	10	10	10
	MEAN	369	349	355	367	357	353	357
	S.D.	31.4	19.3	21.6	15.5	20.9	36.5	14.1

TABLE 4
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
FOOD CONSUMPTION MEANS AND STANDARD DEVIATIONS (G)

	SEX:	FEMALE						
	GROUP:	1	2	3	4	5	6	7
WEEK	DOSE:	0	0	.3	.6	1.5	3	6
-1	N	10	10	10	10	10	10	10
	MEAN	156	129	123	128	128	131	126
	S.D.	8.9	13.4	16.9	11.2	6.8	12.5	18.1
1	N	10	10	9	10	10	10	10
	MEAN	132	142	129	134	130	134	131
	S.D.	7.3	19.3	12.2	8.7	11.8	8.7	16.0
2	N	10	10	10	10	10	10	10
	MEAN	149	158	145	145	146	149	148
	S.D.	12.7	19.5	14.8	9.1	17.6	10.2	16.4
1-2	N	10	10	9	10	10	10	10
	MEAN	280	301	274	279	276	283	279
	S.D.	16.3	37.8	27.0	16.1	28.3	17.7	27.2

Table 5
Gross Pathology Incidence Summary
14-Day Repeated Dose Dermal Study of Triclosan in Rats

TABLE 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
GROSS PATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER OF ANIMALS AFFECTED ---						
SEX:		MALE						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
** TOP OF LIST **								
LIVER (LI)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	9	8	10	10
DARK AREA		0	0	0	1	2	0	0
H-PALE AREA		1	0	0	0	0	0	0
SKIN, UNTREATED (US)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	10	10	10	10
SKIN, TREATED (TS)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	10	10	9	8
ERYTHEMA		0	0	0	0	0	1	0
ESCHAR		0	0	0	0	0	0	2
^COLLECTED/TAKEN (XW)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	0	0	0	0	0	0	0
NO SPECIAL REQUIREMENT		9	9	10	9	10	9	8
CALCULUS (KIDNEY)		0	0	0	1	0	0	0
CALCULUS (URINARY BLADDER)		0	0	0	1	0	0	0
PHOTOGRAPH		1	1	0	1	2	1	2
URINARY BLADDER (UB)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	9	10	10	10
WALL, THICKENED		0	0	0	1	0	0	0
LUMEN, CALCULUS		0	0	0	1	0	0	0
KIDNEY (KD)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	9	10	10	9
PELVIS, DILATED		0	0	0	1	0	0	1
PELVIS, CALCULUS		0	0	0	1	0	0	0

TABLE 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
GROSS PATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---						
SEX:		-MALE-						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	10	10	10	10

** END OF LIST **

TABLE 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
GROSS PATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---						
SEX:		FEMALE						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
** TOP OF LIST **								
LIVER (LI)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	9	10	10	10	10	10
DARK AREA		0	1	0	0	0	0	0
SKIN, UNTREATED (US)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	10	10	10	10
SKIN, TREATED (TS)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	10	9	10	2
ERYTHEMA		0	0	0	0	1	0	1
ESCHAR		0	0	0	0	1	0	2
SCALING		0	0	0	0	0	0	7
^COLLECTED/TAKEN (XW)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	0	0	0	0	0	0	0
NO SPECIAL REQUIREMENT		10	9	10	10	9	10	5
PHOTOGRAPH		0	1	0	0	1	0	5
URINARY BLADDER (UB)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	10	10	10	10
KIDNEY (KD)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	9	10	10	10
PELVIS, DILATED		0	0	0	1	0	0	0
PELVIS, FLUID		0	0	0	1	0	0	0

TABLE 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
GROSS PATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

ORGAN AND KEYWORD(S) OR PHRASE		--- NUMBER-OF-ANIMALS-AFFECTED ---						
SEX:		FEMALE						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
UTERUS (UT)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	9	10	10	10	9
WALL, THICKENED		0	0	0	0	0	0	1
DISTENDED		0	0	1	0	0	0	0
LUMEN, FLUID		0	0	1	0	0	0	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	10	9	10	10	10
ENLARGED		0	0	0	1	0	0	0

** END OF LIST **

Table 6
Organ Weight Data
14-Day Repeated Dose Dermal Study of Triclosan in Rats

TABLE 6
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
ORGAN WEIGHT DATA

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

BRAIN W/STEM

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	270.9	1.92	0.711	1.000
	STANDARD DEV:	19.4	0.09	0.045	0.000
M	2				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	265.6	1.93	0.729	1.000
	STANDARD DEV:	14.2	0.08	0.035	0.000
M	3				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	269.0	1.92	0.716	1.000
	STANDARD DEV:	14.9	0.10	0.034	0.000
M	4				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	279.8	1.91	0.682	1.000
	STANDARD DEV:	13.8	0.12	0.035	0.000

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
F	1				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	184.1	1.85	1.009	1.000
	STANDARD DEV:	10.1	0.06	0.051	0.000
F	2				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	189.9	1.88	0.994	1.000
	STANDARD DEV:	10.6	0.13	0.097	0.000
F	3				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	186.4	1.86	0.998	1.000
	STANDARD DEV:	9.4	0.12	0.074	0.000
F	4				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	183.8	1.87	1.024	1.000
	STANDARD DEV:	10.7	0.08	0.091	0.000

TABLE 6
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
ORGAN WEIGHT DATA

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

BRAIN W/STEM

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M 5					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	271.2	1.91	0.706	1.000
	STANDARD DEV:	9.1	0.08	0.039	0.000
M 6					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	274.8	1.96	0.716	1.000
	STANDARD DEV:	14.9	0.08	0.045	0.000
M 7					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	267.0	1.91	0.715	1.000
	STANDARD DEV:	15.8	0.09	0.039	0.000

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
F 5					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	181.5	1.82	1.009	1.000
	STANDARD DEV:	16.8	0.08	0.096	0.000
F 6					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	182.4	1.87	1.024	1.000
	STANDARD DEV:	8.7	0.10	0.054	0.000
F 7					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	182.3	1.79	0.983	1.000
	STANDARD DEV:	15.5	0.13	0.075	0.000

TABLE 6
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
ORGAN WEIGHT DATA

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

LIVER

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M	1				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	270.9	9.10	3.358	4.743
	STANDARD DEV:	19.4	1.15	0.321	0.601
M	2				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	265.6	8.83	3.319	4.572
	STANDARD DEV:	14.2	0.98	0.259	0.520
M	3				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	269.0	8.93	3.319	4.643
	STANDARD DEV:	14.9	0.69	0.155	0.282
M	4				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	279.8	9.65	3.446	5.074
	STANDARD DEV:	13.8	1.27	0.379	0.705

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
F	1				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	184.1	6.42	3.487	3.463
	STANDARD DEV:	10.1	0.65	0.283	0.346
F	2				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	189.9	6.99	3.672	3.751
	STANDARD DEV:	10.6	0.93	0.345	0.676
F	3				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	186.4	6.75	3.620	3.650
	STANDARD DEV:	9.4	0.96	0.460	0.563
F	4				
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	183.8	6.84	3.731	3.664
	STANDARD DEV:	10.7	0.72	0.412	0.483

TABLE 6
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
ORGAN WEIGHT DATA

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

LIVER

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
M 5					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	271.2	9.22	3.400	4.824
	STANDARD DEV:	9.1	0.53	0.174	0.301
M 6					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	274.8	9.16	3.333	4.667
	STANDARD DEV:	14.9	1.21	0.422	0.626
M 7					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	267.0	8.71	3.264	4.580
	STANDARD DEV:	15.8	0.74	0.234	0.430

SEX DOSE GROUP		TERMINAL BODY WT (g)	ORGAN WEIGHT (g)	ORGAN-TO-BODY WT (%)	ORGAN-TO-BRAIN WT RATIO
F 5					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	181.5	6.50	3.579	3.573
	STANDARD DEV:	16.8	0.81	0.343	0.447
F 6					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	182.4	6.81	3.738	3.653
	STANDARD DEV:	8.7	0.61	0.323	0.297
F 7					
	NUMBER IN GROUP:	10	10	10	10
	MEAN:	182.3	6.96	3.822	3.909
	STANDARD DEV:	15.5	0.75	0.277	0.419

Table 7
Histopathology Incidence Summary
14-Day Repeated Dose Dermal Study of Triclosan in Rats

TABLE 7
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
HISTOPATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER OF ANIMALS AFFECTED ---						
SEX:		MALE						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
** TOP OF LIST **								
LIVER (LI)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	0	1	1	0	0	0	0
--INFLAMMATION, CHRONIC		10	9	9	10	10	10	10
--NECROSIS		0	1	0	1	0	0	0
--MINERALIZATION		0	1	0	0	0	0	0
--HEMORRHAGE		0	0	0	1	1	0	0
--CAPSULE, FIBROSIS		0	0	0	1	0	0	0
SKIN, TREATED (TS)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	0	1	0	0	0	2	0
--HYPERKERATOSIS		10	9	10	10	10	7	10
--ACANTHOSIS		0	0	0	2	0	1	4
--EPIDERMIS, DEBRIS, SUPERFICIAL		0	0	0	0	0	1	1
--INFLAMMATION, CHRONIC		0	0	0	0	0	0	1
SKIN, UNTREATED (US)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	9	10	8	10	8	10	9
--HYPERKERATOSIS		1	0	2	0	2	0	1
^DEATH COMMENT (DC)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	0	0	0	0	0	0	0
--SCHEDULED SACRIFICE		10	10	10	10	10	10	10
MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0

TABLE 7
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
HISTOPATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---						
SEX:		----------MALE----------						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
LN, OTHER (LN)	NUMBER EXAMINED:	1	1	0	0	0	1	1
	NOT REMARKABLE:	1	1	0	0	0	1	1
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
MAMMARY, MALE (MM)	NUMBER EXAMINED:	1	2	1	1	2	2	4
	NOT REMARKABLE:	0	2	1	1	2	2	4
--HYPERPLASIA		1	0	0	0	0	0	0
KIDNEY (KD)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	0
--PELVIS, DILATATION		0	0	0	1	0	0	1
--TUBULE, MINERALIZATION		0	0	0	0	0	0	1
--PYELONEPHRITIS		0	0	0	1	0	0	0
URINARY BLADDER (UB)	NUMBER EXAMINED:	0	0	0	1	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--INFLAMMATION		0	0	0	1	0	0	0
--CALCULUS		0	0	0	1	0	0	0
--HYPERPLASIA		0	0	0	1	0	0	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0

** END OF LIST **

TABLE 7
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
HISTOPATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---						
SEX:		FEMALE						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
** TOP OF LIST **								
LIVER (LI)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	0	0	0	0	0	0	0
--INFLAMMATION, CHRONIC		10	9	10	10	10	10	10
--NECROSIS		2	2	1	2	1	0	0
--VACUOLIZATION, PERIPORTAL		3	4	1	1	2	2	2
--CAPSULE, FIBROSIS		0	0	0	1	0	0	0
SKIN, TREATED (TS)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	6	7	7	6	7	0
--HYPERKERATOSIS		0	4	3	3	3	3	10
--ACANTHOSIS		0	0	0	0	1	0	3
--EPIDERMIS, DEBRIS, SUPERFICIAL		0	0	0	0	2	0	1
--INFLAMMATION, CHRONIC		0	0	0	0	0	0	1
--ULCER		0	0	0	0	1	0	0
SKIN, UNTREATED (US)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	9	10	10	9	10	9
--ACANTHOSIS		0	0	0	0	0	0	1
--HYPERKERATOSIS		0	1	0	0	1	0	1
^DEATH COMMENT (DC)	NUMBER EXAMINED:	10	10	10	10	10	10	10
	NOT REMARKABLE:	0	0	0	0	0	0	0
--SCHEDULED SACRIFICE		10	10	10	10	10	10	10
MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	2	5	1	1	1	1	1
	NOT REMARKABLE:	2	5	1	1	1	1	1

TABLE 7
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
HISTOPATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;FIND=ALL;SUBSET=ALL

ORGAN AND FINDING DESCRIPTION		--- NUMBER-OF-ANIMALS-AFFECTED ---						
SEX:		FEMALE						
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:		10	10	10	10	10	10	10
LN, OTHER (LN)	NUMBER EXAMINED:	1	1	0	0	0	0	0
	NOT REMARKABLE:	1	1	0	0	0	0	0
UTERUS (UT)	NUMBER EXAMINED:	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	1
--DILATATION		0	0	1	0	0	0	0
MAMMARY, MALE (MM)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
KIDNEY (KD)	NUMBER EXAMINED:	0	0	0	1	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--PELVIS, DILATATION		0	0	0	1	0	0	0
--TUBULE, MINERALIZATION		0	0	0	1	0	0	0
--NEPHROPATHY, CHRONIC PROGRESSIVE		0	0	0	1	0	0	0
URINARY BLADDER (UB)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	0	0	0	1	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--HYPERPLASIA, LYMPHOID		0	0	0	1	0	0	0

** END OF LIST **

Appendix 1
Analytical Chemistry Method
14-Day Repeated Dose Dermal Study of Triclosan in Rats

ANALYTICAL CHEMISTRY METHOD

METHOD NO. 629 EFFECTIVE DATE: August 4, 1995

TITLE: Determination of Triclosan in Acetone.

STRUCTURE: On file with sponsor.

DEVELOPED BY: Triclosan Industry Alliance, modified by Corning Hazleton (CHV).

1.0 SCOPE

This method is for the high performance liquid chromatography (HPLC) analysis of Triclosan in acetone in the concentration range of 0.1% (1,000 ppm) and 6.0% (60,000 ppm).

2.0 PRINCIPLE

Triclosan solutions are diluted with acetone so as to fall within the standard curve. Quantitation is achieved by reverse phase high performance liquid chromatography (HPLC).

3.0 EQUIPMENT

3.1 HPLC: Waters Millennium System, Waters WISP 717 autosampler, Waters 600 pump, and Waters 484 variable wavelength UV detector, or equivalent equipment.

3.2 HPLC column: Burdick and Jackson OD5, 150 mm x 4.6 mm.

3.3 Analytical balance: Mettler AE 163, or equivalent.

3.4 General laboratory equipment and (amber)glassware.

4.0 REAGENTS

4.1 Triclosan (Irgasan DP 300): 99.3% pure, supplied by client.

4.2 Acetone: Burdick & Jackson UV grade, or equivalent.

4.3 Methanol (MeOH): Burdick and Jackson UV grade, or equivalent.

4.4 Deionized water (DIH_2O): Millipore Milli-Q, or equivalent.

4.5 Formic Acid: Fisher Scientific, or equivalent.

4.6 Triethylamine: Fisher Scientific, or equivalent.

4.7 Mobile Phase: 70% methanol/30% deionized water, plus 1.0% formic acid and 0.5% triethylamine.

5.0 PROCEDURE

5.1 Preparation of Standard Solutions

5.1.1 Stock standard A (target 2,000 ug/mL)

Accurately weigh approximately 100 mg neat Triclosan, not adjusting for purity, and transfer to a 50 mL volumetric flask. Dissolve in and dilute to volume with acetone.

5.1.2 Preparation of working standards:

Dilute standard A as follows:

Target Concentration (ug/mL)	Standard A (mL)	Final Volume in acetone (mL)
500.0	5.0	20.0
1,000	5.0	10.0
1,500	15.0	20.0
2,000	Std A	

5.2 Sample Preparation

5.2.1 Dilute solutions so that they fall within the standard curve as follows:

Concentration (%)	Aliquot of Solution (mL)	Final Volume in acetone (mL)
0.0	None	None
0.3	2.0	5.0
0.6	2.0	10.0
1.5	1.0	10.0
3.0	0.4	10.0
6.0	0.2	10.0

6.0 Sample Calculation

6.1 Compute the linear regression equation relating the peak heights or areas of the standards to the total nanograms of Triclosan injected for each standard.

6.2 Using the peak height or area of the sample and the regression equation, determine the nanograms detected for each sample. Then,

ppm = nanograms injected x calculation factor

where calculation factor = $\frac{A}{B} \times \frac{1}{C}$

A: Final volume of dilution (mL)
B: Aliquot taken for dilution (mL)
C: Injection volume (uL)

7.0 INSTRUMENT PARAMETERS

High Performance Liquid : Waters Millennium System, Waters WISP 717 autosampler, Waters 600 pump, and Waters 484 variable wavelength UV detector, or equivalent equipment.

Column : Burdick & Jackson OD5, 150 mm x 4.6 mm

Mobile Phase : 70%MeOH/30%H_2O/1%Formic acid/0.5% Triethylamine

Wavelength : 280 nm

Flow rate : 1.5 mL/minute

Injection volume : 20 uL

Triclosan retention time : approximately 8.5 minutes

NOTE: 1. Parameters may be adjusted to achieve optimum chromatography.

8.0 LIST OF FIGURES

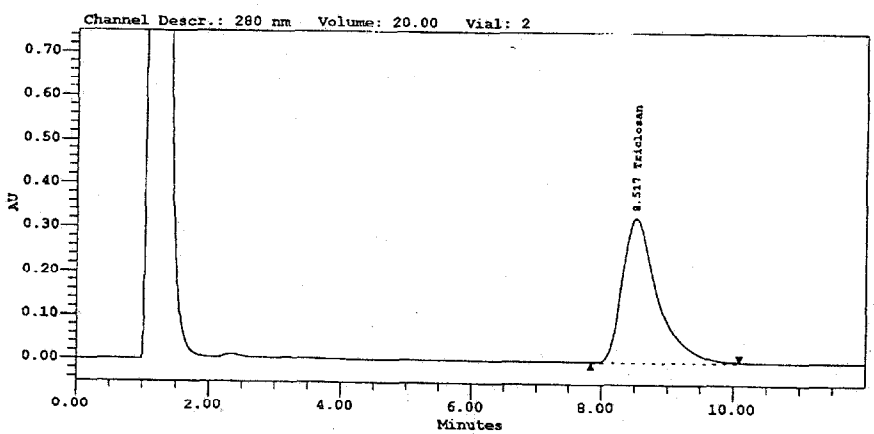
Figure 1. Typical chromatogram, standard.

PROJECT 2763-101

SampleID 1003 ug/mL std

Date Acquired: 08/02/95 04:21:19 PM
Date Processed: 08/03/95 07:47:11 AM
Acq Meth Set: 2763101
Processing Method: 2763101
Set Name: Method_Validation Run #1

Current Date: August 3, 1995
Analyst: MEJ
Units: (uL)
Channel: 486



Peak Results

#	Name	Ret Time (min)	Area (uV*sec)	Height (uV)	Int Type
1	Triclosan	8.517	12124237	326633	BB

Figure 2. Typical standard curve.

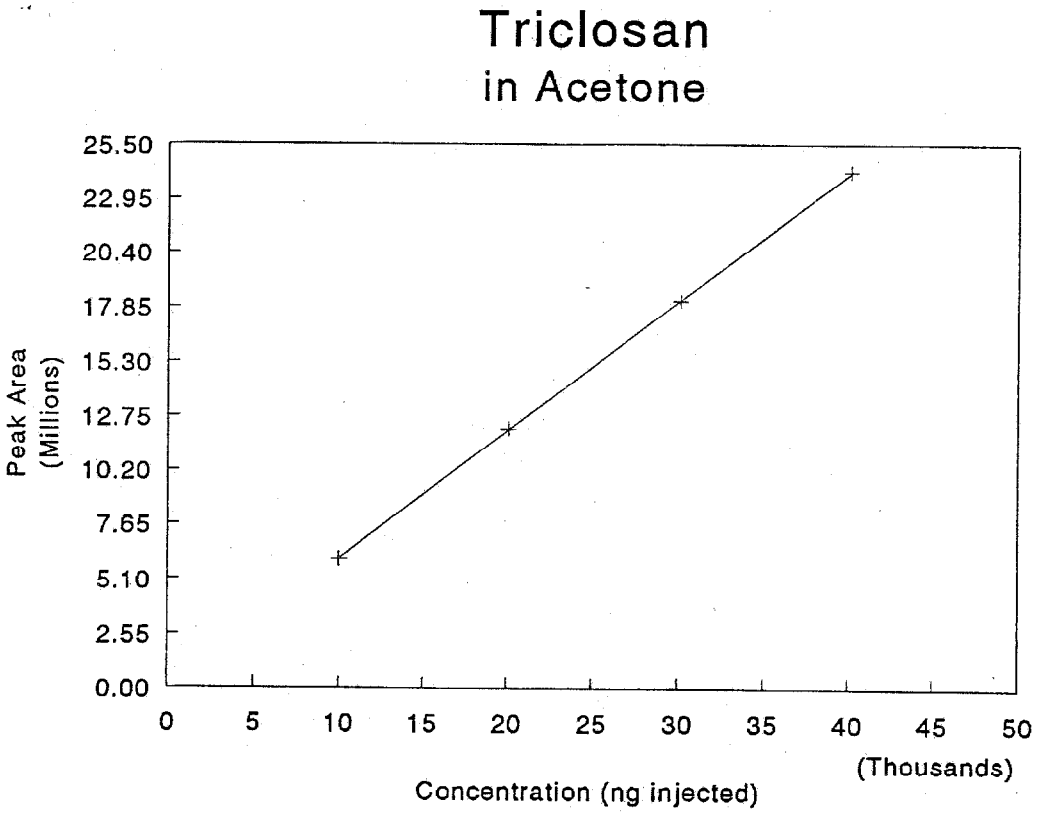


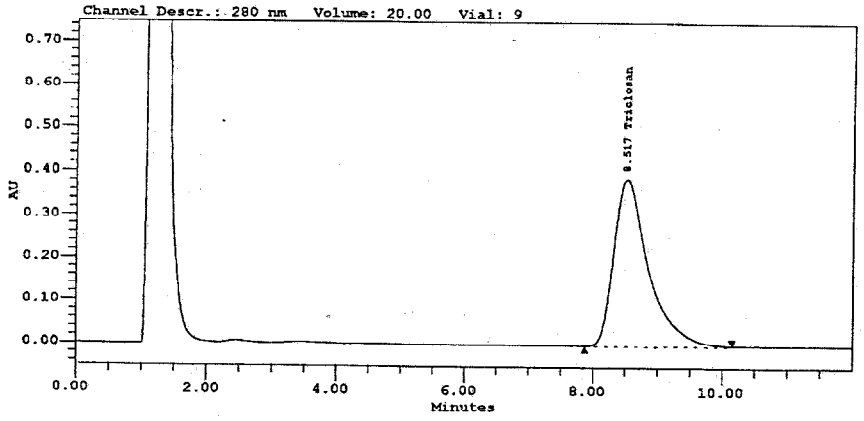
Figure 3. Typical chromatogram, sample.

PROJECT 2763-101

SampleID 6% Sample 5

Date Acquired: 08/02/95 05:56:03 PM
Date Processed: 08/03/95 07:46:08 AM
Acq Meth Set: 2763101
Processing Method: 2763101
Set Name: Method Validation Run #1

Current Date: August 3, 1995
Analyst: MEJ
Units: (uL)
Channel: 486



Peak Results

#	Name	Ret Time (min)	Area (uV*sec)	Height (uV)	Int Type
1	Triclosan	8.517	14485861	389104	BB

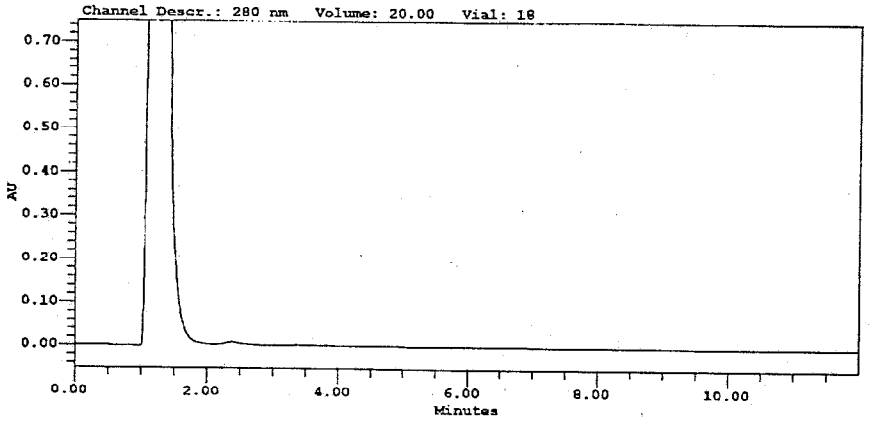
Figure 4. Typical chromatogram, blank.

PROJECT 2763-101

SampleID Acetone Blank

Date Acquired: 08/02/95 07:57:53 PM
Date Processed: 08/03/95 07:45:01 AM
Acq Meth Set: 2763101
Processing Method: 2763101
Set Name: Method_Validation Run #1

Current Date: August 3, 1995
Analyst: MEJ
Units: (uL)
Channel: 486



Peak Results

#	Name	Ret Time (min)	Area (uV*sec)	Height (uV)	Int Type
1	Triclosan	8.550			Missing

Appendix 2
Individual Dermal Irritation Scores
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day.

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER	GROUP: M1 DOSE: 0 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75770	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75771	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75772	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75773	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75774	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75775	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75776	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75777	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75778	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75779	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75790	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75791	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M2 DOSE: 0 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75792	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75793	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75794	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75795	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75796	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M2 DOSE: 0 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75797	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75798	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M2 DOSE: 0 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75799	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M3 DOSE: .3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75810	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75811	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M3 DOSE: .3 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75812	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75813	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER	GROUP: M3 DOSE: .3 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75814	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75815	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M3 DOSE: .3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75816	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75817	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

GROUP: M3 DOSE: .3 MG/DAY

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75818	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75819	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

GROUP: M4 DOSE: .6 MG/DAY

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75830	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75831	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

GROUP: M4 DOSE: .6 MG/DAY

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75832	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75833	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	CODE	DEATH WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M4 DOSE: .6 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75834	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75835	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

GROUP: M4 DOSE: .6 MG/DAY

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75836	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75837	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M4 DOSE: .6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75838	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75839	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M5 DOSE: 1.5 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75852	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75853	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M5 DOSE: 1.5 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75854	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75855	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M5 DOSE: 1.5 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75856	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75857	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M5 DOSE: 1.5 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75858	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75859	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75870	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75871	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75872	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11
			SLIGHT	15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75873	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75874	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75875	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75876	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75877	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75878	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75879	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75890	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 15
			YES (1% TO 20% OF TEST SITE)	8, 11
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75891	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 11, 15
			SLIGHT	8
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75892	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 15
			MODERATE	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 8, 11
			YES (1% TO 20% OF TEST SITE)	4, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75893	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75894	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75895	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 15
			SLIGHT	4
			MODERATE	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 15
			YES (1% TO 20% OF TEST SITE)	8, 11
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75896	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 15
			SLIGHT	4

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
(CONTINUED FROM PREVIOUS PAGE)				
B75896	T	3	EVALUATION OF SKIN REACTIONS	
			SCALING	
			MODERATE	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75897	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 15
			SLIGHT	11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75898	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 11, 15
			SLIGHT	8
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75899	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 15
			MODERATE	8, 11
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 15
			SLIGHT	4
			MODERATE	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: M7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
(CONTINUED FROM PREVIOUS PAGE)				
B75899	T	3	EVALUATION OF SKIN REACTIONS	
			ESCHAR	
			NO	1, 4, 8, 11
			YES (1% TO 20% OF TEST SITE)	15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75780	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75781	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75782	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75783	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75784	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75785	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75786	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75787	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F1 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75788	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75789	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75800	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75801	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75802	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75803	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75804	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75805	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75806	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75807	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F2 DOSE: 0 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75808	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75809	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F3 DOSE: .3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75820	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75821	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F3 DOSE: .3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75822	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75823	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F3 DOSE: .3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75824	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75825	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F3 DOSE: .3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75826	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75827	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F3 DOSE: .3 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75828	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75829	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F4 DOSE: .6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75840	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75841	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F4 DOSE: .6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75842	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75843	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F4 DOSE: .6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75844	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75845	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F4 DOSE: .6 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75846	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75847	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F4 DOSE: .6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75848	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75849	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F5 DOSE: 1.5 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75860	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75861	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F5 DOSE: 1.5 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75862	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75863	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F5 DOSE: 1.5 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75864	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F5 DOSE: 1.5 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75865	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11
			SLIGHT	15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11
			YES (1% TO 20% OF TEST SITE)	15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75866	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F5 DOSE: 1.5 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
(CONTINUED FROM PREVIOUS PAGE)				
B75866	T	3	EVALUATION OF SKIN REACTIONS	
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75867	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75868	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F5 DOSE: 1.5 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75868	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75869	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75880	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75881	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

GROUP: F6 DOSE: 3 MG/DAY

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75882	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 11, 15
			SLIGHT	8
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75883	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75884	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75885	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F6 DOSE: 3 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75886	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 15
			YES (1% TO 20% OF TEST SITE)	8, 11
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75887	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F6 DOSE: 3 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75888	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75889	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75900	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 15
			SLIGHT	8, 11
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4
			SLIGHT	15
			MODERATE	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75901	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 15
			SLIGHT	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
(CONTINUED FROM PREVIOUS PAGE)				
B75901	T	3	EVALUATION OF SKIN REACTIONS	
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75902	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1
			SLIGHT	4
			MODERATE	8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4
			YES (1% TO 20% OF TEST SITE)	8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75903	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1
			SLIGHT	4, 8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 15
			YES (1% TO 20% OF TEST SITE)	11
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75904	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4, 15
			SLIGHT	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 15
			YES (1% TO 20% OF TEST SITE)	8, 11
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75905	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11
			SLIGHT	15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4
			SLIGHT	8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER (GROUP: F7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75906	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4
			SLIGHT	15
			MARKED	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75907	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 15
			SLIGHT	8, 11
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1, 4
			SLIGHT	8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 15
			YES (1% TO 20% OF TEST SITE)	4
			YES (21% TO 40% OF TEST SITE)	8, 11

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F7 DOSE: 6 MG/DAY DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
(CONTINUED FROM PREVIOUS PAGE)				
B75907	T	3	EVALUATION OF SKIN REACTIONS	
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15
B75908	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1, 4, 15
			SLIGHT	8, 11
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1
			SLIGHT	4, 15
			MODERATE	8, 11
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4, 8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 8, 11, 15

APPENDIX 2
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL DERMAL IRRITATION SCORES

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD / QUALIFIER (GROUP: F7 DOSE: 6 MG/DAY)	DAYS 1-15 - OBSERVED DURING EACH SCHEDULED DAY; 'C' INDICATES COMMENT
B75909	T	3	EVALUATION OF SKIN REACTIONS	
			ERYTHEMA	
			NONE	1
			SLIGHT	4, 8, 11, 15
			EDEMA	
			NONE	1, 4, 8, 11, 15
			SCALING	
			NONE	1
			SLIGHT	4
			MODERATE	8, 11, 15
			FISSURING	
			NONE	1, 4, 8, 11, 15
			ESCHAR	
			NO	1, 4
			YES (1% TO 20% OF TEST SITE)	8, 11, 15
			EXFOLIATION	
			NO	1, 4, 8, 11, 15
			ULCER	
			NO	1, 4, 8, 11, 15
			ALOPECIA	
			NO	1, 4, 8, 11, 15
			NONVIABLE (DEAD) TISSUE	
			NO	1, 4, 8, 11, 15
			THICKENING	
			NO	1, 4, 15
			YES	8, 11

Appendix 3A
Individual Body Weights
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day.

APPENDIX 3A
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHTS (G)

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3
GROUP: MALE 1 - 0 MG/DAY			
B75770	229	292	343
B75771	200	242	274
B75772	225	279	316
B75773	223	277	313
B75774	206	251	290
B75775	217	272	314
B75776	200	247	294
B75777	221	279	313
B75778	213	262	293
B75779	206	256	297
GROUP: MALE 2 - 0 MG/DAY			
B75790	229	279	313
B75791	216	276	315
B75792	215	250	278
B75793	220	259	284
B75794	212	257	290
B75795	223	261	300
B75796	215	272	315
B75797	218	265	301
B75798	206	244	274
B75799	231	288	319
GROUP: MALE 3 - .3 MG/DAY			
B75810	215	269	311
B75811	227	274	297
B75812	203	249	274
B75813	223	269	293
B75814	223	272	306
B75815	229	289	339
B75816	220	268	299
B75817	203	245	281
B75818	229	283	322
B75819	217	261	303

APPENDIX 3A
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHTS (G)

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3
GROUP: MALE 4 - .6 MG/DAY			
B75830	230	278	323
B75831	222	270	319
B75832	237	286	336
B75833	209	248	288
B75834	226	276	328
B75835	237	281	324
B75836	219	267	310
B75837	220	267	306
B75838	227	273	307
B75839	221	266	300
GROUP: MALE 5 - 1.5 MG/DAY			
B75850	212	261	303
B75851	223	275	321
B75852	215	274	323
B75853	216	255	295
B75854	208	249	292
B75855	214	262	305
B75856	215	267	312
B75857	223	261	296
B75858	221	266	314
B75859	228	273	309
GROUP: MALE 6 - 3 MG/DAY			
B75870	216	265	307
B75871	209	252	288
B75872	213	251	288
B75873	212	256	302
B75874	222	261	302
B75875	204	262	300
B75876	224	258	293
B75877	236	288	326
B75878	221	270	328
B75879	241	292	335

APPENDIX 3A
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHTS (G)

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3
GROUP:	MALE 7 - 6 MG/DAY		
B75890	208	255	298
B75891	217	271	312
B75892	221	265	295
B75893	209	254	287
B75894	219	276	324
B75895	216	249	268
B75896	222	263	295
B75897	227	279	325
B75898	207	254	286
B75899	221	271	309
GROUP:	FEMALE 1 - 0 MG/DAY		
B75780	166	199	219
B75781	156	182	193
B75782	164	191	221
B75783	162	181	201
B75784	168	195	213
B75785	157	183	193
B75786	169	181	224
B75787	156	186	197
B75788	143	155	191
B75789	148	181	194
GROUP:	FEMALE 2 - 0 MG/DAY		
B75800	150	181	198
B75801	145	171	191
B75802	157	185	203
B75803	169	198	219
B75804	177	198	228
B75805	171	221	226
B75806	163	187	215
B75807	163	180	212
B75808	148	172	194
B75809	172	180	218

APPENDIX 3A
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHTS (G)

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3
GROUP: FEMALE 3 - .3 MG/DAY			
B75820	156	172	206
B75821	168	191	220
B75822	170	191	209
B75823	167	193	204
B75824	164	173	194
B75825	161	171	204
B75826	167	193	216
B75827	161	193	204
B75828	141	170	199
B75829	165	191	201
GROUP: FEMALE 4 - .6 MG/DAY			
B75840	149	169	179
B75841	168	194	219
B75842	155	189	213
B75843	154	179	192
B75844	162	184	210
B75845	171	192	210
B75846	169	192	203
B75847	156	184	210
B75848	153	167	186
B75849	157	171	210
GROUP: FEMALE 5 - 1.5 MG/DAY			
B75860	147	155	171
B75861	162	170	212
B75862	140	159	190
B75863	156	170	191
B75864	153	179	195
B75865	150	166	194
B75866	164	195	209
B75867	163	187	216
B75868	155	187	214
B75869	180	195	231

APPENDIX 3A
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHTS (G)

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3
GROUP: FEMALE 6 - 3 MG/DAY			
B75880	168	186	209
B75881	149	183	213
B75882	154	167	191
B75883	155	181	189
B75884	159	186	205
B75885	160	182	212
B75886	170	197	220
B75887	157	170	206
B75888	148	160	181
B75889	159	177	201
GROUP: FEMALE 7 - 6 MG/DAY			
B75900	149	170	183
B75901	148	171	181
B75902	152	167	202
B75903	162	186	209
B75904	169	199	229
B75905	144	169	189
B75906	144	183	210
B75907	167	192	205
B75908	173	209	235
B75909	176	200	228

Appendix 3B
Individual Body Weight Changes
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day.

APPENDIX 3B
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHT CHANGES (G)

ANIMAL NUMBER	DAY 8	DAY 15	TOTAL 1-15
GROUP:	MALE 1 - 0 MG/DAY		
B75770	63	51	114
B75771	42	32	74
B75772	54	37	91
B75773	54	36	90
B75774	45	39	84
B75775	55	42	97
B75776	47	47	94
B75777	58	34	92
B75778	49	31	80
B75779	50	41	91
GROUP:	MALE 2 - 0 MG/DAY		
B75790	50	34	84
B75791	60	39	99
B75792	35	28	63
B75793	39	25	64
B75794	45	33	78
B75795	38	39	77
B75796	57	43	100
B75797	47	36	83
B75798	38	30	68
B75799	57	31	88
GROUP:	MALE 3 - .3 MG/DAY		
B75810	54	42	96
B75811	47	23	70
B75812	46	25	71
B75813	46	24	70
B75814	49	34	83
B75815	60	50	110
B75816	48	31	79
B75817	42	36	78
B75818	54	39	93
B75819	44	42	86

APPENDIX 3B
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHT CHANGES (G)

ANIMAL NUMBER	DAY 8	DAY 15	TOTAL 1-15
GROUP: MALE 4 - .6 MG/DAY			
B75830	48	45	93
B75831	48	49	97
B75832	49	50	99
B75833	39	40	79
B75834	50	52	102
B75835	44	43	87
B75836	48	43	91
B75837	47	39	86
B75838	46	34	80
B75839	45	34	79
GROUP: MALE 5 - 1.5 MG/DAY			
B75850	49	42	91
B75851	52	46	98
B75852	59	49	108
B75853	39	40	79
B75854	41	43	84
B75855	48	43	91
B75856	52	45	97
B75857	38	35	73
B75858	45	48	93
B75859	45	36	81
GROUP: MALE 6 - 3 MG/DAY			
B75870	49	42	91
B75871	43	36	79
B75872	38	37	75
B75873	44	46	90
B75874	39	41	80
B75875	58	38	96
B75876	34	35	69
B75877	52	38	90
B75878	49	58	107
B75879	51	43	94

APPENDIX 3B
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHT CHANGES (G)

ANIMAL NUMBER	DAY 8	DAY 15	TOTAL 1-15
GROUP: MALE 7 - 6 MG/DAY			
B75890	47	43	90
B75891	54	41	95
B75892	44	30	74
B75893	45	33	78
B75894	57	48	105
B75895	33	19	52
B75896	41	32	73
B75897	52	46	98
B75898	47	32	79
B75899	50	38	88
GROUP: FEMALE 1 - 0 MG/DAY			
B75780	33	20	53
B75781	26	11	37
B75782	27	30	57
B75783	19	20	39
B75784	27	18	45
B75785	26	10	36
B75786	12	43	55
B75787	30	11	41
B75788	12	36	48
B75789	33	13	46
GROUP: FEMALE 2 - 0 MG/DAY			
B75800	31	17	48
B75801	26	20	46
B75802	28	18	46
B75803	29	21	50
B75804	21	30	51
B75805	50	5	55
B75806	24	28	52
B75807	17	32	49
B75808	24	22	46
B75809	8	38	46

APPENDIX 3B
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHT CHANGES (G)

ANIMAL NUMBER	DAY 8	DAY 15	TOTAL 1-15
GROUP: FEMALE 3 - .3 MG/DAY			
B75820	16	34	50
B75821	23	29	52
B75822	21	18	39
B75823	26	11	37
B75824	9	21	30
B75825	10	33	43
B75826	26	23	49
B75827	32	11	43
B75828	29	29	58
B75829	26	10	36
GROUP: FEMALE 4 - .6 MG/DAY			
B75840	20	10	30
B75841	26	25	51
B75842	34	24	58
B75843	25	13	38
B75844	22	26	48
B75845	21	18	39
B75846	23	11	34
B75847	28	26	54
B75848	14	19	33
B75849	14	39	53
GROUP: FEMALE 5 - 1.5 MG/DAY			
B75860	8	16	24
B75861	8	42	50
B75862	19	31	50
B75863	14	21	35
B75864	26	16	42
B75865	16	28	44
B75866	31	14	45
B75867	24	29	53
B75868	32	27	59
B75869	15	36	51

APPENDIX 3B
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL BODY WEIGHT CHANGES (G)

ANIMAL NUMBER	DAY 8	DAY 15	TOTAL 1-15
GROUP: FEMALE 6 - 3 MG/DAY			
B75880	18	23	41
B75881	34	30	64
B75882	13	24	37
B75883	26	8	34
B75884	27	19	46
B75885	22	30	52
B75886	27	23	50
B75887	13	36	49
B75888	12	21	33
B75889	18	24	42
GROUP: FEMALE 7 - 6 MG/DAY			
B75900	21	13	34
B75901	23	10	33
B75902	15	35	50
B75903	24	23	47
B75904	30	30	60
B75905	25	20	45
B75906	39	27	66
B75907	25	13	38
B75908	36	26	62
B75909	24	28	52

Appendix 4
Individual Food Consumption
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Note: Dose levels are measured in mg/animal/day.

APPENDIX 4
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL FOOD CONSUMPTION (G)

ANIMAL NUMBER	PRETREATMENT	DAY 1	DAY 8	TOTAL 1-8
GROUP: MALE 1 - 0 MG/DAY				
B75770	161	190	212	402
B75771	130	143	153	296
B75772	159	173	197	370
B75773	142	168	175	343
B75774	146	167	189	356
B75775	162	181	198	379
B75776	156	180	215	395
B75777	154	194	202	396
B75778	153	185	194	379
B75779	144	175	197	372
GROUP: MALE 2 - 0 MG/DAY				
B75790	159	172	180	352
B75791	151	168	183	351
B75792	162	166	167	333
B75793	154	166	158	324
B75794	155	167	177	344
B75795	145	153	174	327
B75796	150	172	197	369
B75797	149	164	181	345
B75798	153	173	181	354
B75799	160	192	196	388
GROUP: MALE 3 - .3 MG/DAY				
B75810	156	171	198	369
B75811	147	169	174	343
B75812	147	SPILLED	189	
B75813	164	168	176	344
B75814	174	170	184	354
B75815	160	173	206	379
B75816	150	171	191	362
B75817	141	141	168	309
B75818	157	185	193	378
B75819	156	167	189	356

APPENDIX 4
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL FOOD CONSUMPTION (G)

ANIMAL NUMBER	PRETREATMENT	DAY 1	DAY 8	TOTAL 1-8
GROUP: MALE 4 - .6 MG/DAY				
B75830	156	175	185	360
B75831	151	167	180	347
B75832	163	180	200	380
B75833	147	164	176	340
B75834	154	181	197	378
B75835	163	180	184	364
B75836	173	188	196	384
B75837	160	172	186	358
B75838	178	192	191	383
B75839	158	186	189	375
GROUP: MALE 5 - 1.5 MG/DAY				
B75850	150	168	178	346
B75851	161	180	188	368
B75852	162	188	206	394
B75853	115	160	170	330
B75854	144	158	172	330
B75855	146	165	173	338
B75856	153	172	194	366
B75857	156	177	182	359
B75858	173	182	195	377
B75859	158	177	184	361
GROUP: MALE 6 - 3 MG/DAY				
B75870	150	166	179	345
B75871	139	158	159	317
B75872	147	151	161	312
B75873	138	155	181	336
B75874	146	158	170	328
B75875	151	177	187	364
B75876	158	163	174	337
B75877	153	178	187	365
B75878	164	182	216	398
B75879	179	208	219	427

APPENDIX 4
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL FOOD CONSUMPTION (G)

ANIMAL NUMBER	PRETREATMENT	DAY 1	DAY 8	TOTAL 1-8
GROUP: MALE 7 - 6 MG/DAY				
B75890	143	158	178	336
B75891	157	172	182	354
B75892	153	168	184	352
B75893	147	167	179	346
B75894	162	180	209	389
B75895	175	178	175	353
B75896	162	174	186	360
B75897	158	172	187	359
B75898	146	170	185	355
B75899	155	175	194	369
GROUP: FEMALE 1 - 0 MG/DAY				
B75780	113	135	137	272
B75781	133	133	147	280
B75782	111	136	155	291
B75783	149	124	129	253
B75784	154	145	163	308
B75785	131	130	133	263
B75786	133	134	165	299
B75787	126	129	146	275
B75788	117	118	161	279
B75789	128	134	149	283
GROUP: FEMALE 2 - 0 MG/DAY				
B75800	107	134	147	281
B75801	108	118	137	255
B75802	121	136	145	281
B75803	130	142	154	296
B75804	147	136	154	290
B75805	115	190	195	385
B75806	140	138	153	291
B75807	149	157	191	348
B75808	121	135	145	280
B75809	142	136	163	299

APPENDIX 4
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL FOOD CONSUMPTION (G)

ANIMAL NUMBER	PRETREATMENT	DAY 1	DAY 8	TOTAL 1-8
GROUP: FEMALE 3 - .3 MG/DAY				
B75820	131	SPILLED	150	
B75821	136	126	147	273
B75822	126	125	133	258
B75823	103	127	134	261
B75824	124	119	132	251
B75825	92	118	141	259
B75826	144	126	138	264
B75827	127	138	145	283
B75828	109	126	147	273
B75829	141	158	183	341
GROUP: FEMALE 4 - .6 MG/DAY				
B75840	148	135	142	277
B75841	127	136	144	280
B75842	134	137	142	279
B75843	121	128	132	260
B75844	140	145	158	303
B75845	114	126	135	261
B75846	129	131	141	272
B75847	135	150	160	310
B75848	109	131	145	276
B75849	125	121	152	273
GROUP: FEMALE 5 - 1.5 MG/DAY				
B75860	118	104	111	215
B75861	136	144	158	302
B75862	125	127	164	291
B75863	128	118	125	243
B75864	126	129	135	264
B75865	127	137	146	283
B75866	120	142	164	306
B75867	130	133	148	281
B75868	132	134	152	286
B75869	142	133	159	292

APPENDIX 4
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL FOOD CONSUMPTION (G)

ANIMAL NUMBER	PRETREATMENT	DAY 1	DAY 8	TOTAL 1-8
GROUP: FEMALE 6 - 3 MG/DAY				
B75880	135	137	140	277
B75881	122	131	139	270
B75882	119	127	139	266
B75883	160	134	153	287
B75884	122	139	150	289
B75885	143	136	146	282
B75886	139	145	164	309
B75887	132	141	164	305
B75888	117	114	137	251
B75889	129	137	155	292
GROUP: FEMALE 7 - 6 MG/DAY				
B75900	128	116	124	240
B75901	141	116	132	248
B75902	144	163	139	302
B75903	132	123	171	294
B75904	136	137	162	299
B75905	82	113	130	243
B75906	122	126	150	276
B75907	105	136	152	288
B75908	140	150	169	319
B75909	125	133	151	284

Appendix 5
Individual Animal Summary Report
14-Day Repeated Dose Dermal Study of Triclosan in Rats

-H- = Observation entered at time of tissue trimming.
Note: The pathologist indicated in this presentation is the attending pathologist at necropsy.

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75770 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 303.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:07 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.96	.647 %	1.000	WEIGHT TAKEN
LIVER (LI)	11.32	3.735 %	5.769	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS, LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S

NECROPSY

LIVER (LI) :
-H-PALE AREA; MEDIAN LOBE, ONE, TAN, 2 X 2 MM

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75771 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 243.1 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:22 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.97	.812 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.04	3.308 %	4.073	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75772 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 295.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:38 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.02	.682 %	1.000	WEIGHT TAKEN
LIVER (LI)	10.21	3.450 %	5.056	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75773 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 281.9 GRAMS
DATE AND TIME OF NECROPSY: 05/09/99 9:50 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.02	.715 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.21	2.911 %	4.072	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS. LAST DERMAL
EVALUATIONS:NORMAL-NO REMARKABLE
OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS.
MAMMARY, MALE (MM) :
-HYPERPLASIA,-PRESENT
SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75774 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 258.4 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:15 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.72	.667 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.30	3.600 %	5.397	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75775 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 279.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:32 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.94	.694 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.72	3.118 %	4.493	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-SLIGHT SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75776 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 259.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:48 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.92	.740 %	1.000	WEIGHT TAKEN
LIVER (LI)	10.08	3.889 %	5.256	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75777 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 276.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:27 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.98	.718 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.93	3.232 %	4.503	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-SLIGHT SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE SKIN, UNTREATED (US) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75778 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 254.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:43 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.82	.718 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.52	2.959 %	4.122	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75779 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 257.6 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 13:00 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.86	.721 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.71	3.381 %	4.691	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75790 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 274.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:07 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.96	.715 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.30	3.025 %	4.229	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-NECROSIS,-MINIMAL
-MINERALIZATION,-MINIMAL
SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75791 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 278.5 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:25 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.05	.734 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.27	3.330 %	4.534	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
		SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75792 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 249.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:39 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.82	.729 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.25	3.312 %	4.542	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75793 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 251.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:55 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.94	.770 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.89	3.135 %	4.070	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75794 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 257.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:15 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.88	.730 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.90	3.462 %	4.741	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75795 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 264.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:35 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.08	.786 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.51	3.213 %	4.086	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75796 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 280.5 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:52 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.91	.682 %	1.000	WEIGHT TAKEN
LIVER (LI)	11.11	3.960 %	5.810	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

PATHOLOGY OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75797 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 270.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:30 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.89	.699 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.09	3.357 %	4.806	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL LN, OTHER (LN) : >UNREMARKABLE >NOTE:>SUBCUTANEOUS. SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75798 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 244.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:45 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.85	.756 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.67	3.134 %	4.148	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75799 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 284.5 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 13:04 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.95	.686 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.26	3.256 %	4.747	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75810 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 276.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:08 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.99	.721 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.42	3.405 %	4.723	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75811 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 264.3 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:25 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.97	.744 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.48	3.208 %	4.310	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
SKIN, UNTREATED (US) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75812 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 249.9 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:41 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.77	.708 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.32	3.327 %	4.701	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75813 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 264.4 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:57 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.74	.660 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.16	3.088 %	4.681	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75814 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 269.9 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:16 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.99	.736 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.46	3.505 %	4.763	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75819 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 270.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 13:04 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.96	.724 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.76	3.246 %	4.481	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75830 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 288.3 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:08 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.94	.673 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.57	3.320 %	4.932	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75831 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 290.9 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:28 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.06	.707 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.27	2.845 %	4.024	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-SLIGHT, DIFFUSE
-ACANTHOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75832 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 296.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:43 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.09	.705 %	1.000	WEIGHT TAKEN
LIVER (LI)	11.94	4.033 %	5.720	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS. LAST DERMAL
EVALUATIONS:NORMAL-NO REMARKABLE
OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
-ACANTHOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75833 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 253.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:00 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.91	.751 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.13	3.204 %	4.266	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

KIDNEY (KD) :
-PELVIS, DILATED, MODERATE; BOTH
-PELVIS, CALCULUS; BOTH, SEVERAL, FIRM, TAN, PINPOINT TO 1 X 1 MM
LIVER (LI) :
-DARK AREA; LEFT LATERAL LOBE, AT MARGIN, ONE, DARK RED, 5 X 4 MM

URINARY BLADDER (UB) :
-WALL, THICKENED, MODERATE
-LUMEN, CALCULUS; MULTIPLE, FIRM, TAN, PINPOINT TO 5 X 5 MM
^COLLECTED/TAKEN (XW) :
-CALCULUS (KIDNEY)
-CALCULUS (URINARY BLADDER)
-PHOTOGRAPH

HISTOPATHOLOGY

KIDNEY (KD) :
-PELVIS, DILATATION,-PRESENT
-PYELONEPHRITIS,-PRESENT

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-HEMORRHAGE,-PRESENT
SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
URINARY BLADDER (UB) :
-INFLAMMATION,-PRESENT
-CALCULUS,-PRESENT
-HYPERPLASIA,-PRESENT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75833 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 253.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:00 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75834 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 293.4 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:20 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.96	.668 %	1.000	WEIGHT TAKEN
LIVER (LI)	10.61	3.616 %	5.411	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75835 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 286.6 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:37 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.96	.685 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.95	3.471 %	5.067	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-SLIGHT -NECROSIS,-SLIGHT SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75836 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 279.6 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:19 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.85	.660 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.20	3.290 %	4.986	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75837 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 273.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:32 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.73	.634 %	1.000	WEIGHT TAKEN
LIVER (LI)	11.11	4.067 %	6.417	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75838 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 272.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:46 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.74	.639 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.37	3.434 %	5.370	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-CAPSULE, FIBROSIS,-PRESENT

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75839 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 263.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 13:06 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.84	.698 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.38	3.178 %	4.552	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-SLIGHT
		SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75850 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 266.1 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:17 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.90	.715 %	1.000	WEIGHT TAKEN
LIVER (LI)	10.10	3.797 %	5.311	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75851 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 280.5 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:33 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.92	.686 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.32	3.324 %	4.847	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75852 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 284.3 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:45 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	2.00	.704 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.85	3.463 %	4.917	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

PATHOLOGY OBSERVATIONS

NECROPSY

LIVER (LI) :
-DARK AREA; MEDIAN LOBE, ONE, DARK RED, 1 X 1 MM

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT
-PHOTOGRAPH

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-HEMORRHAGE,-PRESENT

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
SKIN, UNTREATED (US) :
-HYPERKERATOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75853 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 257.9 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:05 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.94	.752 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.44	3.271 %	4.353	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75854 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 260.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:24 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.99	.762 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.68	3.327 %	4.364	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75855 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 272.3 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:40 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.95	.716 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.03	3.316 %	4.631	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -DARK AREA; LEFT LATERAL LOBE, ONE, DARK RED, 5 X 4 MM ^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75856 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 279.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:20 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.74	.625 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.86	3.176 %	5.085	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
SKIN, UNTREATED (US) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75857 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 262.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:35 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.86	.709 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.99	3.433 %	4.840	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
		SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75858 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 276.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:53 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.87	.676 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.24	3.349 %	4.954	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75859 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 273.3 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 13:10 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.96	.718 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.69	3.545 %	4.934	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75870 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 271.4 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:18 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.00	.736 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.72	3.580 %	4.865	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75871 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 260.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:37 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.85	.710 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.51	2.888 %	4.069	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS. LAST DERMAL
EVALUATIONS:NORMAL-NO REMARKABLE
OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT

LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>ABDOMINAL.

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75872 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 262.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:50 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.00	.761 %	1.000	WEIGHT TAKEN
LIVER (LI)	11.44	4.355 %	5.720	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:ERYTHEMA, SLIGHT

P A T H O L O G Y O B S E R V A T I O N S

NECROPSY

SKIN, TREATED (TS) :
-ERYTHEMA, SLIGHT

^COLLECTED/TAKEN (XW) :
-PHOTOGRAPH

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-ACANTHOSIS,-SLIGHT, FOCAL
-EPIDERMIS, DEBRIS, SUPERFICIAL,-PRESENT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75873 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 271.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:05 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.98	.728 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.69	3.197 %	4.390	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75874 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 268.1 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:25 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.99	.743 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.42	3.142 %	4.228	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75875 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 269.3 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:44 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.00	.741 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.85	2.914 %	3.931	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75876 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 259.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:20 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.93	.743 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.41	3.239 %	4.360	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75877 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 294.5 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:37 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	2.13	.722 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.30	3.157 %	4.375	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75878 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 289.0 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:55 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.94	.673 %	1.000	WEIGHT TAKEN
LIVER (LI)	10.09	3.491 %	5.190	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
		SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75879 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 301.8 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 13:11 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.84	.609 %	1.000	WEIGHT TAKEN
LIVER (LI)	10.18	3.372 %	5.540	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	SKIN, TREATED (TS) : -HYPERKERATOSIS,-SLIGHT, DIFFUSE
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75890 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 256.4 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:17 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.80	.701 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.61	2.968 %	4.235	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75892 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 259.4 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 9:52 PROSECTOR: DOUGLAS HERNDON RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.90	.732 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.01	3.088 %	4.217	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:ESCHAR-YES(1% TO 20% OF TEST SITE)		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	SKIN, TREATED (TS) : -ESCHAR; 1% TO 20 % OF TEST SITE	SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL -ACANTHOSIS,-MODERATE, MULTI-FOCAL -EPIDERMIS, DEBRIS, SUPERFICIAL,-PRESENT -INFLAMMATION, CHRONIC,-MINIMAL
	^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75895 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 241.6 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 10:46 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.77	.732 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.04	3.741 %	5.111	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	KIDNEY (KD) : -PELVIS, DILATED, MODERATE; RIGHT ^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	KIDNEY (KD) : -PELVIS, DILATATION,-PRESENT -TUBULE, MINERALIZATION,-PRESENT LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75896 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 260.5 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:22 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.97	.758 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.52	3.269 %	4.314	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75897 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 288.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:38 PROSECTOR: CURTIS BUSH RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.01	.699 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.15	3.176 %	4.546	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75898 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 257.2 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 12:58 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.88	.732 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.83	3.046 %	4.161	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-SLIGHT SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75899 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/09/96 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 273.7 GRAMS
DATE AND TIME OF NECROPSY: 05/09/96 13:16 PROSECTOR: KATHERINE BOLDEN RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.89	.692 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.72	3.551 %	5.129	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:ESCHAR-YES (1% TO 20% OF TEST SITE)

NECROPSY

SKIN, TREATED (TS) :
-ESCHAR; 1% TO 20% OF TEST SITE

^COLLECTED/TAKEN (XW) :
-PHOTOGRAPH

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
-ACANTHOSIS,-SLIGHT, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, MALE (MM), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75780 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 189.6 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:15 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.88	.992 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.99	3.160 %	3.185	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-NECROSIS,-MINIMAL

LN, OTHER (LN) :
>UNREMARKABLE.
>NOTE:>SUBCUTANEOUS.

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75781 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 180.1 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:29 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.79	.991 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.68	3.710 %	3.742	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75783 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 180.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:59 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.87	1.033 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.34	3.508 %	3.397	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-NECROSIS,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75784 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 190.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:12 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.92	1.008 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.07	3.713 %	3.682	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75785 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 178.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:31 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.83	1.026 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.85	3.280 %	3.198	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75786 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 194.4 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:46 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.90	.976 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.20	3.703 %	3.794	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75787 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 183.5 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:05 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.94	1.056 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.52	3.009 %	2.849	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-SLIGHT ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75788 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 162.7 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:20 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.81	1.114 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.13	3.765 %	3.379	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75789 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 181.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:30 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.75	.963 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.95	3.270 %	3.398	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75800 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 188.4 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:16 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.75	.927 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.71	3.560 %	3.841	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT
-NECROSIS,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75801 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 177.5 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:30 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.98	1.118 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.34	3.009 %	2.691	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75802 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 182.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:45 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.84	1.010 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.44	3.533 %	3.497	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75803 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 187.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:00 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	2.10	1.116 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.19	3.298 %	2.956	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75804 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 205.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:17 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.67	.813 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.59	4.183 %	5.147	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75805 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 207.6 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:31 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.82	.875 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.70	3.708 %	4.237	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

PATHOLOGY OBSERVATIONS

NECROPSY

LIVER (LI) :
-DARK AREA; LEFT LATERAL LOBE, ONE, DARK RED, 5 X 3 MM

^COLLECTED/TAKEN (XW) :
-PHOTOGRAPH

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75806 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 192.9 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:50 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.93	1.000 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.76	4.024 %	4.024	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

SKIN, UNTREATED (US) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75807 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 188.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:06 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.94	1.030 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.39	3.927 %	3.814	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS.

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75808 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 175.0 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:21 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.78	1.016 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.56	3.751 %	3.693	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75809 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 193.6 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:35 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.00	1.032 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.21	3.726 %	3.610	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS, LAST DERMAL
EVALUATIONS:NORMAL-NO REMARKABLE
OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-NECROSIS,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75820 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 184.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:17 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.91	1.038 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.30	3.421 %	3.295	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75821 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 197.7 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:35 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.89	.956 %	1.000	WEIGHT TAKEN
LIVER (LI)	9.21	4.656 %	4.870	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75824 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 170.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:18 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.78	1.044 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.77	3.964 %	3.796	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75827 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 185.9 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:07 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.85	.993 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.82	3.130 %	3.150	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75828 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 176.0 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:22 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.90	1.078 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.93	3.936 %	3.650	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	UTERUS (UT) : -DISTENDED, MODERATE; BOTH HORNS -LUMEN, FLUID; BOTH HORNS, MODERATE AMOUNT, CLEAR ^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	UTERUS (UT) : -DILATATION,-PRESENT
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75829 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 192.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:37 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.76	.913 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.41	3.338 %	3.654	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75840 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 169.5 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:18 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.87	1.105 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.64	3.330 %	3.014	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75841 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 191.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:28 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.85	.968 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.27	3.802 %	3.929	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-NECROSIS,-MINIMAL
-CAPSULE, FIBROSIS,-PRESENT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75842 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 186.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:51 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.93	1.038 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.64	3.566 %	3.435	WEIGHT TAKEN

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL -NECROSIS,-MINIMAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75843 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 179.9 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:07 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.95	1.085 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.99	3.886 %	3.581	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75844 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 195.5 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:18 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.70	.869 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.11	3.635 %	4.185	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75845 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 191.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:34 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.83	.959 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.70	3.501 %	3.651	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	LN, MANDIBULAR (MN) : -ENLARGED, MODERATE	LN, MANDIBULAR (MN) : -HYPERPLASIA, LYMPHOID,-PRESENT
		SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75846 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 191.6 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:56 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.97	1.028 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.35	3.314 %	3.224	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75847 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 186.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:11 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.80	.968 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.38	4.500 %	4.647	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75848 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 161.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:23 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.93	1.194 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.05	4.355 %	3.648	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75849 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 184.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:38 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.90	1.031 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.31	3.423 %	3.322	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

KIDNEY (KD) :
-PELVIS, DILATED, SEVERE; RIGHT
-PELVIS, FLUID; RIGHT, MODERATE AMOUNT, CLEAR

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

KIDNEY (KD) :
-PELVIS, DILATATION,-PRESENT
-TUBULE, MINERALIZATION,-PRESENT
-NEPHROPATHY, CHRONIC PROGRESSIVE,-PRESENT
LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75860 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 153.9 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:22 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.80	1.171 %	1.000	WEIGHT TAKEN
LIVER (LI)	4.60	2.990 %	2.553	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75861 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 193.7 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:37 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.73	.895 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.24	3.740 %	4.177	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL -VACUOLIZATION, PERIPORTAL,-SLIGHT ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75862 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 166.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:53 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.81	1.084 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.04	4.220 %	3.895	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75863 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 168.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:09 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.79	1.058 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.80	3.436 %	3.248	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75864 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 180.7 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:21 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.70	.942 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.18	3.420 %	3.630	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, FOCAL
-EPIDERMIS, DEBRIS, SUPERFICIAL,-PRESENT

SKIN, UNTREATED (US) :
-HYPERKERATOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75865 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 165.4 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:38 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.89	1.140 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.47	3.912 %	3.430	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:ERYTHEMA, SLIGHT; ESCHAR-YES (1% TO 20% OF TEST SITE)		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	SKIN, TREATED (TS) : -ERYTHEMA, SLIGHT -ESCHAR; 1% TO 20% OF TEST SITE	SKIN, TREATED (TS) : -ACANTHOSIS,-SLIGHT, DIFFUSE -EPIDERMIS, DEBRIS, SUPERFICIAL,-PRESENT -ULCER,-SLIGHT, FOCAL
	^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75866 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 196.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:56 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.85	.941 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.85	3.488 %	3.707	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL -NECROSIS,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75867 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 189.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:14 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.77	.937 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.93	3.664 %	3.911	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

PATHOLOGY OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75868 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 197.4 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:29 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.94	.984 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.21	3.652 %	3.711	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75869 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 203.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:40 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.92	.943 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.64	3.267 %	3.466	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75880 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 194.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:26 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.90	.979 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.63	3.929 %	4.014	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75881 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 186.7 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:39 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.74	.935 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.86	3.676 %	3.933	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -INFLAMMATION, CHRONIC,-SLIGHT
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75882 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 178.4 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:53 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.86	1.041 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.93	3.884 %	3.733	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-SLIGHT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75883 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 176.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:10 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.78	1.007 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.46	3.088 %	3.066	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75884 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 182.1 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:26 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.78	.976 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.58	3.612 %	3.702	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75885 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 184.4 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:42 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.89	1.023 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.31	3.964 %	3.877	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75886 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 194.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:00 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.10	1.080 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.21	3.709 %	3.436	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75887 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 185.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:14 PROSECTOR: LINDA RUMBLE RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.88	1.016 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.23	3.363 %	3.311	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS, LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75888 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 165.7 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:29 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.83	1.106 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.92	4.175 %	3.773	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, TREATED (TS), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75889 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 175.9 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:45 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.90	1.079 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.99	3.975 %	3.683	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75900 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 161.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:28 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.59	.984 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.13	3.804 %	3.864	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:SCALING, SLIGHT

NECROPSY

SKIN, TREATED (TS) :
-SCALING, SLIGHT
UTERUS (UT) :
-WALL, THICKENED, SLIGHT; BOTH HORNS
^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL
UTERUS (UT) :
>UNREMARKABLE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75901 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 164.4 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:43 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
BRAIN W/STEM (BR)	1.82	1.110 %	1.000	WEIGHT TAKEN
LIVER (LI)	5.77	3.508 %	3.161	WEIGHT TAKEN

PATHOLOGY OBSERVATIONS

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75902 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 174.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 8:57 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.66	.955 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.41	4.252 %	4.455	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:SCALING, MODERATE; ESCHAR-YES(1% TO 20% OF TEST SITE)		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	SKIN, TREATED (TS) : -ESCHAR; 1% TO 20% OF TEST SITE -SCALING, MODERATE ^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL -ACANTHOSIS,-MINIMAL, FOCAL
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75903 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 181.0 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:13 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.72	.949 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.65	3.677 %	3.874	WEIGHT TAKEN

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:SCALING, SLIGHT	SKIN, TREATED (TS) : -SCALING, SLIGHT ^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75904 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 198.3 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:27 PROSECTOR: MEREDITH HILL RECORDER: RIKKI KANE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.83	.921 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.99	3.523 %	3.824	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:NORMAL-NO REMARKABLE OBSERVATIONS

NECROPSY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
SKIN, UNTREATED (US) :
-ACANTHOSIS,-MINIMAL, FOCAL
-HYPERKERATOSIS,-MINIMAL, MULTI-FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, TREATED (TS), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75905 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 167.8 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 9:50 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.68	.999 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.67	3.973 %	3.977	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:ERYTHEMA, SLIGHT; SCALING, SLIGHT

NECROPSY

SKIN, TREATED (TS) :
-SCALING, SLIGHT

^COLLECTED/TAKEN (XW) :
-PHOTOGRAPH

GENERAL INFORMATION (XX) :
>NOTE:>ERYTHEMA, NOT EVIDENT AT NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL
-VACUOLIZATION, PERIPORTAL,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, FOCAL
-EPIDERMIS, DEBRIS, SUPERFICIAL,-PRESENT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
MAMMARY, FEMALE (MF), SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75906 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 186.7 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:01 PROSECTOR: KATHERINE BOLDEN RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.91	1.023 %	1.000	WEIGHT TAKEN
LIVER (LI)	7.95	4.256 %	4.162	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:SCALING, SLIGHT	SKIN, TREATED (TS) : -SCALING, SLIGHT ^COLLECTED/TAKEN (XW) : -PHOTOGRAPH	LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL -VACUOLIZATION, PERIPORTAL,-MINIMAL SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75907 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 185.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:15 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	2.03	1.095 %	1.000	WEIGHT TAKEN
LIVER (LI)	6.64	3.585 %	3.273	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:SCALING, SLIGHT

NECROPSY

SKIN, TREATED (TS) :
-SCALING, SLIGHT

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC,-MINIMAL

SKIN, TREATED (TS) :
-HYPERKERATOSIS,-MINIMAL, DIFFUSE
-ACANTHOSIS,-MINIMAL, FOCAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 5
14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS
INDIVIDUAL ANIMAL SUMMARY REPORT

ANIMAL NUMBER: B75908 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 05/10/96 STUDY DAY OF DEATH: 17 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 207.2 GRAMS
DATE AND TIME OF NECROPSY: 05/10/96 10:30 PROSECTOR: SONNY DIKES RECORDER: KELCEY BECKER
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: SID JONES, DVM, PHD WEIGHER: LINH NGUYEN

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
BRAIN W/STEM (BR)	1.90	.915 %	1.000	WEIGHT TAKEN
LIVER (LI)	8.17	3.942 %	4.307	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S

CLINICAL OBSERVATIONS	NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS. LAST DERMAL EVALUATIONS:SCALING, SLIGHT		LIVER (LI) : -INFLAMMATION, CHRONIC,-MINIMAL
	SKIN, TREATED (TS) : -SCALING, SLIGHT ^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	SKIN, TREATED (TS) : -HYPERKERATOSIS,-MINIMAL, DIFFUSE
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), LN, MANDIBULAR (MN), SKIN, UNTREATED (US), URINARY BLADDER (UB), UTERUS (UT)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
SKIN, UNTREATED (US)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

Appendix 6
Plasma Analysis Report
14-Day Repeated Dose Dermal Study of Triclosan in Rats

PLASMA SAMPLE ANALYSIS REPORT

SUMMARY

The test material, Triclosan, was administered to the skin of Crl:CD®BR rats at dosage levels of 0, 0, 0.3, 0.6, 1.5, 3.0, and 6.0 mg/rat/day (Groups 1-7, respectively) for at least 14 days. Blood samples were collected on the day of necropsy, Days 16 and 17 (male and females, respectively). Plasma was collected and analyzed by gas chromatography using an electron capture detector (GC/ECD) for concentration of Triclosan.

The following is a summary of the mean concentration, standard deviation (SD), and coefficient of variation (CV) for the combined males and females at the different dose levels.

Text Table 1
Sample Analysis Summary

Group	Sex	Dose Level mg/rat/day	Mean Concentration µg/mL	SD	CV %
1	M	0	ND	NA	NA
1	F	0	ND[a]	NA	NA
2	M	0	ND	NA	NA
2	F	0	ND	NA	NA
3	M	0.3	1.015	0.692	68.2
3	F	0.3	1.221	0.793	64.9
4	M	0.6	2.066	1.03	49.9
4	F	0.6	2.402	0.930	38.7
5	M	1.5	6.634	3.02	45.5
5	F	1.5	5.234	3.21	61.3
6	M	3.0	14.13	4.13	29.3
6	F	3.0	9.173[a]	3.78	41.2
7	M	6.0	31.55	13.2	41.8
7	F	6.0	18.11	7.16	39.6

ND - Not detectable
NA - Not applicable
[a] - See explanation on page 323.

The results indicate increasing exposure to Triclosan as the dermal dose was increased from 0 to 6.0 mg/rat/day. Males appear to have higher levels of Triclosan than females at the higher dose levels (1.5, 3.0, and 6.0 mg/rat/day).

INTRODUCTION

This study was designed to evaluate the dermal toxicity of Triclosan in acetone when applied to the skin of Crl:CD®BR rats seven times a week for at least 14 days, and to provide a scientific basis for dose selection in a possible subsequent 90-day dermal study. On the day of necropsy, blood was taken from the fasted rats by puncture of the orbital plexus (following carbon dioxide/oxygen inhalation anesthesia), collected in lithium-heparinized tubes and processed for plasma. The plasma samples were stored at approximately -20°C until analysis for Triclosan using a validated GC/ECD method.

METHODS

Analytical Method

The plasma samples were assayed for Triclosan using a GC/ECD method validated by CHV (CHV Analytical Method No. 638).

The quality control (QC) samples and the internal standards (ISTD) were prepared in pools, aliquotted, and kept frozen at approximately -20°C. The QC samples and the ISTD were treated the same as the plasma samples after thawing at room temperature. Preparation of the ISTD and the QC samples is detailed in CHV Analytical Method No. 638 (Attachment 1).

Triclosan was hydrolysed using concentrated HCl and extracted from the rat plasma samples with hexane by shaking, followed by centrifugation. Aliquots of the extracts were dried under nitrogen and reconstituted with additional hexane. Final sample solutions were analyzed by gas chromatography using an electron capture detector (GC/ECD).

Each analytical run consisted of one blank (pooled blank rat plasma from commercial source), eight standard curve points (20.16, 10.08, 5.040, 3.024, 1.512, 1.008, 0.2016, and 0.1008 μg/mL, respectively), and duplicate QC samples consisting of 5, 10, and 15 μg/mL of Triclosan (low, mid, and high, respectively).

Peak area ratios of Triclosan and the ISTD were calculated. The standard curves were obtained by least-squares linear regression analysis. The equations of the standard curves were then used to caluculate the concentration of Triclosan in the plasma and QC samples from their peak area ratios.

Five separate analytical runs (analysis runs) were required for the samples for this study. The lower limit of quantitation for each analysis group was set at 0.1μg/mL for Triclosan in rat plasma.

A minimum of four QC samples will be within 100±15% (100±20% for the low QC sample) of their nominal value and no two QC samples at the same concentration level will be allowed outside that range in the same run. If the QC sample results did not meet these criteria, the run was rejected and the assay repeated.

RESULTS

Performance of the Assay

Standard curve: An eight point standard curve was run with each plasma sample analysis (excluding a blank). The linearity of the standard curve is indicated by the back-fitted value as well as correlation coefficient (R). The correlation coefficient of 0.9993 or better was obtained from all standard curves. The individual linearity and slope of each standard curve are summarized in Table 1.

Specificity: When assayed for Triclosan, the blank rat plasma contained no interfering peaks at the retention time of Triclosan or the ISTD. The blank was prepared from pooled rat plasma obtained from a commercial source. Typical chromatograms of blank rat plasma, representative standards, and study samples are presented in the CHV Analytical Method No. 638.

Sensitivity: The limit of quantitation (LOQ) for Triclosan was established during the validation at 0.1 μg/mL.

Calculation: A linear regression of peak area versus the concentration was performed on the standard points of each analytical run and a set of parameters (correlation coefficient, slope and y-intercept) was generated by the regression. Triclosan concentrations in the rat plasma samples as well as the QC samples were calculated by using the standard curve parameters generated above and the peak area ratios of the samples.

QC samples: Six QC samples were analyzed with each sample analysis run, two of each at low, mid, and high concentrations. In a total of five runs, the percent target and CV of the low, mid, and high QC samples yielded results of 104 and 12.4%; 98.0 and 4.28%; and 98.9 and 8.89%, respectively. The results of the QC samples are summarized in Table 2.

Sample Analysis

The concentration of Triclosan in the rat plasma samples is presented in Tables 3-9, for Groups 1-7, respectively.

Five analytical runs were performed on the rat plasma samples. Analysis for Groups 5 and 6 was repeated based on the high QC sample results outside the defined range. The data for the repeat analysis is reported.

Rat plasma samples 75789 (Group 1 female), 75889 (Group 6 female), and 75900 (Group 7 female) were repeated for concentration confirmation. The results of the repeated analysis are reported.

There was no Triclosan detected in the animals for Groups 1[a] and 2.

The mean concentration of Triclosan detected in Group 3 animals is 1.015 and 1.221 μg/mL (males and females, respectively); in Group 4 animals is 2.066 and 2.402 μg/mL (males and females, respectively); in Group 5 animals is 6.634 and 5.234 μg/mL (males and females, respectively); in Group 6 animals is 14.13 and 9.173[a] μg/mL (males and females, respectively); and in Group 7 animals is 31.55 and 18.11 μg/mL (males and females, respectively).

CONCLUSIONS

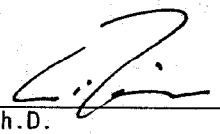
Concentration of Triclosan detected in rat plasma after at least 14-days of dermal exposure increased as the dose level increased from 0 to 6.0 mg/rat/day.

[a] Based on the possibility that the plasma samples were inadvertently switched during processing for animals 75789 (Group 1 female) and 75889 (Group 6 female) interpretation of the analyses is reported with the values excluded. Summary statistics with and without the questionable data values are reported in Tables 3, for animal 75789, and 8, for animal 75889.

SAMPLE RETENTION

Residual plasma samples will be stored at approximately -20°C until report finalization and then discarded.

SIGNATURE PAGE



Li Tian, Ph.D.
Department of Chemistry

11/13/96
Date

ABBREVIATIONS

°C	centigrade degrees
%	percent
CV	coefficient of variation
%CV	percent CV
->	greater than
<	less than
min	minute
hr	hour
pg	picogram
ng	nanogram
µg	microgram
µL	microliter
mL	milliliter
µm	micrometer
cm	centimeter
M	molar concentration
N	normal concentration
QC	quality control
R	correlation coefficient
SD	standard deviation
LOQ	lower limit of quantitation
ND	not detectable
GC/ECD	gas chromatography using an electron capture detector
UV	ultra-violet
AUFS	absorbance unit full scale
MeOH	methanol
ACN	acetonitrile

TABLE 1

Summary of Standard Curves

Summary of Standard Curve Information

Conc. (μg/mL)	Standard Curves 1	2	3	4	5*	5*	Mean	SD	CV
20.16	19.64	19.71	21.03	19.44	18.38	18.30	19.42	1.006	5.18
10.08	10.08	9.777	8.762	9.971	9.561	9.544	9.616	0.470	4.89
5.040	5.161	5.021	4.373	4.904	4.941	4.959	4.893	0.270	5.52
3.024	3.146	3.037	2.538	3.071	2.991	2.976	2.960	0.216	7.29
1.512	1.484	1.631	1.346	1.587	1.545	1.542	1.523	0.0995	6.53
1.008	1.004	1.063	0.965	1.074	1.061	1.057	1.037	0.0432	4.17
0.2016	0.1972	0.1802	0.2418	0.1883	0.2785	0.2781	0.2273	0.0449	19.7
0.1008	0.1021	0.1085	0.0885	0.1045	0.0859	0.1795	0.1115	0.0345	30.9
R	0.9993	0.9998	0.9998	0.9998	0.9998		0.9997	0.0002	0.0
Slope	992601	1028647	488676	1025355	996697		906395	234079	25.8
Y-intercept	13240	31909	84954	42433	-38919		26723	45153	169

Note: Standard curves 1, 2, 3, 4, and 5 are from sample analysis run 1, 2, 3, 4, and 5, respectively.

* - Two standard curves were used for sample analysis run 5, regression was based on both analyses.

TABLE 2

Summary of QC Samples

Summary of QC Samples

Analytical Run Number	Percent Target of QC		
	Low	Mid	High
1	104	99.6	99.5
1	103	99.0	101
2	95.8	92.5	95.3
2	97.5	95.2	95.3
3	103	106	115
3	101	102	113
4	97.5	97.6	96.8
4	139	98.5	88.7
5	97.9	95.0	92.1
5	98.1	93.6	91.7
Mean	104	98.0	98.9
SD	12.8	4.19	8.78
CV	12.4	4.28	8.89

TABLE 3
Summary of Rat Plasma Samples
(Group 1 male and female)

Day 17 (Female) and Day 16 (Male)

Group Number	Sex	Animal Number	Concentration ug/mL	Mean concentration	SD	CV
1	Male	75770	0			
1	Male	75771	0			
1	Male	75772	0			
1	Male	75773	0			
1	Male	75774	0	0.000	0.00	0.00
1	Male	75775	0			
1	Male	75776	0			
1	Male	75777	0			
1	Male	75778	0			
1	Male	75779	0			
1	Female	75780	0			
1	Female	75781	0			
1	Female	75782	0			
1	Female	75783	0			
1	Female	75784	0	0.4374	1.38	316
1	Female	75785	0	0.000*	0.00*	0.00*
1	Female	75786	0			
1	Female	75787	0			
1	Female	75788	0			
1	Female	75789	4.374			

* Data from animal No. 75789 excluded.

TABLE 4
Summary of Rat Plasma Samples
(Group 2 male and female)

Day 17 (Female) and Day 16 (Male)

Group Number	Sex	Animal Number	Concentration ug/mL	Mean concentration	SD	CV
2	Male	75790	0.000			
2	Male	75791	0.000			
2	Male	75792	0.000			
2	Male	75793	0.000			
2	Male	75794	0.000	0.000	0.00	0.00
2	Male	75795	0.000			
2	Male	75796	0.000			
2	Male	75797	0.000			
2	Male	75798	0.000			
2	Male	75799	0.000			
2	Female	75800	0.000			
2	Female	75801	0.000			
2	Female	75802	0.000			
2	Female	75803	0.000			
2	Female	75804	0.000	0.000	0.00	0.00
2	Female	75805	0.000			
2	Female	75806	0.000			
2	Female	75807	0.000			
2	Female	75808	0.000			
2	Female	75809	0.000			

TABLE 5
Summary of Rat Plasma Samples
(Group 3 male and female)

Day 17 (Female) and Day 16 (Male)

Group Number	Sex	Animal Number	Concentration ug/mL	Mean concentration	SD	CV
3	Male	75810	0.7946			
3	Male	75811	0.3385			
3	Male	75812	1.745			
3	Male	75813	0.6382			
3	Male	75814	0.6321	1.015	0.692	68.2
3	Male	75815	0.6918			
3	Male	75816	1.077			
3	Male	75817	2.640			
3	Male	75818	0.5282			
3	Male	75819	1.062			
3	Female	75820	1.331			
3	Female	75821	1.743			
3	Female	75822	1.549			
3	Female	75823	2.920			
3	Female	75824	1.438	1.221	0.793	64.9
3	Female	75825	1.255			
3	Female	75826	0.1457			
3	Female	75827	0.6956			
3	Female	75828	0.4251			
3	Female	75829	0.7065			

TABLE 6
Summary of Rat Plasma Samples
(Group 4 male and female)

Day 17 (Female) and Day 16 (Male)

Group Number	Sex	Animal Number	Concentration ug/mL	Mean concentration	SD	CV
4	Male	75830	2.532			
4	Male	75831	4.497			
4	Male	75832	2.459			
4	Male	75833	1.476			
4	Male	75834	2.611	2.066	1.03	49.9
4	Male	75835	1.410			
4	Male	75836	1.452			
4	Male	75836	0.8369			
4	Male	75838	1.870			
4	Male	75839	1.519			
4	Female	75840	1.589			
4	Female	75841	1.492			
4	Female	75842	1.500			
4	Female	75843	4.252			
4	Female	75844	1.741	2.402	0.930	38.7
4	Female	75845	3.192			
4	Female	75846	2.083			
4	Female	75847	3.296			
4	Female	75848	2.217			
4	Female	75849	2.658			

TABLE 7
Summary of Rat Plasma Samples
(Group 5 male and female)

Day 17 (Female) and Day 16 (Male) Repeat

Group Number	Sex	Animal Number	Concentration ug/mL	Mean concentration	SD	CV
5	Male	75850	8.694			
5	Male	75851	11.91			
5	Male	75852	3.114			
5	Male	75853	9.529			
5	Male	75854	6.709	6.634	3.02	45.5
5	Male	75855	5.071			
5	Male	75856	3.995			
5	Male	75857	8.532			
5	Male	75858	6.123			
5	Male	75859	2.662			
5	Female	75860	2.838			
5	Female	75861	3.338			
5	Female	75862	12.86			
5	Female	75863	4.122			
5	Female	75864	3.754	5.234	3.21	61.3
5	Female	75865	8.588			
5	Female	75866	4.465			
5	Female	75867	2.951			
5	Female	75868	3.268			

TABLE 8
Summary of Rat Plasma Samples
(Group 6 male and female)

Day 17 (Female) and Day 16 (male)

Group Number	Sex	Animal Number	Concentration ug/mL	Mean concentration	SD	CV
6	Male	75870	10.05			
6	Male	75871	16.48			
6	Male	75872	17.08			
6	Male	75873	19.47			
6	Male	75874	15.17	14.13	4.13	29.3
6	Male	75875	12.97			
6	Male	75876	8.010			
6	Male	75877	8.129			
6	Male	75878	18.13			
6	Male	75879	15.76			
6	Female	75880	15.93			
6	Female	75881	12.94			
6	Female	75882	7.712			
6	Female	75883	9.664			
6	Female	75884	5.457	8.255	4.60	55.7
6	Female	75885	7.618	9.173*	3.78*	41.2*
6	Female	75886	5.167			
6	Female	75887	12.18			
6	Female	75888	5.888			
6	Female	75889	0.000			

* Data from animal No. 75889 excluded.

TABLE 9
Summary of Rat Plasma Samples
(Group 7 male and female)

Day 17

Group Number	Sex	Animal Number	Concentration ug/mL	Mean concentration	SD	CV
7	Male	75890	36.00			
7	Male	75891	19.57			
7	Male	75892	27.12			
7	Male	75893	25.01			
7	Male	75894	18.49	31.55	13.2	41.8
7	Male	75895	17.62			
7	Male	75896	42.62			
7	Male	75897	26.05			
7	Male	75898	55.10			
7	Male	75899	47.90			
7	Female	75900	11.68			
7	Female	75901	25.22			
7	Female	75902	19.83			
7	Female	75903	12.54			
7	Female	75904	22.33	18.11	7.16	39.6
7	Female	75905	13.84			
7	Female	75906	29.54			
7	Female	75907	24.82			
7	Female	75908	13.09			
7	Female	75909	8.165			

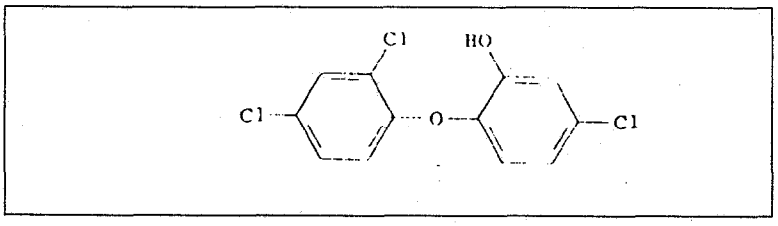
CORNING HAZLETON VIENNA
ANALYTICAL CHEMISTRY METHOD

ANALYTICAL METHOD NO. 638

EFFECTIVE DATE: October 23, 1995
APPROVAL: Li Tian Ph.D.

TITLE: Determination of Triclosan in Plasma

STRUCTURE:



DEVELOPED BY: Corning Hazleton Virginia, (CHV).

1.0 SCOPE:

This method is for the gas chromatography (GC/ECD) analysis of Triclosan in plasma at concentrations in the approximate range of 0.1000 μg/mL to 20.00 μg/mL.

2.0 PRINCIPLE:

Triclosan is first hydrolysed using concentrated HCl then extracted from plasma with hexane by shaking followed by centrifugation. Aliquots of the extracts are then dried down under nitrogen and finally reconstituted with additional hexane. Final sample solutions are analyzed by gas chromatography using an electron capture detector(GC/ECD).

3.0 EQUIPMENT:

3.1 Gas Chromatography: Apparatus consists of a Hewlett-Packard HP 5890 Series II gas chromatograph, HP 3365 ChemStation Series II Software, and an HP7673 autosampler and controller or equivalent.

3.2 Column: J&W fused silica megabore column, DB-1 liquid phase, 1.5 μm film thickness, 30 m X 0.53 mm or equivalent.

3.3 Vortexer: Baxter multitube vortexer, or equivalent.

3.4 Centrifuge: With trunions to hold centrifuge tubes.

3.5 General laboratory equipment and glassware.

4.0 REAGENTS:

4.1 Methanol (MeOH): Burdick & Jackson, high purity solvent, lot AW571, CAS 67-56-1, or equivalent.

4.2 Water (H_2O): Milli-Q™ distilled and deionized.

4.3 Hexane: Burdick and Jackson, high purity solvent, lot AV362,CAS 110-54-3, or equivalent.

4.4 Hydrochloric acid (HCl): Baker analyzed reagent, lot 308042, CAS 7647-01-0, or equivalent.

5.0 PROCEDURE:

5.1 Preparation of standard solutions.

5.1.1 Preparation of stock standard (target 500.0 μg/mL):

Accurately weigh approximately (to four decimal points, not adjusting for purity), 0.0500 g of triclosan and transfer to a 100 mL volumetric flask. Dissolve in and dilute to volume with methanol.

5.1.2 Preparation of working standards (see concentrations below):

Pipet the required amount of standard into separate volumetric flasks according to the following scheme:

Standard I.D.	Target Concentration (µg/mL)	Volume of Standard (mL)	Final Volume in MeOH (mL)	Conc. in 0.5 mL Plasma (µg/mL)
H	100.0	10 mL stock	50	20
G	50.00	10 mL stock	100	10
F	25.00	5 mL stock	100	5
E	15.00	3 mL stock	100	3
D	7.500	1.5 mL stock	100	1.5
C	5.000	1 mL stock	100	1.0
B	1.000	1 mL G	50	0.2
A	0.5000	1 mL G	100	0.1

Note : These dilutions are typical dilutions and may change as analysis requirements dictate.

5.2 Preparation of matrix standards :

5.2.1 Using an SMI pipet, add 0.5 mL of blank plasma to individual 15.0 mL centrifuge tubes, one for each standard to be prepared.

5.2.2 Add 100 µL of each working standard (A-H) into its appropriate centrifuge tube.

5.2.3 Process these matrix standards in the same manner as the samples (beginning at step 5.3.2).

5.3 Sample preparation :

5.3.1 Using an SMI pipet, transfer 0.5 mL of plasma to a 15.0 mL centrifuge tube.

5.3.2 Using an Eppendorf pipet, transfer 100 µL of methanol to the contents of each tube.

5.3.3 Add 2.0 mL of concentrated hydrochloric acid to the plasma and mix gently.

5.3.4 Place the centrifuge tubes on a heating block at approximately 100°C for 60 minutes. Note: A change in color to a dark purple should occur.

5.3.5 Allow the samples to come to room temperature.

5.3.6 Add 10.0 mL of hexane to each sample.

5.3.7 Extract the samples on a mechanical floor shaker for 15 minutes.

5.3.8 Centrifuge the tubes at 2000 rpm for 10 minutes.

5.3.9 Transfer 5.0 mL of the upper organic layer to another 15.0 mL centrifuge tube.

5.3.10 Take to dryness under nitrogen in evaporator at approximately 30°C.

5.3.11 Reconstitute the sample with 1.0 mL of hexane.

5.3.12 Inject 2.0 µL onto the column for analysis by GC/ECD.

5.4 Concentration calculation :

5.4.1 Compute the weighted linear regression equation relating the standard response (peak area or peak height) to the concentration of triclosan in the plasma for each standard.

5.4.2 Using the sample response (peak area or peak height), and the weighted linear regression curve parameters, determine the concentration of triclosan in the plasma in µg/mL.

6.0 INSTRUMENT PARAMETERS:

Gas chromatograph	: Hewlett-Packard HP5890A gas chromatograph, HP 3365 Series II ChemStation Software, and HP7673 autosampler and controller
Detector	: Electron capture (ECD)
Column	: J&W fused silica megabore column, DB-1, 1.5 µm film, 30 m X 0.53 mm, or equivalent
Carrier gas	: Helium; 20 mL/minute
Modulating gas	: Nitrogen; 60 mL/minute
Oven temperature	: Initial Temp. 195°C : Initial Time 8.0 mins. : Rate 15°C/min.

	: Final Temp. 240°C
Detector temperature	: 250°C
Injector temperature	: 220°C
Peak width	: 0.053
Injection volume	: 2 μL
Run time	: 20 minutes
Approximate retention time Triclosan	: 6.9 minutes

NOTE: The above conditions may be changed to optimize the instrument response and analyte detection.

7.0 LIST OF FIGURES:

Figure 1. Typical chromatogram, matrix standard.

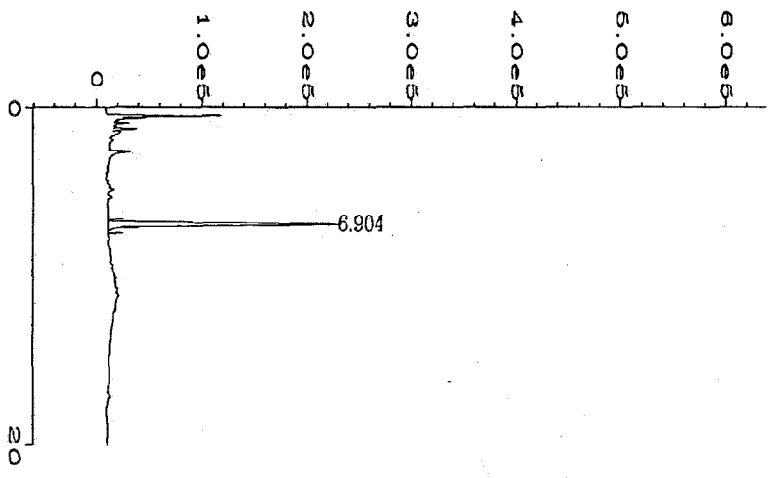
Figure 2. Typical standard curve.

Figure 3. Typical chromatogram, sample.

Figure 4. Typical chromatogram, plasma blank.

Figure 5. Typical chromatogram, solvent blank.

Figure 1. Typical Chromatogram, Matrix Standard



Area Percent Report

Data File Name : C:\HPCHEM\1\DATA\101395\005F0401.D
Operator : Caparoon
Instrument : INSTRUMEN
Sample Name : E 3ug/mL
Run Time Bar Code:
Acquired on : 14 Oct 95 04:00 PM
Report Created on: 15 Oct 95 08:58 AM

Page Number : 1
Vial Number : 5
Injection Number : 1
Sequence Line : 4
Instrument Method: 2763100F.MTH
Analysis Method : 2763100F.MTH

Sig. 1 in C:\HPCHEM\1\DATA\101395\005F0401.D

Pk#	Ret Time	Area	Height	Type	Width	Area %
1	6.904	2482308	218926	BB	0.174	100.0000

Total area = 2482308

Figure 2. Typical Standard Curve

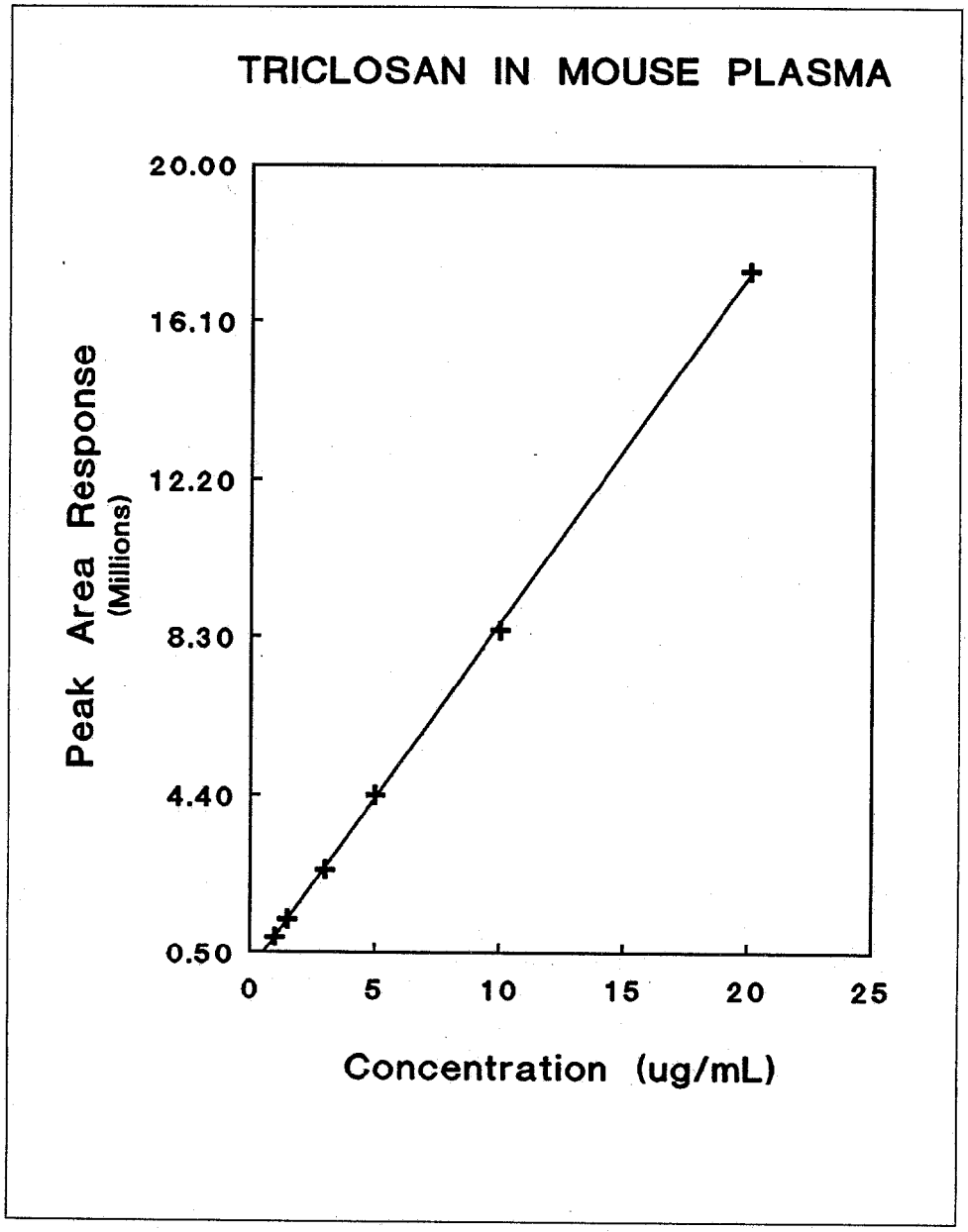
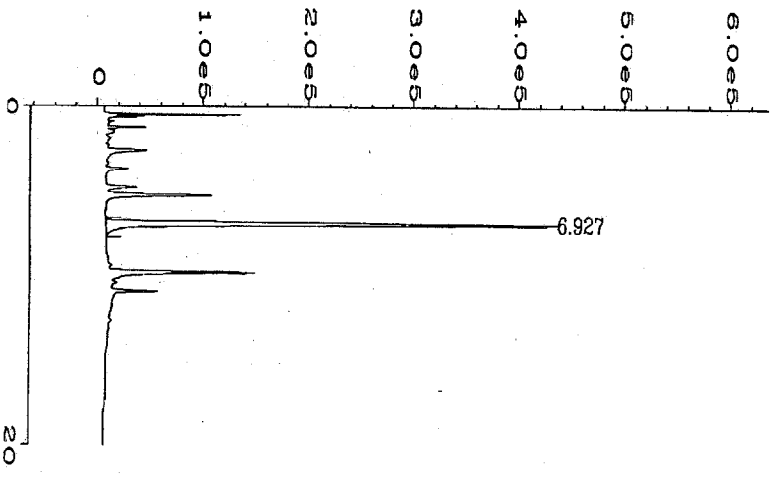


Figure 3. Typical Chromatogram, Sample



Area Percent Report

Data File Name : C:\HPCHEM\1\DATA\102395\078F1001.D
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Instrument : INSTRUMEN
Sample Name : F4B DILUTED
Run Time Bar Code:
Acquired on : 23 Oct 95 07:35 AM
Report Created on: 23 Oct 95 09:25 AM

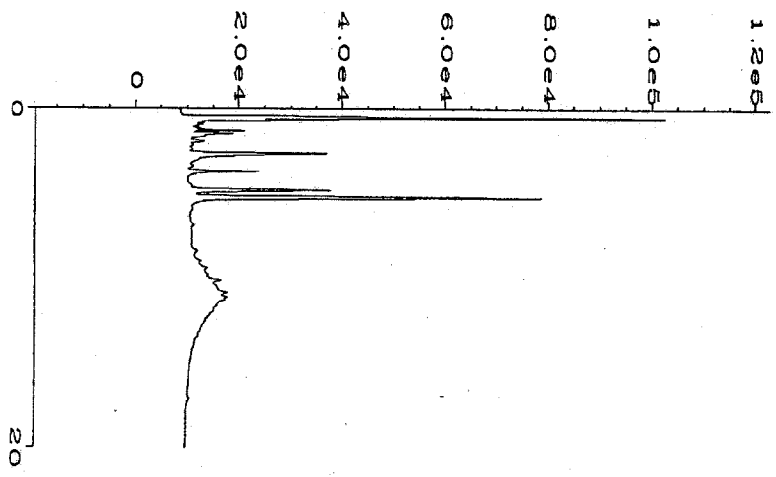
Page Number : 1
Vial Number : 78
Injection Number : 1
Sequence Line : 10
Instrument Method: 2763100F.MTH
Analysis Method : 2763100F.MTH

Sig. 1 in C:\HPCHEM\1\DATA\102395\078F1001.D

Pk#	Ret Time	Area	Height	Type	Width	Area %
1	6.927	5358322	427977	BB	0.191	100.0000

Total area = 5358322

Figure 4. Typical Chromatogram, Plasma Blank



Area Percent Report

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Operator : Caparoon
Instrument : INSTRUMEN
Sample Name : CTR Plasma
Run Time Bar Code:
Acquired on : 15 Oct 95 02:24 AM
Report Created on: 15 Oct 95 09:08 AM

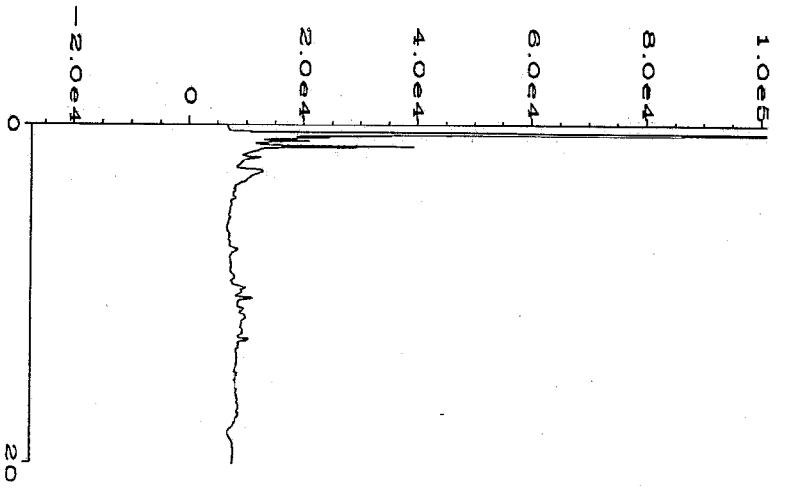
Page Number : 1
Vial Number : 28
Injection Number : 1
Sequence Line : 9
Instrument Method: 2763100F.MTH
Analysis Method : 2763100F.MTH

Sig. 1 in C:\HPCHEM\1\DATA\101395\028F0901.D

Pk#	Ret Time	Area	Height	Type	Width	Area %

Total area = 0

Figure 5. Typical Chromatogram, Solvent Blank



Area Percent Report

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Instrument : INSTRUMEN
Sample Name : CTR S
Run Time Bar Code:
Acquired on : 23 Oct 95 05:14 PM
Report Created on: 24 Oct 95 06:59 AM

Page Number : 1
Vial Number : 44
Injection Number : 1
Sequence Line : 19
Instrument Method: 2763100F.MTH
Analysis Method : 2763100F.MTH

Sig. 1 in C:\HPCHEM\1\DATA\102395\044F1901.D

Pk#	Ret Time	Area	Height	Type	Width	Area %

Total area = 0

CORNING HAZLETON VIRGINIA
ANALYTICAL CHEMISTRY METHOD

METHOD NO. 638

AMENDMENT NO: 1
EFFECTIVE DATE: August 22,1996
APPROVAL: Li Tian, Ph.D.

TITLE: Determination of Triclosan in Plasma

Amendment: Following are the changes to the analytical method.

Header Page 1 CORNING HAZLETON VIRGINIA to replace
CORNING HAZLETON VIENNA

Reason : Correction to company name.

Appendix 7
Study Protocol
14-Day Repeated Dose Dermal Study of Triclosan in Rats

PROTOCOL

STUDY	14-Day Repeated Dose Dermal Study of Triclosan in Rats
PURPOSE	The purpose of this study is (1) to evaluate the dermal toxicity of Triclosan in acetone when applied to the skin of rats 7 times a week, for at least 14 days, and (2) to provide a scientific basis for dose selection in a possible subsequent 90-day dermal study.
STUDY LOCATION	Corning Hazleton Inc. (CHV) 9200 Leesburg Pike Vienna, VA 22182-1699
SPONSOR'S NAME AND ADDRESS	Triclosan Industry Alliance Contact: Ciba-Geigy Corporation, Chemicals Division P.O. Box 18300 Greensboro, NC 27419-8300
Study Monitor	Keith A. Hostetler, Ph.D., D.A.B.T. Chemicals Division Ciba-Geigy Corporation P.O. Box 18300 Greensboro, NC 27419-8300 Telephone No: (910) 632-7237 Facsimile No: (910) 632-7523
CHV STUDY DIRECTOR	John M. Burns, M.S., D.V.M., M.B.A., M.A.
CHV Scientific Director	Michael R. Moore, Ph.D., D.A.B.T.
CHV Toxicologist	David Dehler, M.A.
REGULATORY COMPLIANCE	This study will be conducted in compliance with the Good Laboratory Practice Regulations as set forth in Title 21 of the U.S. Code of Federal Regulations Part 58, issued December 22, 1978 (effective June 20, 1979), and with any applicable amendments.
REGULATORY GUIDELINE(S)	Not applicable.

QUALITY ASSURANCE	The protocol, all critical in-life phases*, and the final report will be audited by the CHV Quality Assurance Unit. *Critical in-life phases to be inspected: test article preparation test article sampling and/or analysis test article administration clinical sampling necropsy
PROPOSED STUDY TIMETABLE	Initiation of Dosing: April 24, 1996 Terminal Sacrifice: May 9-10, 1996 Audited Draft Report: September 1996
PERSONNEL HEALTH AND SAFETY	The safety precautions used for materials of unknown toxic potential will be employed in the handling of the test article. A copy of the Material Safety Data Sheet is provided in Attachment 3.
TEST MATERIAL	
Identification	Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether)
Lot Number	To be provided; a single lot will be used for this and subsequent subchronic and chronic dermal studies.
CAS Number	3380-34-5
Molecular Formula	$C_{12}H_7Cl_3O_2$
Formula Weight (g)	289.5
Purity	>99%
Characteristics	Information on the methods of synthesis and stability and data on composition or other characteristics which define the test material are on file with the Sponsor.
Storage Conditions	Test article and dosing solutions: Room temperature and protected from light in brown glass bottles.

Vehicle	Acetone (A.C.S. grade)
Archive Samples of Test Article and Vehicle	Archive samples of the test article (5 grams) and vehicle (10 mLs) will be taken at initiation and retained until completion of the in-life phase. At this time, these samples are containerized by Formulations and sent to archives for long term storage. (See Record Retention)
Test Article Disposition	Unused test article will be used in subsequent studies.

ANIMALS/HUSBANDRY

Species	Rat
Strain/Source	Crl:CD®BR/Charles River Laboratories, Inc., Raleigh, NC.
Age at Initiation of Dosing	Preferably 6 weeks of age, but not more than 8 weeks of age.
Body Weight at Initiation of Dosing	Weight applicable only as defined by randomization. Actual weights will be documented in the study records.
Number/Sex	70/sex. A sufficient number of rats will be purchased to ensure adequacy for pre-test and study evaluation.
Identification	Each animal will be individually identified by cage, group, sex and implantable microidentification device. The individual animal number plus the project number will comprise a unique identification number for each animal.
Housing	Individually in suspended wire-mesh cages following randomization. Groups 1 and 2 will be placed on a separate rack within the animal room. Cage racks will be rotated weekly to ensure similar exposure to light. Rotations will be documented. One animal room will be used exclusively for the entire duration of this study.

Food	PMI® Certified Rodent Diet® 5002, ad libitum, except during designated fasting periods. Feed is analyzed by the manufacturer for concentrations of specified heavy metals, aflatoxin, chlorinated hydrocarbons, organophosphates, and specified nutrients. Each lot utilized will be identified and recorded. Specified nutrient and contaminant analyses are on file at CHV.
Water	Tap water, ad libitum. The water is routinely monitored for specified microorganisms, pesticides, heavy metals, alkalinity and halogens. The results of these analyses are on file at CHV.
Contaminants	No contaminants are known to be present in the diet or water at levels which might interfere with the study.
Environment	Controls are set to maintain temperatures at 22 ± 4°C (64.4-78.8°F) with a relative humidity of 55 ± 15%. Temperature and humidity are recorded at least once daily. Controls are also set to maintain a 12-hour light/12-hour dark cycle (lights on approximately 0600 to 1800 hrs); and ten or greater air changes/hour in the study room.
Acclimation	Not less than one week
Randomization	Using computer-generated random numbers with assignment to groups. At the time of randomization, the weight variation of the animals of each sex used should not exceed ± 2 S.D. of the mean weight, and the mean body weights for each group of each sex will not be statistically different.
Justification for Number on Study	This study was designed to use the fewest number of animals possible, consistent with the objective of the study, the scientific needs of the Sponsor, contemporary scientific standards and in consideration of applicable regulatory requirements.

Justification for Species Selection

Rats may be used in subsequent subchronic and chronic oncogenicity studies. Rats historically have been used in dermal carcinogenicity evaluations and are recommended by appropriate regulatory agencies. A large database on longevity and the incidence of spontaneous pathologic lesions exists for the rat.

GROUP DESIGNATION AND DOSAGE LEVELS

Group No.	No. of Animals male	No. of Animals female	%(wt/vol)	Dosage Levels mg/animal/day	mg/ml
1 (Untreated Control)	10	10	0	0	-
2 (Vehicle Control)	10	10	0	0	-
3	10	10	0.30	0.3	1.00
4	10	10	0.60	0.6	2.00
5	10	10	1.50	1.5	5.00
6	10	10	3.00	3.0	10.00
7	10	10	6.00	6.0	20.00

DOSING PROCEDURES

Method of Administration

Dermal application to the dorsal skin, 7 days per week for at least 14 consecutive days. The test animals will be treated at approximately the same time each day. Treatment will continue until the day before necropsy.

Reason for Dosing Route

The dermal route is an expected route of human exposure and is the route to be used in subsequent subchronic and chronic studies of Triclosan in rats.

ANALYSIS OF DOSING SOLUTIONS

Stability	Determined in a companion study.
Homogeneity	Homogeneity determinations are not deemed appropriate for solutions.
Routine Analyses	Routine analyses will be performed on all concentration levels, including the vehicle control, on Study Day 1 and Study Day 8.
Method of Analysis	HPLC. (see companion study report)

OBSERVATION OF ANIMALS

Clinical Observations	Twice daily (at least 6 hours between observations) for evidence of mortality or moribundity. Once daily - cageside observation for obvious indications of a toxic effect. These effects will be recorded as they are observed, noting only those animals for which an observation is made. Because these are cageside animal checks, the observations will not be as specific as and may not necessarily duplicate those observations recorded when thorough physical examinations are conducted. If overt signs of toxicity/ill health observed, a physical examination (as described below) will be performed and findings will be recorded on the day first observed. Subsequently, these signs will be recorded during the prescheduled clinical observations or physical examinations as appropriate.
Physical Examinations	Once prior to initiation of dosing and weekly thereafter (examinations will be done prior to daily dosing). This examination will include pharmacological and toxicological findings. The persistence or disappearance of these findings will be documented at the next weekly physical examination.

The following information on each grossly visible or palpable mass will be recorded.

time of onset
location
size
appearance
progression

The dimensions and locations of each tumor/animal will be mapped on a diagram. The diagram will indicate the treatment area and whether the tumors are observed within this area.

Dermal Irritation

The treated skin will be graded for irritation prior to treatment (Day 1) and on Days 4, 8, 11 and 15 according to the scale in Attachment 1, prior to that day's dosing.

Body Weights

Once prior to initiation (randomization weights), at initiation (Day 1), weekly thereafter and at study termination.

Food Consumption

Individual food consumption will be recorded one week before treatment initiates and weekly during the study.

Blood Sampling at Termination

A maximum amount of blood will be taken from each surviving rat in the study at necropsy by venipuncture of the posterior vena cava (following anesthesia with sodium pentobarbital), collected in a lithium heparinized container, and plasma will be prepared. Animals will be fasted overnight (with water available) prior to the blood collection. Plasma samples will be maintained individually at approximately -20°C. Plasma samples will be analyzed individually. Residual plasma samples will be maintained at approximately -20°C until report finalization and then discarded.

TERMINATION

Unscheduled Necropsies

Any animals showing signs of severe debility or toxicity, particularly if death appears imminent, will be euthanized for humane reasons and to prevent loss of tissues through autolysis. Necropsies, by trained personnel under the direct supervision of a board-certified pathologist, will be conducted on all moribund animals (anesthetized with sodium pentobarbital and exsanguinated) on the day of death and on all animals that die. Animals that are found dead/sacrificed after working hours will be refrigerated and necropsies performed the next working day.

Scheduled Necropsies

After at least 14 days of treatment, all surviving animals will be weighed, anesthetized with sodium pentobarbital and exsanguinated. Necropsies will be conducted on each animal by trained personnel under the direct supervision of a board-certified pathologist.

POSTMORTEM PROCEDURES

Gross Necropsy

The necropsy will include examination of:

All orifices
Carcass
Cranial cavity
External surface of the brain (at necropsy); the external surface of the spinal cord and cut surfaces of the brain and spinal cord will be examined whenever tissue trimming is performed.
The cervical tissues and organs
The thoracic, abdominal and pelvic cavities and their viscera
The external body surface
The nasal cavity and paranasal sinuses
Application site (see Attachment 1 - each category will be evaluated and findings documented)

Findings will be recorded.

Photographs of gross lesions that are representative of the findings will be taken for each dose level with color print film.

Organ Weights

For each animal killed at study termination, the following organs (when present) will be weighed following careful dissection and trimming to remove fat and other contiguous tissue in a uniform manner:

brain
liver

Tissue Preservation

The following tissues (when present) from each animal will be preserved in 10% neutral-buffered formalin.

lesions
liver (three sections including left lateral, right lateral and median lobe)
skin (treated and untreated sites; including subcutis and muscular layers)[a]

[a] The proper preparation of skin sections requires tissues to be free of artifacts and oriented to permit evaluations of epidermal, dermal, and folliculosebaceous units. Section of skin will be taken from the site of application with respect to the longitudinal axis of the animal and will include subcutis and muscular layers. Skin samples collected at necropsy will be flattened, gently stretched to remove wrinkles, and fixed in formalin prior to trimming.

Histopathology

The following tissues from all animals will be embedded in paraffin, sectioned, stained with hematoxylin and eosin, and examined microscopically: skin from the application site, untreated skin from the lateral side, liver, and macroscopic lesions.

Sectioning of the skin samples should permit full histopathological evaluation of all major skin structures.

Tissues that are unintentionally sectioned or present in the plane with a required tissue will be examined and findings documented.

FINAL REPORT

At termination of the study, a final report (ten copies) which includes the following information (as appropriate) will be prepared and submitted:

- Experimental Design and Methods

- Results:

mortality
clinical observations
skin irritation
body weights and changes
food consumption
organ weights, organ/body weight and organ/brain weight ratios
gross pathology
histopathology

- Statistical Analyses:

Statistical methods will be those presented in Attachment #2. Statistical analyses of observations in Groups 3-7 will be done versus those in Group 2. Observations in Group 1 will not be statistically compared to Group 2 or other groups without prior Sponsor approval.

- Statistical Evaluation (as deemed appropriate):

absolute body weights and body weight change
weekly and total food consumption
local irritancy scores
organ weights, organ/body weight and organ/brain weight ratios

-Tables (as deemed appropriate):

cumulative survival rates
mean body weights and changes
mean food consumption values
summary of clinical signs for each test group to include: a list of each finding and number of animals affected
analytical chemistry results
mean organ weights, organ/body weight and organ/brain weight ratios
summary incidence of gross pathology findings
summary incidence of histopathology findings
summary of skin irritation scores

- Appendices (as deemed appropriate):

week of death for each animal
individual body weights/changes
individual food consumption
individual clinical signs for each animal to include: the week of observation of each sign, a description of each sign, and its subsequent course
individual skin irritation scores
individual organ weights and relative ratios
individual gross pathology findings
individual histopathology findings
statistical methods references
study protocol
analytical chemistry methods
photographs

- Graphs (as appropriate):

mean body weights
mean food consumption

At the end of one year after issue of the Audited Draft Report, if no requested revisions or instructions not to finalize have been communicated by the Sponsor, then the Audited Draft Report will be considered 'final' and issued as the Final Report, signed by the Study Director, and submitted to the Sponsor.

Any modifications or changes to the audited Draft Report requested after one year will be performed at additional cost to the Sponsor.

RECORD RETENTION

All paper raw data, documentation, records, protocol, specimens (wet tissues, paraffin blocks, and slides), archive samples of test article and vehicle, and final report generated as a result of this study will be archived in the storage facilities of Corning Hazleton for a period

of ten years following submission of the final report (final report completion date). Ten years after submission of the final report, all of the aforementioned materials will be sent to the Sponsor and a return fee will be charged. The Sponsor may elect to have the materials retained in the Corning Hazleton Archives for an additional period of time and Corning Hazleton will charge a storage fee. If the Sponsor chooses to have Corning Hazleton dispose of the materials, a disposal fee will be charged. All raw data stored on magnetic media will be retained by Corning Hazleton.

ANIMAL CARE AND USE STATEMENT

This study is being conducted with the ultimate goal of submitting a data package to the appropriate regulatory agency(ies). This study is necessary to support approval of this material and, in the opinion of the undersigned professionals, does not unnecessarily duplicate any previous work with this material. No alternatives to animal use are currently available. This protocol will be reviewed by the CHV-IACUC for compliance with regulatory guidelines concerning the care and use of animals. If not in compliance, modification will be required.

SIGNATURE PAGE

14-DAY REPEATED DOSE DERMAL STUDY OF TRICLOSAN IN RATS

APPROVED BY:

Corning Hazleton Inc.

John M. Burns, M.S., D.V.M., M.B.A., M.A.
Study Director
Department of Toxicology

Date: 4/22/96

Triclosan Industry Alliance

Keith A. Hostetler, Ph.D., D.A.B.T.
Study Monitor

Date: _____

ATTACHMENT #1

Scale for Evaluation of Skin Reactions

Erythema (not including eschar area)
0 - None
1 - Slight (barely perceptible)
2 - Moderate (well-defined)
3 - Marked (beet red)

Edema (not including eschar area)
0 - None
1 - Slight (barely perceptible)
2 - Moderate (raised approximately 1 mm)
3 - Marked (raised more than 1 mm)

Scaling (not including eschar area)
0 - None
1 - Slight (slight scaling without evidence of peeling)
2 - Moderate (large flakes with sloughing)
3 - Marked (pronounced flaking denuded areas)

Fissuring (not including eschar area)
0 - None
1 - Slight (definite cracks in epidermis)
2 - Moderate (cracks in dermis)
3 - Marked (cracks with bleeding)

Eschar** (exudate, crust)
N - No
Y - Yes

Exfoliation** (sloughing of the eschar tissue)
N - No
Y - Yes

Ulcer** (loss of epidermis)
N - No
Y - Yes

Alopecia***
N - No
Y - Yes

Nonviable (dead) tissue**
N - No
Y - Yes

ATTACHMENT #1 - Continued

Thickening (not including eschar area)
N - No
Y - Yes

* Grades assigned should be based on the most severely affected area except where area is judged to be <20% of the treatment site. Severe reactions occurring on <20% of a site should be described in a footnote.

** Discontinue scoring on portion of test site with eschar, exfoliation, ulcer or nonviable (dead) tissue. The dimensions of the individual lesions or the approximate percentage of the treated area affected will be noted.

*** The approximate percentage of the treatment area affected will be noted.

CHEMICALS DIVISION
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1-800-888-8372

PRODUCT SAFETY INFORMATION

MSDS 305197099

MATERIAL SAFETY DATA SHEET

REVISION: 4 02/28/94
SECTIONS REVISED: III,IX

TRADE NAME: IRGASAN DP 300 55 LBS
CHEMICAL FAMILY: 2,4,4'-TRICHLORO-2'-HYDROXYDIPHENYL ETHER
GENERIC NAME: TRICLOSAN
OSHA HAZARDOUS SUBSTANCE? YES X NO
BASIS: REFER TO SECTIONS I AND IV
FOR STATE RIGHT-TO-KNOW INFORMATION, SEE SECTION XI
HMIS RATING: HEALTH 2 FLAMMABILITY 1 REACTIVITY 0 PERS. PROTECT. EQUIP E

SECTION I - OSHA HAZARDOUS SUBSTANCE(S)

IRGASAN DP 300
CAS NO: 3380-34-5
PERCENT: 100.00
OSHA PEL: NOT ESTABLISHED
ACGIH TLV: NOT ESTABLISHED
NTP CARCINOGEN: NOT LISTED
IARC CARCINOGEN: NOT LISTED

SECTION II - PHYSICAL DATA

APPEARANCE AND ODOR: WHITE POWDER, ODORLESS
BOILING POINT: NOT EVALUATED
DECOMPOSITION TEMPERATURE: > 280 C
EVAPORATION RATE: NOT EVALUATED
MELTING POINT: 55-60 C
PERCENT VOLATILE: NOT EVALUATED
PH: NOT EVALUATED
SOLUBILITY IN WATER: 0.01 G/L AT 20 C
SPECIFIC GRAVITY: NOT EVALUATED
VAPOR DENSITY: NOT EVALUATED
VAPOR PRESSURE: NOT EVALUATED
VOC (EPA METHOD 24/24A): NOT EVALUATED

SECTION III - FIRE, EXPLOSION, AND REACTIVITY INFORMATION

PHYSICAL HAZARD(S): NONE KNOWN
FLASH POINT: 223 C
FLAMMABLE LIMITS IN AIR-LOWER: NOT EVALUATED
FLAMMABLE LIMITS IN AIR-UPPER: NOT EVALUATED
EXTINGUISHING MEDIA: CARBON DIOXIDE, DRY CHEMICAL, FOAM, WATER.
SPECIAL FIRE FIGHTING PROCEDURES: NONE REQUIRED.
HAZARDOUS DECOMPOSITION PRODUCTS:
BURNING MAY PRODUCE HYDROGEN CHLORIDE, CHLORINE AND OXIDES OF CARBON.
FIRE AND EXPLOSION HAZARDS: NO UNUSUAL HAZARDS.
STABILITY: STABLE
INCOMPATIBILITY: AVOID CONTACT WITH CHLORINATING SUBSTANCES.
HAZARDOUS POLYMERIZATION: WILL NOT OCCUR.

SECTION IV - HEALTH HAZARD INFORMATION

SPILL PROCEDURES: SHOVEL INTO APPROVED DISPOSAL CONTAINER. VACUUM
CONTAMINATED AREA. AVOID CREATING DUSTY CONDITIONS.
EMERGENCY RESPONSE GUIDEBOOK PAGE: NONE
WASTE DISPOSAL METHOD:
BURY OR INCINERATE IN APPROVED SITE OR FACILITY IN
ACCORDANCE WITH LOCAL, STATE AND FEDERAL REGULATIONS.
CONTAINER REUSE:
EMPTIED CONTAINER MAY CONTAIN PRODUCT RESIDUE AND SHOULD NOT
BE REUSED.

SECTION IX - ENVIRONMENTAL DATA

BOD 5: < 0.01 G/G
COD: 1.116 G/G
FISH TOXICITY: (ZEBRA FISH) LC50 = 0.7 MG/L (48 HR)
EFFECT ON WASTE TREATMENT BACTERIA: NOT EVALUATED
ACTIVATED SLUDGE RESPIRATION INHIBITION TEST:
INHIBITION @ 20 MG/L (3 HR)
CWA TOXIC POLLUTANTS: NONE KNOWN
ADDITIONAL ENVIRONMENTAL DATA:
DAPHNIA TOXICITY (OECD 202) - EC50 = 0.4 MG/L (48 HR)
ALGAE TOXICTY (OECD 201) - EC50 = 0.2 MG/L (72 HR)
BIOLOGICAL ELIMINATION: 10-25%, TOC/DOC ANALYSIS, OECD 303A(MOD)
TOC: 50%

SECTION X - FEDERAL REGULATORY INFORMATION

TSCA: CAS NO. 3380-34-5: LISTED IN THE TSCA INVENTORY
FIFRA: EPA REGISTRATION NO. 100-502
CERCLA STATUS:
NOT A HAZARDOUS SUBSTANCE UNDER CERCLA (40 CFR 302.4).
RCRA STATUS: NOT A HAZARDOUS WASTE UNDER RCRA (40 CFR 261).
DOT STATUS: NOT REGULATED
IATA: NOT REGULATED
IMDG: NOT REGULATED
SARA: SECTION 311/312 HAZARD CATEGORY: IMMEDIATE
SARA 313 CHEMICAL(S):
NOT REPORTABLE
OTHER REGULATORY INFORMATION: NONE

SECTION XI - STATE RIGHT-TO-KNOW INFORMATION

HAZARDOUS INGREDIENT(S): NOT REGULATED

FOR FURTHER INFORMATION, PLEASE CONTACT:
SAFETY AND ENVIRONMENTAL AFFAIRS DEPARTMENT (910) 632-7368
THE INFORMATION AND RECOMMENDATIONS CONTAINED HEREIN ARE BASED
UPON DATA BELIEVED TO BE CORRECT. HOWEVER, NO GUARANTEE OR
WARRANTY OF ANY KIND EXPRESSED OR IMPLIED IS MADE WITH RESPECT
TO THE INFORMATION CONTAINED HEREIN. THIS MATERIAL SAFETY DATA
SHEET WAS PREPARED TO COMPLY WITH THE OSHA HAZARD COMMUNICATION
STANDARD (29 CFR 1910.1200).
THIS SUPERCEDES ANY PREVIOUS INFORMATION.
MSDS 305197099

PROTOCOL AMENDMENT

PROJECT NO.: 6718-102			**AMENDMENT NO.:** 1
STUDY TITLE: 14-Day Repeated Dose Dermal Study of Triclosan in Rats			
DISTRIBUTION: SEND ORIGINAL SIGNED COPY TO PSO			
Rodent Tox	Quality Assurance	EH&S	Pathology
Formulations	Contracts	PTS	Histology
Scientific Res	Pricing	Tox Admin	ClinLab
Lab Animal Med	Scheduling	Sponsor	Necropsy
Archive Prep	Project Mgmt	Analyt Chem	Toxicologist
Other: A. Wakefield, D. Dehler			
Date and Means of Sponsor Authorization (if appropriate):			

Amendment: PROTOCOL IS AMENDED AS INDICATED BELOW:

1) ITEM

TEST MATERIAL

Lot Number

CHANGE

To be provided;....

TO

Batch number P409198;....

REASON: PROVIDE MISSING INFORMATION

2) ITEM

OBSERVATION OF ANIMALS

Blood Sampling at Termination

CHANGE

A maximum amount of blood will be taken from each surviving rat in the study at necropsy by venipuncture of the posterior vena cava (following anesthesia with sodium pentobarbital,....

TO

On the day of necropsy, blood will be obtained from each surviving rat by puncture of the orbital plexus (following carbon dioxide/oxygen inhalation anesthesia; target 2 mL whole blood from each animal),....

REASON: ALTERNATIVE BLOOD COLLECTION TECHNIQUE

STUDY DIRECTOR: _____

DATE: 5/7/96

PROTOCOL AMENDMENT
Page 1 of 1

PROJECT NO.: 6718-102			AMENDMENT NO.: 2
STUDY TITLE: 14-Day Repeated Dose Dermal Study of Triclosan in Rats			
DISTRIBUTION: SEND ORIGINAL SIGNED COPY TO PSO			
Rodent Tox	Quality Assurance	EH&S	Pathology
Formulations	Contracts	PTS	Histology
Scientific Res	Pricing	Tox Admin	ClinLab
Lab Animal Med	Scheduling	Sponsor	Necropsy
Archive Prep	Project Mgmt	Analyt Chem	Toxicologist
Other: A. Wakefield, D. Dehler			
Date and Means of Sponsor Authorization (if appropriate):			

Amendment: PROTOCOL IS AMENDED AS INDICATED BELOW:

1) ITEM

OBSERVATION OF ANIMALS

Blood Sampling at Termination

CHANGE

.... Plasma samples will be analyzed individually....

TO

.... Plasma samples will be analyzed **individually for the** test material....

REASON: CLARIFICATION

STUDY DIRECTOR: John K. Bennett

DATE: 9/10/96

Appendix 8
Protocol Deviations
14-Day Repeated Dose Dermal Study of Triclosan in Rats

Appendix 8
Protocol Deviations
14-Day Repeated Dose Dermal Study of Triclosan in Rats

The following protocol deviations were noted:

On Day 6 of the acclimation period, the animals were moved to a different room due to facilities difficulties. Protocol requirements stipulated that one animal room would be used exclusively for the entire duration of the study.

The protocol requires photographs of gross lesions using color print film. However, the photographs were taken with color slide film.

No photographs were taken for Group 3 animals.