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COMMENTS PRESENTED BY AKZO NOBEL ON CHLORAMINE T AND p-TSA AT THE NATIONAL TOXICOLOGY PROGRAM BOARD OF SCIENTIFIC COUNSELORS MEETING

SEPTEMBER 18, 2002

Good morning. My name is Edwin Bisinger and I am the Manager of Regulatory Affairs and Toxicology for Akzo Nobel Chemicals Inc. Akzo Nobel Chemicals Inc. is the U.S. representative of Axcentive BV, the current submitter of an INAD for chloramine T. I will provide very brief comments on chloramine T and its primary degradation product, p-TSA

I have previously provided written comments to Dr. Scott Masten and so this morning I would like to simply clarify two issues: first, there is only minimal human exposure in the U.S. to chloramine T and its degradation product in aquaculture and disinfectant uses; and second, the FDA has recently concluded that sufficient genotoxicity data exist on chloramine T and p-TSA and that neither compound should be considered genotoxic.

First, there is no appreciable human exposure to chloramine T or p-TSA in the United States in aquaculture. Currently there is little if any human exposure to chloramine T in aquaculture because this is a brand new use and the Axcentive INAD has not yet been approved. The FDA is the federal agency authorized by the U.S. Congress under the Federal Food, Drug and Cosmetic Act (FFDCA) to ensure the safety of animal (e. g., aquaculture) drugs before these drugs are allowed on the U.S. market. Chloramine T will not be allowed in the channels of U.S. commerce for aquaculture use until FDA has concluded that the drug is safe based on the Agency's review of adequate toxicology studies. Even when the INAD is approved, chloramine T will only be used in a low ppm concentration to intermittently treat diseased fish. However, chloramine T rapidly reacts in situ and extensive marker residue studies conducted by the USFWS and the USGS have proven that chloramine T residues are not found in edible fish tissues. Further, these same studies document that the residues of the degradation product of chloramine T, p-TSA, decline rapidly in fish tissues and are not analytically detectable in fish that attain the size fit for human consumption. There will no detectable human exposure with respect to the ingestion of p-TSA in chloramine T treated fish.

There is no human exposure to chloramine T in the U.S. as a result of disinfectant use. Historically chloramine T has been used as a disinfectant, but primarily outside of the U.S. In the U.S. this use requires specific approval from the EPA under FIFRA. In the mid 1980's the U.S. EPA issued a generic data-in notice for all FIFRA registered antimicrobial products, including chloramine T. Because the U.S. market for chloramine T was so small, all of the companies who held disinfectant registrations for chloramine T at that time allowed those registrations to lapse, and as a result there has been no approved disinfectant use of chloramine T in over 12 years in the

U.S.. Therefore there is no human exposure in the U.S. with respect to this use. I have included as an attachment to this presentation a current printout (dated September 16, 2002) of chloramine T historical registrations, obtained from the U.S. EPA website of FIFRA regulated products. This printout confirms that there are no current FIFRA registrations for chloramine T and that all previous registrations had been cancelled more than 12 years ago.

Second, FDA has recently concluded that all required genotoxicity data on chloramine T and p-TSA have now been completed. I have been very diligently working with the U.S. FDA Center for Veterinary Medicine (CVM) to identify FDA mammalian safety concerns and to generate new genotoxicity test data to satisfy those concerns. We have been actively engaged in providing *in vivo* and *in vitro* genotoxicity data to FDA. Further, the genotoxicity study reports that have been reviewed and accepted by FDA on chloramine T and p-TSA have shown no genotoxic activity. FDA is not requiring that any additional genotoxicity tests be conducted on either chloramine T or p-TSA. Although the study reports and supporting data are proprietary under the Axcentive INAD and should not be released to the public, we would be willing to discuss whether a subset of information may be useful to NTP during its deliberations on these chemical substances. For example, NTP may wish to review the FDA letter that concludes no further genotoxicity testing is required.

In conclusion, based on extremely low human exposure in the U.S. and based on their lack of genotoxic activity, these substances would appear to pose a very low risk to public health in the U.S.

Thank you for the opportunity to present these brief comments,

Edwin Bisinger
Manager of Regulatory Affairs & Toxicology
Akzo Nobel Chemicals Inc.

USEPA/OPP PC Code: 076502**Common Name:**

- CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- CAS REG. NO. 127-65-1

Synonym(s):

- SODIUM PARATOLUENESULFONCHLORAMIDE
- SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE

Scientific Name(s):

- CHLORAMINE T

CAS Numbers

- CAS REG. NO. 127-65-1
- 0000127651

List all products for this chemical or, just the active products.

List Unique Registrants (Active/Inactive)

Output Reporting USEPA/OPP Chemical Information

Query Parameters

PC Code(s): 076502

7 labels match.

Select a sort method

Sort by firm number ▼

Scroll down and put a check by all the products you would like more details on.

Then press the Report button:

- 7504-2 (Cancelled) CHLOROZOL
- 11652-1 (Cancelled) HELIOGEN DIATOMIC IODINE SANITIZER
- 11652-2 (Cancelled) HELIOGEN DIATOMIC IODINE SANITIZER POWDER
- 10575-1 (Cancelled) KETJENSEPT TC CHLORAMINE T
- 1130-3 (Cancelled) KRYSTYL-T BACTERICIDE
- 8501-17 (Cancelled) MOSS STOP
- 11650-2 (Cancelled) PRODUCT NAME NOT AVAILABLE

KRYSTYL-T BACTERICIDE**Registration number:** 001130- 00003**Please report any suspected data errors to USEPA/OPP .**View **USEPA/OPP** Label Images (tiff format) for this Product: [Click Here](#)**Company:** BURNISHINE PRODUCTS*NOTICE: address and contact information are not kept current for inactive companies*

DIVISION OF THE HERBERT STANLEYCO,LLC

1100 LAKESIDE DR

GURNEE, IL 60031

USA

Contact: CARL DEMASI

Contact Phone: 8472633500

Status: Cancelled**Approval date:** 01/11/1956**Cancel or Transfer date:** 05/01/1987**Existing Stocks date:** //**Cancel reason:** Label Improvement Program**EPA Product manager:** Velma Noble -- (703)308-6233**Chemical(s):**

20.0000 % of (076502)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 127-65-1
- o CHLORAMINE T
- o CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- o SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE
- o SODIUM PARATOLUENESULFONCHLORAMIDE

CHLOROZOL**Registration number:** 007504- 00002**Please report any suspected data errors to USEPA/OPP .**View **USEPA/OPP** Label Images (tiff format) for this Product: [Click Here](#)**Company:** TABLETTING INC.*NOTICE: address and contact information are not kept current for inactive companies*

4201 DANVERS CT.

GRAND RAPIDS, MI 49508

USA

Contact:

Contact Phone:

Status: Cancelled

Approval date: 04/17/1963

Cancel or Transfer date: 07/01/1987

Existing Stocks date:: //

Cancel reason: Generic Data Exemption Call-in

EPA Product manager: Robert Brennis -- (703)308-6264

Chemical(s):

99.9999 % of (076502)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 127-65-1
- o CHLORAMINE T
- o CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- o SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE
- o SODIUM PARATOLUENESULFONCHLORAMIDE

MOSS STOP

Registration number: 008501- 00017

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500 7TH AVE S

KIRKLAND, WA 98033

Contact:

Contact Phone:

Status: Cancelled

Approval date: 01/17/1972

Cancel or Transfer date: 05/20/1983

Existing Stocks date:: //

Cancel reason: Federal Register

EPA Product manager: Herbicide Branch -- (703)305-6287

Chemical(s):

9.7000 % of (064220)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 3784-03-0
- o PHENOL, 2,4,6-TRICHLORO-, SODIUM SALT
- o SODIUM 2,4,6-TRICHLOROPHENATE
- o TRICHLOROPHENOL, SODIUM SALT

18.4000 % of (076502)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 127-65-1
- o CHLORAMINE T
- o CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- o SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE
- o SODIUM PARATOLUENESULFONCHLORAMIDE

KETJENSEPT TC CHLORAMINE T**Registration number:** 010575- 00001**Please report any suspected data errors to USEPA/OPP .**View **USEPA/OPP** Label Images (tiff format) for this Product: [Click Here](#)**Company:** KONINKLIJKE ZWAVELZURFABRIEJEN Z/H*NOTICE: address and contact information are not kept current for inactive companies*

1445 E. PUTNAM AVE.

OLD GREENWICH,, CT 06870

USA

Contact:

Contact Phone:

Status: Cancelled**Approval date:** 12/05/1969**Cancel or Transfer date:** 10/10/1989**Existing Stocks date::** 03/01/1990**Cancel reason:** Maint. Fee Non-Payment - Undeliverable**EPA Product manager:** Robert Brennis -- (703)308-6264**Chemical(s):**

99.9999 % of (076502)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 127-65-1
- o CHLORAMINE T
- o CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- o SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE
- o SODIUM PARATOLUENESULFONCHLORAMIDE

PRODUCT NAME NOT AVAILABLE**Registration number:** 011650- 00002**Please report any suspected data errors to USEPA/OPP .**View **USEPA/OPP** Label Images (tiff format) for this Product: [Click Here](#)**Company:** STERN CHEMICAL CORPORATION*NOTICE: address and contact information are not kept current for inactive companies*

BOX 5070-2725 DESIARD STREET
MONROE, LA 71201
Contact:
Contact Phone:

Status: Cancelled
Approval date: //
Cancel or Transfer date: //
Existing Stocks date: //
Cancel reason:

EPA Product manager: Adam Heyward -- (703)308-6422

Chemical(s):

27.0000 % of (075701)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 7681-11-0
- o POTASSIUM IODIDE

20.0000 % of (076502)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 127-65-1
- o CHLORAMINE T
- o CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- o SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE
- o SODIUM PARATOLUENESULFONCHLORAMIDE

HELIOGEN DIATOMIC IODINE SANITIZER

Registration number: 011652- 00001

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Company: BROWN PHARMACEUTICAL

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8060 MELROSE AVENUE
LOS ANGELES, CA 90046
USA

Contact:
Contact Phone:

Status: Cancelled
Approval date: 10/04/1972
Cancel or Transfer date: 05/01/1987
Existing Stocks date: //
Cancel reason: Label Improvement Program

EPA Product manager: Robert Brennis -- (703)308-6264

Chemical(s):

27.0000 % of (075701)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 7681-11-0
- o POTASSIUM IODIDE

20.0000 % of (076502)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 127-65-1
- o CHLORAMINE T
- o CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- o SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE
- o SODIUM PARATOLUENESULFONCHLORAMIDE

HELIOGEN DIATOMIC IODINE SANITIZER POWDER

Registration number: 011652- 00002

Please report any suspected data errors to USEPA/OPP .View USEPA/OPP Label Images (tiff format) for this Product: [Click Here](#)**Company:** BROWN PHARMACEUTICAL*NOTICE: address and contact information are not kept current for inactive companies*8060 MELROSE AVENUE
LOS ANGELES, CA 90046
USA

Contact:

Contact Phone:

Status: Cancelled**Approval date:** 07/30/1973**Cancel or Transfer date:** 05/01/1987**Existing Stocks date:** //**Cancel reason:** Label Improvement Program**EPA Product manager:** Robert Brennis -- (703)308-6264**Chemical(s):**

27.0000 % of (075701)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 7681-11-0
- o POTASSIUM IODIDE

20.0000 % of (076502)

Chemical Names:(Common Name, Synonym, Trade Names)

- o CAS REG. NO. 127-65-1
- o CHLORAMINE T
- o CHLORO-4-METHYLBENZENESULFONAMIDE, SODIUM SALT
- o SODIUM N-CHLORO-P-TOLUENESULFONCHLORAMIDE

○ SODIUM PARATOLUENESULFONCHLORAMIDE