

Bayer Corporation
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December 28, 2001

Dockets Management Branch
Food & Drug Administration
Department of Health & Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

**Citizen Petition to Classify Triclocarban Category I for Efficacy in the
Tentative Final Monograph for Health-Care Antiseptic Drug Products:
Docket 75N-183H**

Enclosed are four (4) copies of the above referenced Citizen Petition. This submission consists of four (4) Volumes:

- Volume 1: Citizen Petition & Attachments 1 - 15
- Volume 2: Attachments 16 & 17
- Volume 3: Attachment 18
- Volume 4: Attachment 19

Sincerely,



Kevin I. Ajoku
Market Segment Manager
Bayer Corporation

December 28, 2001

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Department of Health & Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CC: Dr. Ganley & Ms. Lumpkins (w/o Attachments)

**Citizen Petition to Classify Triclocarban Category I for Efficacy in the
Tentative Final Monograph for Health-Care Antiseptic Drug Products:
Docket 75N-183H**

The undersigned submits this petition under 21 CFR § 10.30 of the Federal Food, Drug & Cosmetic Act to request the Commissioner of Food & Drugs to take the following action on proposed 21 CFR Part 333, the OTC Tentative Final Monograph for Health-Care Antiseptic Drug Products:

- To incorporate the Health Care Continuum Model (HCCM) proposed June 13, 1995 by the Cosmetic Toiletry, and Fragrance Association (CTFA) and the Soap and Detergent Association (SDA) into the Monograph.
- To classify Triclocarban as Category I for efficacy as a health-care personnel handwash and for additional topical antimicrobial product categories proposed by the HCCM.

ACTION REQUESTED

The Petitioner requests that the Commissioner consider this petition to amend proposed 21 CFR 333, presented in the June 17, 1994 Tentative Final Monograph for Health-Care Products Proposed Rule (59 FR 31401) as follows:

- Amend 21 CFR 333 to include the additional product categories of the HCCM into the Monograph, specifically food handler, consumer hand and consumer body OTC drug products as proposed in the June 13, 1995 comments submitted by the CTFA/SDA and the April 2, 2001 Citizen Petition from the CTFA/SDA (See Attachments 1 and 2, respectively).

- Amend 21 CFR 333.410 to include Triclocarban as an active ingredient up to and including a concentration of 1.5% in antiseptic health-care personnel handwash products.
- Amend 21 CFR 333 to include Triclocarban as an active ingredient up to and including a concentration of 1.5% in the additional product categories provided by the HCCM, specifically food handler, consumer hand, and consumer body OTC drug products.

STATEMENT OF GROUNDS

Bayer Corporation is a manufacturer of Triclocarban and is a member of the CTFA/SDA Industry Coalition, which was established in 1994 to respond to the June 17, 1994 Tentative Final Monograph for Health-Care Antiseptic Drug Products (59 FR 31401). Through the CTFA and SDA, that industry coalition has worked with the Agency to progress the final rule making for the regulation of topical antimicrobial products. The purpose of this citizen's petition is to indicate Bayer's support for prior comments submitted by the CTFA/SDA with regard to the proposed HCCM and classification of Triclocarban as Category IE for efficacy. More recent publications and newly generated data are provided in this submission in continued support of the classification of Triclocarban as Category IE of efficacy.

Health-Care Continuum Model

On June 13, 1995, the Industry Coalition submitted detailed comments on the Monograph (See Attachment 1). Those comments included presentation of a proposed HCCM for consideration by the Agency. On April 2, 2001, the CTFA/SDA submitted a Citizen's Petition (See Attachment 2) to amend the OTC labeling proposal provided in the June 13, 1995 comments. Bayer supports the recognition of the HCCM proposed by the CTFA/SDA. In addition to the health-care personnel handwash, surgical scrub, and pre-operative skin preparation products recognized in the 1994 Temporary Final Monograph, the HCCM proposes that the Monograph recognizes and includes food handler, consumer hand and consumer body OTC drug products.

Classification of Triclocarban as Category IE for Efficacy

The purpose of this citizen's petition is to help consolidate and update information that should be considered by the Agency for classification of Triclocarban as Category IE for efficacy. For the convenience of the Agency, this petition provides copies of prior submissions that addressed the issue of Triclocarban efficacy. Studies published in the open literature subsequent to those submissions and results from new studies sponsored by Bayer Corporation are provided in this Petition. The newest results are from recently conducted minimum inhibitory concentration (MIC), time-kill, and clinical handwash studies.

Prior submissions submitted to the Agency in support of classification of Triclocarban as Category IE for efficacy have included:

- December 13, 1995 comments to Docket 75N-183H submitted by The Dial Corporation (See Attachment 3).

- December 14, 1995 comments to Docket 75N-183H submitted by the CTFA/SDA (See Attachment 4).
- March 7, 1996 comments to Docket 75N-183H submitted by the CTFA/SDA (See Attachment 5).
- August 2, 2000 letter from the CTFA/SDA to Dr. Charles Ganley placed in Docket 75N-183H – Follow-up to a July 29, 1998 meeting with the Nonprescription Drugs Advisory Committee convened by the FDA (See Attachment 6).

Some of the citations in those submissions include unpublished study data and abstracts of studies presented at conferences and symposia. It is understood that such information per se, is, likely to be considered inappropriate to support a citizen petition. Therefore, attention is directed to the peer-reviewed journal articles published within the past 35 years cited in those submissions.

Studies testing samples with multiple active ingredients, including Triclocarban, include the following:

- In a study of 225 subjects (93 control subjects), the effects of routine use of a 1% trichlorocarbanilide (Triclocarban) plus 0.5% trifluoromethyldichlorocarbanilide (Cloflucarban) antibacterial soap was monitored. The test soap produced significant reductions in geometric mean counts of the total aerobic flora with an overall reduction on all sites tested by 62% ($p < 0.001$). The prevalence of *S. aureus* at five out of six skin sites was significantly ($p < 0.001$) reduced. The prevalence of *S. aureus* was virtually eliminated from all skin sites tested with the exception of the axilla. This 7-month study suggests a cumulative persistence in the inhibition of *S. aureus*. (Voss, 1975; Attachment 7)
- A 6-month study at the US Naval Academy compared the number of cutaneous bacterial infections among 1,201 first year midshipmen. The test group used bar soap containing 0.75% hexachlorophene and 0.75% Triclocarban and the control group used bland soap. While 6.84% of the subjects in the control group developed infections, only 3.82% (a 44% reduction; highly significant reduction - $p < 0.01$) of the subjects in the test group developed infections. (Mackenzie, 1970; Attachment 8)
- Sixty-one patients undergoing cancer chemotherapy were randomly assigned to bathe with either a preparation containing hexachlorophene or a bar soap containing 1% Triclosan and 1% Triclocarban. Both test preparations substantially reduced the microbial flora on the skin. Although the hexachlorophene was considered significantly more effective in reducing overall levels of microbial flora, transient acquisition of gram-negative bacteria occurred significantly less often in the patients who bathed with the bar soap containing Triclosan and Triclocarban. The authors noted that the Triclosan/Triclocarban bar soap was as active as the hexachlorophene against potentially pathogenic organisms and that considerably higher concentrations of hexachlorophene are absorbed through the skin during repeated bathing. (Bodey, *et. al.*, 1978; Attachment 9)

- A nine month double blind crossover study of 2,550 prison farm workers subdivided into 4 groups demonstrated a significant reduction of superficial pyogenic skin infections associated with the use of bar soap containing 2% of a mixture of active ingredients, Triclocarban/Tribromsalan/Cloflucarban (ratios not stated). The two groups that bathed regularly exhibited infections 2.5 to 3.3 times less often than during the use of placebo soap (p=0.05 and 0.01). Interpretation of the results from the remaining two groups was confounded by a lack of regular bathing and a 40% change in population, which occurred during the crossover period. The authors noted the apparent presence of a bacteriostatic residue that persisted for about 2 weeks following cessation of use. (Duncan, *et. al.*, 1969; Attachment 10)

Studies testing samples with Triclocarban as the sole active ingredient include the following:

- In a study of perineum colonization of male patients with spinal cord injuries, the number of *P. aeruginosa*, *K. pneumoniae*, and total aerobic bacteria were monitored before and after washing with either Triclocarban-containing bar soap (Prux Premier), povidone-iodine (Betadine surgical scrub), 4% chlorhexidine gluconate with 4% isopropanol (Hibiclens), or a low pH skin cleanser (pHresh, pH 3.5). Bathing with any of the four test materials reduced the number of bacteria on the perineum and penile shaft and no one agent was found to be significantly more effective than the other in reducing the total aerobic bacteria count. However, Triclocarban bar soap was significantly (p<0.05) more effective in removing *K. pneumoniae*, a frequent colonizer of those patients, than the povidone-iodine scrub or the low pH skin cleanser. (Gilmore *et. al.*, 1984; Attachment 11)
- Sixty subjects were used to conduct an *in vivo* study of the effect of bar soap containing either 1.5% or 0.8% Triclocarban on two strains of pathogenic bacteria, *Staphylococcus aureus* and *Corynebacterium minutissimum*. Both the 1.5% and 0.8% Triclocarban containing bar soaps significantly (p<0.05) lowered the counts for both organisms on the test sites when compared to the placebo bar soap. There was no significant difference in efficacy between the two bars of soap containing Triclocarban. (Finkey, *et. al.*, 1984; Attachment 12)
- An *in vivo* method, the “agar patch test,” was used to test the efficacy of a bar soap containing 1.5% Triclocarban against two isolates of *S. epidermidis*. Six to eight panelists were used for each test comparing the antimicrobial bar soap and a placebo bar soap. The results indicated that the extent of Triclocarban residual activity deposited on the skin washed with the 1.5% Triclocarban containing bar soap reached a statistically significant level after 7 washes and remained at that level through at least 13 washes. (Yachovich and Heinze, 1985; Attachment 13)

Subsequent to the above-mentioned submissions, the following studies were published in the literature:

- For 9 weeks, 50 patients with moderately severe atopic dermatitis bathed daily with either a placebo soap or a soap containing 1.5% Triclocarban. The antimicrobial soap regimen caused significantly greater improvement in the severity and extent of skin lesions over that observed with the placebo soap regimen. Those observations correlated with reductions in *S. aureus* in patients with positive cultures at baseline as well as reductions in total aerobic organisms. The antibacterial soap was well tolerated, provided clinical improvement, and reduced levels of skin microorganisms. (Breneman et al., 2000; Attachment 14)
- Antibiotic and biocide resistance was studied in methicillin-resistant *S. aureus* and vancomycin-resistant enterococcus. The MIC values of Triclocarban were similar for all 17 of the antibiotic-resistant strains as well as for the two antibiotic-sensitive strains tested in the study. That is, there was no apparent resistance to Triclocarban demonstrated. (Suller and Russell, 1999; Attachment 15)

New Studies Conducted in Support of This Petition

Subsequent to the above-mentioned submissions and published articles, Bayer Corporation sponsored several efficacy studies. Hill Top Research, Inc. conducted a time-kill study and Biosciences Laboratories, Inc conducted an MIC study, a time-kill study, and a clinical hand-washing study. Each of these studies are being made available in support of this citizen's petition to classify Triclocarban as Category IE for health-care personnel handwash products as well as for food handler, consumer hand and consumer body OTC drug products proposed by the HCCM.

Liquid soap formulations were tested at 10%, 50%, and 90% concentrations with 30 seconds, one minute, and five minutes of exposure against four test organisms, *E. coli*, *K. pneumoniae*, *P. aeruginosa*, and *S. aureus*. Test samples included two placebo liquid soap formulations, liquid soap containing either 0.3% or 0.7% Triclocarban, and liquid soap containing either 0.3% or 0.7% Triclosan. The placebo samples and the Triclocarban-containing samples showed comparable results against *E. coli*, *K. pneumoniae*, and *P. aeruginosa*. When tested against *S. aureus*, the presence of Triclocarban in the formulations markedly improved the activity of the liquid soap formulation. The results of this time-kill study (Hill Top Research study no. 97-5467-11 dated March 26, 1998) are summarized in Tables 1-4. The full study report is provided in Attachment 16.

Bar soap containing 1.5% Triclocarban and a placebo bar soap containing no active ingredient were tested against each of 50 microorganisms (an ATCC and clinical isolate of each of 25) identified in the 1994 Tentative Final Monograph. The results of this MIC study (Biosciences report no. 010613-202 dated December 21, 2001) sponsored by Bayer are presented in Table 5. Triclocarban dramatically increases the effectiveness of the bar soap against gram-positive organisms as well as against some gram-negative bacteria (e.g., *B. fragilis*, 3 of 4 strains of *E. faecalis*, and a clinical isolate of *H. influenzae*). The full study report is provided in Attachment 17.

**Table 1: Summary of Results
For *Escherichia coli*, ATCC 11229**

Test Article	Exposure Time	Exposure	Average Count (CFU/mL sample)	Percent Reduction	Log Reduction
Liquid Soap, SB 0306-7M, without a.i., August 1997 HTR Project No. 97-5451-11	10%	30 sec.	9.1 x 10 ⁶	39.333	0.22
		1 min.	9.3 x 10 ⁶	45.294	0.26
		5 min.	9.8 x 10 ⁶	36.750	0.21
	50%	30 sec.	8.7 x 10 ⁶	42.000	0.24
		1 min.	8.7 x 10 ⁶	48.824	0.29
		5 min.	7.7 x 10 ⁶	51.824	0.32
	90%	30 sec.	8.3 x 10 ⁶	44.667	0.26
		1 min.	5.1 x 10 ⁶	70.000	0.52
		5 min.	2.5 x 10 ⁶	84.375	0.81
Liquid Soap, SB 0793-1M, 0.7% TCC August 1997 HTR Project No. 97-5450-11	10%	30 sec.	7.4 x 10 ⁶	58.889	0.39
		1 min.	7.6 x 10 ⁶	52.500	0.32
		5 min.	4.9 x 10 ⁶	71.176	0.54
	50%	30 sec.	4.0 x 10 ⁶	77.778	0.65
		1 min.	4.0 x 10 ⁶	75.000	0.60
		5 min.	3.4 x 10 ⁶	80.000	0.70
	90%	30 sec.	3.3 x 10 ⁶	81.667	0.74
		1 min.	1.9 x 10 ⁶	88.125	0.93
		5 min.	3.9 x 10 ⁶	77.059	0.64
Liquid Soap, SB 0306-1M, 0.3% TCC, August 1997 HTR Project No. 97-5449-11	10%	30 sec.	7.1 x 10 ⁶	64.500	0.45
		1 min.	8.2 x 10 ⁶	56.842	0.36
		5 min.	7.8 x 10 ⁶	58.947	0.39
	50%	30 sec.	6.7 x 10 ⁶	66.500	0.47
		1 min.	7.5 x 10 ⁶	60.526	0.40
		5 min.	7.3 x 10 ⁶	61.579	0.42
	90%	30 sec.	6.0 x 10 ⁶	70.000	0.52
		1 min.	5.2 x 10 ⁶	72.632	0.56
		5 min.	2.6 x 10 ⁶	86.316	0.86

**Table 2: Summary of Results
For *Klebsiella pneumoniae*, ATCC 10031**

Test Article	Exposure Time	Exposure	Average Count (CFU/mL sample)	Percent Reduction	Log Reduction
Liquid Soap, SB 0306-7M, without a.i., August 1997 HTR Project No. 97-5451-11	10%	30 sec.	7.4 x 10 ⁶	38.33	0.21
		1 min.	5.6 x 10 ⁶	49.091	0.29
		5 min.	3.0 x 10 ⁶	76.923	0.64
	50%	30 sec.	7.4 x 10 ⁶	38.333	0.21
		1 min.	7.2 x 10 ⁶	34.545	0.18
		5 min.	3.7 x 10 ⁶	71.538	0.55
	90%	30 sec.	1.1 x 10 ⁶	8.333	0.04
		1 min.	9.2 x 10 ⁶	16.364	0.08
		5 min.	3.5 x 10 ⁶	73.077	0.57
Liquid Soap, SB 0793-1M, 0.7% TCC, August 1997 HTR Project No. 97-5450-11	10%	30 sec.	4.6 x 10 ⁶	29.231	0.15
		1 min.	3.2 x 10 ⁶	48.387	0.29
		5 min.	2.0 x 10 ⁶	65.517	0.46
	50%	30 sec.	2.6 x 10 ⁶	60.000	0.40
		1 min.	2.9 x 10 ⁶	53.226	0.33
		5 min.	2.2 x 10 ⁶	62.069	0.42
	90%	30 sec.	5.7 x 10 ⁶	12.308	0.06
		1 min.	4.2 x 10 ⁶	32.258	0.17
		5 min.	3.2 x 10 ⁶	44.828	0.26
Liquid Soap, SB 0306-1M, 0.3% TCC, August 1997 HTR Project No. 97-5449-11	10%	30 sec.	6.2 x 10 ⁶	52.308	0.32
		1 min.	3.4 x 10 ⁶	73.846	0.58
		5 min.	3.2 x 10 ⁶	97.333	1.57
	50%	30 sec.	8.0 x 10 ⁶	38.462	0.21
		1 min.	7.7 x 10 ⁶	40.769	0.23
		5 min.	2.2 x 10 ⁶	81.667	0.74
	90%	30 sec.	7.9 x 10 ⁶	39.237	0.22
		1 min.	7.1 x 10 ⁶	45.385	0.26
		5 min.	1.6 x 10 ⁶	86.667	0.88

**Table 3: Summary of Results
For *Pseudomonas areuginosa*, ATCC 9027**

Test Article	Exposure Time	Exposure	Average Count (CFU/mL sample)	Percent Reduction	Log Reduction
Liquid Soap, SB 0306-7M, without a.i., August 1997 HTR Project No. 97-5451-11	10%	30 sec.	2.9 x 10 ⁶	48.214	0.29
		1 min.	3.0 x 10 ⁶	57.746	0.37
		5 min.	1.6 x 10 ⁶	75.000	0.60
	50%	30 sec.	3.4 x 10 ⁶	39.286	0.22
		1 min.	2.6 x 10 ⁶	63.380	0.44
		5 min.	3.7 x 10 ⁵	94.219	1.24
	90%	30 sec.	4.3 x 10 ⁶	23.214	0.11
		1 min.	2.7 x 10 ⁶	61.972	0.42
		5 min.	1.3 x 10 ⁵	97.969	1.69
Liquid Soap, SB 0793-1M, 0.7% TCC August 1997 HTR Project No. 97-5450-11	10%	30 sec.	5.3 x 10 ⁶	42.391	0.24
		1 min.	7.4 x 10 ⁶	24.490	0.12
		5 min.	2.7 x 10 ⁶	56.452	0.36
	50%	30 sec.	3.7 x 10 ⁶	59.783	0.40
		1 min.	3.1 x 10 ⁶	68.367	0.50
		5 min.	3.8 x 10 ⁵	93.871	1.21
	90%	30 sec.	3.0 x 10 ⁶	67.391	0.49
		1 min.	1.7 x 10 ⁶	82.653	0.76
		5 min.	1.6 x 10 ⁵	97.419	1.59
Liquid Soap, SB 0306-1M, 0.3% TCC, August 1997 HTR Project No. 97-5449-11	10%	30 sec.	2.7 x 10 ⁶	64.474	0.45
		1 min.	2.0 x 10 ⁶	68.750	0.50
		5 min.	9.4 x 10 ⁵	84.839	0.82
	50%	30 sec.	2.8 x 10 ⁶	63.158	0.43
		1 min.	2.3 x 10 ⁶	64.062	0.44
		5 min.	2.0 x 10 ⁵	96.774	1.49
	90%	30 sec.	3.6 x 10 ⁶	52.632	0.32
		1 min.	3.0 x 10 ⁶	53.125	0.33
		5 min.	7.8 x 10 ⁴	98.742	1.90

**Table 4: Summary of Results
For *Staphylococcus aureus*, ATCC 6538**

Test Article	Exposure Time	Exposure	Average Count (CFU/mL sample)	Percent Reduction	Log Reduction
Liquid Soap, SB 0306-7M, without a.i., August 1997 HTR Project No. 97-5451-11	10%	30 sec.	4.5×10^6	18.182	0.09
		1 min.	5.7×10^5	86.428	0.87
		5 min.	4.5×10^4	99.167	2.08
	50%	30 sec.	1.2×10^6	78.182	0.66
		1 min.	7.5×10^5	82.143	0.75
		5 min.	2.4×10^5	95.556	1.35
	90%	30 sec.	1.8×10^6	67.273	0.48
		1 min.	1.1×10^6	73.810	0.58
		5 min.	5.3×10^5	90.185	1.01
Liquid Soap, SB 0793-1M, 0.7% TCC August 1997 HTR Project No. 97-5450-11	10%	30 sec.	2.6×10^6	68.675	0.50
		1 min.	2.2×10^6	71.053	0.54
		5 min.	4.4×10^5	94.211	1.24
	50%	30 sec.	2.8×10^5	96.626	1.47
		1 min.	1.5×10^5	98.026	1.70
		5 min.	3.2×10^4	99.579	2.38
	90%	30 sec.	1.2×10^5	98.554	1.84
		1 min.	7.5×10^4	99.013	2.01
		5 min.	2.8×10^4	99.632	2.43
Liquid Soap, SB 0306-1M, 0.3% TCC, August 1997 HTR Project No. 97-5449-11	10%	30 sec.	3.2×10^5	95.789	1.38
		1 min.	4.0×10^4	99.444	2.26
		5 min.	6.1×10^3	99.898	2.99
	50%	30 sec.	3.5×10^4	99.539	2.34
		1 min.	1.9×10^4	99.736	2.58
		5 min.	7.9×10^3	99.868	2.88
	90%	30 sec.	5.2×10^4	99.316	2.16
		1 min.	2.1×10^4	99.708	2.54
		5 min.	1.1×10^4	99.817	2.74

Table 5: Minimum Inhibitory Concentrations, Expressed as Product Dilution, for Each Product Versus Each of the Fifty (50) Microorganisms Tested.

Microorganism Species	ATCC or BSLI# ^❶	Minimum Inhibitory Concentration – Expressed as Product Dilution	
		Test Product 53BSTO Soap with 1.5% (w/w) TCC	Placebo Product 52BSTO Soap with nil TCC
<i>Acinetobacter baumannii</i>	19606	< 1 : 128	< 1 : 128
<i>Acinetobacter baumannii</i>	061901Ab1 ^❶	< 1 : 128	< 1 : 128
<i>Bacteroides fragilis</i>	25285	1 : 16,384	< 1 : 128
<i>Bacteroides fragilis</i>	061901Bf2 ^❶	1 : 12,288	< 1 : 128
<i>Candida albicans</i>	10231	< 1 : 128	< 1 : 128
<i>Candida albicans</i>	040400Ca2 ^❶	< 1 : 128	< 1 : 128
<i>Candida tropicalis</i>	750	< 1 : 128	< 1 : 128
<i>Candida tropicalis</i>	040400Ct2 ^❶	< 1 : 128	< 1 : 128
<i>Enterobacter aerogenes</i>	13048	< 1 : 128	< 1 : 128
<i>Enterobacter aerogenes</i>	040400Ea1 ^❶	< 1 : 128	< 1 : 128
<i>Enterococcus faecalis</i>	29212	1 : 1,024	< 1 : 128
<i>Enterococcus faecalis</i>	040400Esp17 ^❶	1 : 768	< 1 : 128
<i>Enterococcus faecium</i>	51559	1 : 512	< 1 : 128
<i>Enterococcus faecium</i>	061901Efm2 ^❶	< 1 : 128	< 1 : 128
<i>Escherichia coli</i>	11229	< 1 : 128	< 1 : 128
<i>Escherichia coli</i>	051599Ec ^❶	< 1 : 128	< 1 : 128
<i>Escherichia coli</i>	25922	< 1 : 128	< 1 : 128
<i>Escherichia coli</i>	070399Ec ^❶	< 1 : 128	< 1 : 128
<i>Haemophilus influenzae</i>	19418	< 1 : 128	< 1 : 128
<i>Haemophilus influenzae</i>	121699Hi1 ^❶	1 : 1,536	< 1 : 128
<i>Klebsiella oxytoca</i>	43165	< 1 : 128	< 1 : 128
<i>Klebsiella oxytoca</i>	061901Ko1 ^❶	< 1 : 128	< 1 : 128
<i>Klebsiella pneumoniae</i>	13883	< 1 : 128	< 1 : 128
<i>Klebsiella pneumoniae</i>	061901Kpn1 ^❶	< 1 : 128	< 1 : 128
<i>Micrococcus luteus</i>	7468	< 1 : 1,024	< 1 : 1,024
<i>Micrococcus luteus</i>	061901Ml1 ^❶	< 1 : 1,024	< 1 : 512
<i>Proteus mirabilis</i>	7002	< 1 : 128	< 1 : 128
<i>Proteus mirabilis</i>	081299Pm ^❶	< 1 : 128	< 1 : 128
<i>Pseudomonas aeruginosa</i>	15442	< 1 : 128	< 1 : 128
<i>Pseudomonas aeruginosa</i>	053099Pa ^❶	< 1 : 128	< 1 : 128
<i>Pseudomonas aeruginosa</i>	27853	< 1 : 32	< 1 : 32
<i>Pseudomonas aeruginosa</i>	070199Pa ^❶	< 1 : 32	< 1 : 32

❶ = Clinical Isolate

**Table 5: Minimum Inhibitory Concentrations, Expressed as Product Dilution,
for Each Product Versus Each of the Fifty (50) Microorganisms Tested.
(Continued)**

Microorganism Species	ATCC or BSLI#●	Minimum Inhibitory Concentration – Expressed as Product Dilution	
		Test Product 53BSTO Soap with 1.5% (w/w) TCC	Placebo Product 52BSTO Soap with nil TCC
<i>Serratia marcescens</i>	14756	< 1 : 4	< 1 : 128
<i>Serratia marcescens</i>	081499Sm●	< 1 : 128	< 1 : 128
<i>Staphylococcus aureus</i>	6538	1 : 16,384	< 1 : 128
<i>Staphylococcus aureus</i>	061901Sa1●	1 : 16,384	< 1 : 128
<i>Staphylococcus aureus</i>	29213	1 : 16,384	< 1 : 128
<i>Staphylococcus aureus</i>	061901Sa2●	1 : 16,384	< 1 : 128
<i>Staphylococcus epidermidis</i>	12228	1 : 12,288	< 1 : 128
<i>Staphylococcus epidermidis</i>	010500Se2●	1 : 16,384	< 1 : 128
<i>Staphylococcus haemolyticus</i>	29970	1 : 8,192	< 1 : 128
<i>Staphylococcus haemolyticus</i>	060700Sh1●	1 : 12,288	< 1 : 128
<i>Staphylococcus hominis</i>	27844	1 : 3,072	< 1 : 128
<i>Staphylococcus hominis</i>	060700Sho2●	1 : 16,384	< 1 : 128
<i>Staphylococcus saprophyticus</i>	15305	1 : 8,192	< 1 : 128
<i>Staphylococcus saprophyticus</i>	081399Ss●	1 : 12,288	< 1 : 128
<i>Streptococcus pneumoniae</i>	33400	1 : 4,096	< 1 : 128
<i>Streptococcus pneumoniae</i>	081700Spn5●	1 : 24,576	< 1 : 128
<i>Streptococcus pyogenes</i>	19615	1 : 1,024	< 1 : 128
<i>Streptococcus pyogenes</i>	061901Spy2●	< 1 : 128	< 1 : 128

● = Clinical Isolate

Bar soap containing 1.5% Triclocarban and a placebo bar soap containing no active ingredient were tested against each of 50 microorganisms (ATCC and a clinical isolate) identified in the 1994 Tentative Final Monograph. The results of this time-kill study (Biosciences report no. 010612-201 dated December 21, 2001) sponsored by Bayer are presented in Tables 6 and 7. Table 6 presents the Log₁₀ reductions and percent reductions for the bar soap containing 1.5% Triclocarban at a 10% (v/v) concentration versus each of the 50 microorganisms tested. Table 7 presents the Log₁₀ reductions and percent reductions for the placebo bar soap at a 10% (v/v) concentration versus each of the 50 microorganisms tested. The study report is provided in Attachment 18.

Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Acinetobacter baumannii</i>	19606	15 seconds	4.1800	99.9934%
		1 minute	6.4472	99.9999%
		3 minutes	6.4472	99.9999%
		6 minutes	6.4472	99.9999%
		9 minutes	6.4472	99.9999%
		12 minutes	6.4472	99.9999%
		15 minutes	6.4472	99.9999%
		20 minutes	6.4472	99.9999%
		30 minutes	6.4472	99.9999%
<i>Acinetobacter baumannii</i>	061901Ab1 ^❶	15 seconds	2.0000	99.0000%
		1 minute	6.5740	99.9999%
		3 minutes	6.5740	99.9999%
		6 minutes	6.5740	99.9999%
		9 minutes	6.5740	99.9999%
		12 minutes	6.5740	99.9999%
		15 minutes	6.5740	99.9999%
		20 minutes	6.5740	99.9999%
		30 minutes	6.5740	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Bacteroides fragilis</i>	25285	15 seconds	5.1492	99.9993%
		1 minute	5.1492	99.9993%
		3 minutes	5.1492	99.9993%
		6 minutes	5.1492	99.9993%
		9 minutes	5.1492	99.9993%
		12 minutes	5.1492	99.9993%
		15 minutes	5.1492	99.9993%
		20 minutes	5.1492	99.9993%
		30 minutes	5.1492	99.9993%
<i>Bacteroides fragilis</i>	061901Bf2 ^❶	15 seconds	6.6675	99.9999%
		1 minute	6.6675	99.9999%
		3 minutes	6.6675	99.9999%
		6 minutes	6.6675	99.9999%
		9 minutes	6.6675	99.9999%
		12 minutes	6.6675	99.9999%
		15 minutes	6.6675	99.9999%
		20 minutes	6.6675	99.9999%
		30 minutes	6.6675	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Candida albicans</i>	10231	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.0658	14.0625%
		6 minutes	0.3629	56.6406%
		9 minutes	0.7325	81.4844%
		12 minutes	0.9428	88.5938%
		15 minutes	1.1778	93.3594%
		20 minutes	1.6758	97.8906%
		30 minutes	2.6554	99.7789%
<i>Candida albicans</i>	040400Ca2 ^❶	15 seconds	0.4898	67.6230%
		1 minute	0.5009	68.4426%
		3 minutes	0.4580	65.1639%
		6 minutes	0.4953	68.0328%
		9 minutes	0.6392	77.0492%
		12 minutes	0.4605	65.3689%
		15 minutes	0.5123	69.2623%
		20 minutes	0.4898	67.6230%
		30 minutes	0.6841	79.3033%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Candida tropicalis</i>	750	15 seconds	0.2379	42.1818%
		1 minute	0.3355	53.8182%
		3 minutes	0.4875	67.4545%
		6 minutes	0.6911	79.6364%
		9 minutes	1.0537	91.1636%
		12 minutes	1.1426	92.8000%
		15 minutes	1.3940	95.9636%
		20 minutes	1.6834	97.9273%
		30 minutes	2.2379	99.4218%
<i>Candida tropicalis</i>	040400Ct2 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.0246	5.4945%
		3 minutes	0.0000	0.00009%
		6 minutes	0.0488	10.6227%
		9 minutes	0.1181	23.8095%
		12 minutes	0.2135	38.8278%
		15 minutes	0.3358	53.8462%
		20 minutes	0.6300	76.5568%
		30 minutes	1.1484	92.8938%

^❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Enterobacter aerogenes</i>	13048	15 seconds	0.5932	74.4828%
		1 minute	0.2169	39.3103%
		3 minutes	2.8150	99.8469%
		6 minutes	6.1614	99.9999%
		9 minutes	6.1614	99.9999%
		12 minutes	6.1614	99.9999%
		15 minutes	6.1614	99.9999%
		20 minutes	6.1614	99.9999%
		30 minutes	6.1614	99.9999%
<i>Enterobacter aerogenes</i>	040400Ea1 ^❶	15 seconds	0.0307	6.8323%
		1 minute	0.4075	60.8696%
		3 minutes	5.2526	99.9994%
		6 minutes	6.2068	99.9999%
		9 minutes	6.2068	99.9999%
		12 minutes	6.2068	99.9999%
		15 minutes	6.2068	99.9999%
		20 minutes	6.2068	99.9999%
		30 minutes	6.2068	99.9999%

^❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Enterococcus faecalis</i>	29212	15 seconds	0.3087	50.8772%
		1 minute	0.9298	88.2456%
		3 minutes	4.4592	99.9965%
		6 minutes	6.7559	99.9999%
		9 minutes	6.7559	99.9999%
		12 minutes	6.7559	99.9999%
		15 minutes	6.7559	99.9999%
		20 minutes	6.7559	99.9999%
		30 minutes	6.7559	99.9999%
<i>Enterococcus faecalis</i>	040400Esp17 ^❶	15 seconds	0.3299	53.2099%
		1 minute	0.2505	43.8272%
		3 minutes	1.1526	92.9630%
		6 minutes	3.2457	99.9432%
		9 minutes	4.4130	99.9961%
		12 minutes	5.0990	99.9992%
		15 minutes	5.6185	99.9998%
		20 minutes	6.0956	99.9999%
		30 minutes	6.9085	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Enterococcus faecium</i>	51559	15 seconds	0.0181	4.0741%
		1 minute	0.1934	35.9259%
		3 minutes	0.2113	38.5185%
		6 minutes	0.5393	71.1111%
		9 minutes	1.3242	95.2593%
		12 minutes	2.3450	99.5481%
		15 minutes	3.2791	99.9474%
		20 minutes	4.2884	99.9949%
		30 minutes	4.8751	99.9987%
<i>Enterococcus faecium</i>	061700Efm1 ^❶	15 seconds	0.0549	11.8750%
		1 minute	0.0280	6.2500%
		3 minutes	0.3046	50.4167%
		6 minutes	0.6856	79.3750%
		9 minutes	1.1014	92.0833%
		12 minutes	1.3549	95.5833%
		15 minutes	1.4533	96.4792%
		20 minutes	1.6518	97.7708%
		30 minutes	1.9488	98.8750%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Escherichia coli</i>	11229	15 seconds	0.0000	0.0000%
		1 minute	1.3319	95.3431%
		3 minutes	6.0086	99.9999%
		6 minutes	6.0086	99.9999%
		9 minutes	6.0086	99.9999%
		12 minutes	6.0086	99.9999%
		15 minutes	6.0086	99.9999%
		20 minutes	6.0086	99.9999%
		30 minutes	6.0086	99.9999%
<i>Escherichia coli</i>	051599Ec ^❶	15 seconds	0.5323	70.6468%
		1 minute	0.5914	74.3781%
		3 minutes	3.5323	99.9706%
		6 minutes	6.3032	99.9999%
		9 minutes	6.3032	99.9999%
		12 minutes	6.3032	99.9999%
		15 minutes	6.3032	99.9999%
		20 minutes	6.3032	99.9999%
		30 minutes	6.3032	99.9999%

^❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Escherichia coli</i>	25922	15 seconds	0.0000	0.0000%
		1 minute	1.0829	91.7361%
		3 minutes	6.1584	99.9999%
		6 minutes	6.1584	99.9999%
		9 minutes	6.1584	99.9999%
		12 minutes	6.1584	99.9999%
		15 minutes	6.1584	99.9999%
		20 minutes	6.1584	99.9999%
		30 minutes	6.1584	99.9999%
<i>Escherichia coli</i>	013100Ec1 ^❶	15 seconds	0.3362	53.8889%
		1 minute	0.1760	33.3333%
		3 minutes	5.9542	99.9999%
		6 minutes	5.9542	99.9999%
		9 minutes	5.9542	99.9999%
		12 minutes	5.9542	99.9999%
		15 minutes	5.9542	99.9999%
		20 minutes	5.9542	99.9999%
		30 minutes	5.9542	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Haemophilus influenzae</i>	19418	15 seconds	7.0128	99.9999%
		1 minute	7.0128	99.9999%
		3 minutes	7.0128	99.9999%
		6 minutes	7.0128	99.9999%
		9 minutes	7.0128	99.9999%
		12 minutes	7.0128	99.9999%
		15 minutes	7.0128	99.9999%
		20 minutes	7.0128	99.9999%
		30 minutes	7.0128	99.9999%
<i>Haemophilus influenzae</i>	121699Hi1 ^❶	15 seconds	6.9085	99.9999%
		1 minute	6.9085	99.9999%
		3 minutes	6.9085	99.9999%
		6 minutes	6.9085	99.9999%
		9 minutes	6.9085	99.9999%
		12 minutes	6.9085	99.9999%
		15 minutes	6.9085	99.9999%
		20 minutes	6.9085	99.9999%
		30 minutes	6.9085	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Klebsiella oxytoca</i>	43165	15 seconds	0.0397	8.7302%
		1 minute	0.9360	88.4127%
		3 minutes	4.6690	99.9979%
		6 minutes	6.1004	99.9999%
		9 minutes	6.1004	99.9999%
		12 minutes	6.1004	99.9999%
		15 minutes	6.1004	99.9999%
		20 minutes	6.1004	99.9999%
		30 minutes	6.1004	99.9999%
<i>Klebsiella oxytoca</i>	061901Ko1 ^❶	15 seconds	0.4872	67.4342%
		1 minute	0.3557	55.9211%
		3 minutes	1.5534	97.2039%
		6 minutes	3.8494	99.9859%
		9 minutes	4.6568	99.9978%
		12 minutes	6.1818	99.9999%
		15 minutes	6.1818	99.9999%
		20 minutes	6.1818	99.9999%
		30 minutes	6.1818	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Klebsiella pneumoniae</i>	13883	15 seconds	0.7281	81.2970%
		1 minute	1.1348	92.6692%
		3 minutes	2.0447	99.0977%
		6 minutes	6.0269	99.9999%
		9 minutes	6.7259	99.9999%
		12 minutes	6.7259	99.9999%
		15 minutes	6.7259	99.9999%
		20 minutes	6.7259	99.9999%
		30 minutes	6.7259	99.9999%
<i>Klebsiella pneumoniae</i>	061091Kpn1 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.6533	77.7778%
		3 minutes	1.6482	97.7516%
		6 minutes	5.8837	99.9999%
		9 minutes	5.8837	99.9999%
		12 minutes	5.8837	99.9999%
		15 minutes	5.8837	99.9999%
		20 minutes	5.8837	99.9999%
		30 minutes	5.8837	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Micrococcus luteus</i>	7468	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.0000	0.0000%
		6 minutes	0.0000	0.0000%
		9 minutes	0.0000	0.0000%
		12 minutes	0.0000	0.0000%
		15 minutes	0.0000	0.0000%
		20 minutes	0.0000	0.0000%
		30 minutes	0.0000	0.0000%
<i>Micrococcus luteus</i>	061901M11 ^❶	15 seconds	0.9198	87.9730%
		1 minute	1.0658	91.4054%
		3 minutes	1.1226	92.4595%
		6 minutes	1.0768	91.6216%
		9 minutes	1.1583	93.0541%
		12 minutes	1.1826	93.4324%
		15 minutes	1.2672	94.5946%
		20 minutes	1.3302	95.3243%
		30 minutes	1.4890	96.7568%

^❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Proteus mirabilis</i>	7002	15 seconds	0.2499	43.7500%
		1 minute	0.5274	70.3125%
		3 minutes	5.1072	99.9992%
		6 minutes	6.2041	99.9999%
		9 minutes	6.2041	99.9999%
		12 minutes	6.2041	99.9999%
		15 minutes	6.2041	99.9999%
		20 minutes	6.2041	99.9999%
		30 minutes	6.2041	99.9999%
<i>Proteus mirabilis</i>	081299Pm ^❶	15 seconds	0.2132	38.7850%
		1 minute	0.9539	88.8785%
		3 minutes	5.5523	99.9997%
		6 minutes	6.0294	99.9999%
		9 minutes	6.0294	99.9999%
		12 minutes	6.0294	99.9999%
		15 minutes	6.0294	99.9999%
		20 minutes	6.0294	99.9999%
		30 minutes	6.0294	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Pseudomonas aeruginosa</i>	15442	15 seconds	6.0682	99.9999%
		1 minute	6.0682	99.9999%
		3 minutes	6.0682	99.9999%
		6 minutes	6.0682	99.9999%
		9 minutes	6.0682	99.9999%
		12 minutes	6.0682	99.9999%
		15 minutes	6.0682	99.9999%
		20 minutes	6.0682	99.9999%
		30 minutes	6.0682	99.9999%
<i>Pseudomonas aeruginosa</i>	053099Pa ^❶	15 seconds	2.7308	99.8141%
		1 minute	5.9638	99.9999%
		3 minutes	5.9638	99.9999%
		6 minutes	5.9638	99.9999%
		9 minutes	5.9638	99.9999%
		12 minutes	5.9638	99.9999%
		15 minutes	5.9638	99.9999%
		20 minutes	5.9638	99.9999%
		30 minutes	5.9638	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Pseudomonas aeruginosa</i>	27853	15 seconds	6.1139	99.9999%
		1 minute	6.1139	99.9999%
		3 minutes	6.1139	99.9999%
		6 minutes	6.1139	99.9999%
		9 minutes	6.1139	99.9999%
		12 minutes	6.1139	99.9999%
		15 minutes	6.1139	99.9999%
		20 minutes	6.1139	99.9999%
		30 minutes	6.1139	99.9999%
<i>Pseudomonas aeruginosa</i>	070199Pa ^❶	15 seconds	5.5993	99.9997%
		1 minute	6.2014	99.9999%
		3 minutes	6.2014	99.9999%
		6 minutes	6.2014	99.9999%
		9 minutes	6.2014	99.9999%
		12 minutes	6.2014	99.9999%
		15 minutes	6.2014	99.9999%
		20 minutes	6.2014	99.9999%
		30 minutes	6.2014	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI#^❶	Exposure Time	Log₁₀ Reduction	Percent Reduction
<i>Serratia marcescens</i>	14756	15 seconds	0.1131	22.9299%
		1 minute	0.7116	80.5732%
		3 minutes	3.3797	99.9583%
		6 minutes	6.1959	99.9999%
		9 minutes	6.1959	99.9999%
		12 minutes	6.1959	99.9999%
		15 minutes	6.1959	99.9999%
		20 minutes	6.1959	99.9999%
		30 minutes	6.1959	99.9999%
<i>Serratia marcescens</i>	081499Sm ^❶	15 seconds	0.1780	33.6364%
		1 minute	0.5431	71.3636%
		3 minutes	5.4973	99.9997%
		6 minutes	6.3424	99.9999%
		9 minutes	6.3424	99.9999%
		12 minutes	6.3424	99.9999%
		15 minutes	6.3424	99.9999%
		20 minutes	6.3424	99.9999%
		30 minutes	6.3424	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus aureus</i>	6538	15 seconds	0.0000	0.0000%
		1 minute	0.2234	40.2062%
		3 minutes	0.6990	80.0000%
		6 minutes	1.4683	96.5979%
		9 minutes	2.0183	99.0412%
		12 minutes	2.5274	99.7031%
		15 minutes	2.8050	99.8433%
		20 minutes	3.2425	99.9428%
		30 minutes	3.7881	99.9837%
<i>Staphylococcus aureus</i>	040400Sa1 ^❶	15 seconds	0.2441	43.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.3500	55.3333%
		6 minutes	0.8050	84.3333%
		9 minutes	1.0522	91.1333%
		12 minutes	1.2570	94.4667%
		15 minutes	1.3310	95.3333%
		20 minutes	1.6021	97.5000%
		30 minutes	1.7368	98.1667%

^❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus aureus</i>	29213	15 seconds	0.0766	16.1765%
		1 minute	0.2359	41.9118%
		3 minutes	1.0000	90.0000%
		6 minutes	1.5712	97.3162%
		9 minutes	2.0543	99.1176%
		12 minutes	2.2277	99.4081%
		15 minutes	2.5772	99.7353%
		20 minutes	2.8855	99.8699%
		30 minutes	3.3446	99.9548%
<i>Staphylococcus aureus</i>	061901Sa1 ^❶	15 seconds	0.0324	7.1856%
		1 minute	0.1545	29.9401%
		3 minutes	0.8725	86.5868%
		6 minutes	1.3715	95.7485%
		9 minutes	1.9463	98.8683%
		12 minutes	2.1022	99.2096%
		15 minutes	2.4303	99.6287%
		20 minutes	3.0241	99.9054%
		30 minutes	3.9651	99.9892%

^❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus epidermidis</i>	12228	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.1895	35.3659%
		6 minutes	0.3575	56.0976%
		9 minutes	0.6171	25.8537%
		12 minutes	0.6990	80.0000%
		15 minutes	0.7954	83.9837%
		20 minutes	0.9438	88.6179%
		30 minutes	1.1504	92.9268%
<i>Staphylococcus epidermidis</i>	010500Se2 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.1003	20.6250%
		3 minutes	0.4521	64.6875%
		6 minutes	0.6418	77.1875%
		9 minutes	0.5913	74.3750%
		12 minutes	0.6478	77.5000%
		15 minutes	0.7328	81.5000%
		20 minutes	0.8132	84.6250%
		30 minutes	0.9737	89.3750%

^❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus haemolyticus</i>	29970	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.0000	0.0000%
		6 minutes	0.0000	0.0000%
		9 minutes	0.0000	0.0000%
		12 minutes	0.0815	17.1053%
		15 minutes	0.1566	30.2632%
		20 minutes	0.2638	45.5263%
		30 minutes	0.3951	59.7368%
<i>Staphylococcus haemolyticus</i>	060700Sh1 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.1399	27.5362%
		6 minutes	0.0000	0.0000%
		9 minutes	0.1330	26.3768%
		12 minutes	0.1296	25.7971%
		15 minutes	0.1178	23.7681%
		20 minutes	0.2636	45.5072%
		30 minutes	0.2522	44.0580%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus hominis</i>	27844	15 seconds	0.0055	1.2658%
		1 minute	0.0983	20.2532%
		3 minutes	0.1800	33.9241%
		6 minutes	0.2128	39.4937%
		9 minutes	0.2827	47.8481%
		12 minutes	0.3925	59.4937%
		15 minutes	0.4176	61.7722%
		20 minutes	0.4205	62.0253%
		30 minutes	0.7546	82.4051%
<i>Staphylococcus hominis</i>	060700Sho2 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.0867	18.1034%
		3 minutes	0.6952	79.8276%
		6 minutes	1.1199	92.4138%
		9 minutes	1.4230	96.2241%
		12 minutes	1.3760	95.7931%
		15 minutes	1.4962	96.8103%
		20 minutes	1.6428	97.7241%
		30 minutes	1.8140	98.4655%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Streptococcus saprophyticus</i>	15305	15 seconds	0.1063	21.7143%
		1 minute	0.0000	0.0000%
		3 minutes	0.1496	29.1429%
		6 minutes	0.2608	45.1429%
		9 minutes	0.2745	46.8571%
		12 minutes	0.3857	58.8571%
		15 minutes	0.4235	62.2857%
		20 minutes	0.6388	77.0286%
		30 minutes	1.1159	92.3429%
<i>Streptococcus saprophyticus</i>	081399Ss ^❶	15 seconds	0.0241	5.3892%
		1 minute	0.0079	1.7964%
		3 minutes	0.0213	4.7904%
		6 minutes	0.0735	15.5689%
		9 minutes	0.0026	0.5988%
		12 minutes	0.0735	15.5689%
		15 minutes	0.0268	5.9880%
		20 minutes	0.2832	47.9042%
		30 minutes	0.3089	50.8982%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Streptococcus pneumoniae</i>	33400	15 seconds	5.3892	99.9996%
		1 minute	5.3892	99.9996%
		3 minutes	5.3892	99.9996%
		6 minutes	5.3892	99.9996%
		9 minutes	5.3892	99.9996%
		12 minutes	5.3892	99.9996%
		15 minutes	5.3892	99.9996%
		20 minutes	5.3892	99.9996%
		30 minutes	5.3892	99.9996%
<i>Streptococcus pneumoniae</i>	081700Spn ^❶	15 seconds	6.2148	99.9999%
		1 minute	6.2148	99.9999%
		3 minutes	6.2148	99.9999%
		6 minutes	6.2148	99.9999%
		9 minutes	6.2148	99.9999%
		12 minutes	6.2148	99.9999%
		15 minutes	6.2148	99.9999%
		20 minutes	6.2148	99.9999%
		30 minutes	6.2148	99.9999%

❶ = Clinical Isolate

**Table 6: Test Product – 10% (v/v) concentration 53BSTO Soap with 1.5% (w/w) TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Streptococcus pyogenes</i>	19615	15 seconds	4.9108	99.9988%
		1 minute	6.0569	99.9999%
		3 minutes	6.0569	99.9999%
		6 minutes	6.0569	99.9999%
		9 minutes	6.0569	99.9999%
		12 minutes	6.0569	99.9999%
		15 minutes	6.0569	99.9999%
		20 minutes	6.0569	99.9999%
		30 minutes	6.0569	99.9999%
<i>Streptococcus pyogenes</i>	061901Spy2 ^❶	15 seconds	5.9269	99.9999%
		1 minute	5.9269	99.9999%
		3 minutes	5.9269	99.9999%
		6 minutes	5.9269	99.9999%
		9 minutes	5.9269	99.9999%
		12 minutes	5.9269	99.9999%
		15 minutes	5.9269	99.9999%
		20 minutes	5.9269	99.9999%
		30 minutes	5.9269	99.9999%

❶ = Clinical Isolate

Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC

Microorganism Species	ATCC or BSLI#^❶	Exposure Time	Log₁₀ Reduction	Percent Reduction
<i>Acinetobacter baumannii</i>	19606	15 seconds	5.6690	99.9998%
		1 minute	6.4472	99.9999%
		3 minutes	6.4472	99.9999%
		6 minutes	6.4472	99.9999%
		9 minutes	6.4472	99.9999%
		12 minutes	6.4472	99.9999%
		15 minutes	6.4472	99.9999%
		20 minutes	6.4472	99.9999%
		30 minutes	6.4472	99.9999%
<i>Acinetobacter baumannii</i>	061901Ab1 ^❶	15 seconds	2.1993	99.3680%
		1 minute	6.5740	99.9999%
		3 minutes	6.5740	99.9999%
		6 minutes	6.5740	99.9999%
		9 minutes	6.5740	99.9999%
		12 minutes	6.5740	99.9999%
		15 minutes	6.5740	99.9999%
		20 minutes	6.5740	99.9999%
		30 minutes	6.5740	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Bacteroides fragilis</i>	25285	15 seconds	5.1492	99.9993%
		1 minute	5.1492	99.9993%
		3 minutes	5.1492	99.9993%
		6 minutes	5.1492	99.9993%
		9 minutes	5.1492	99.9993%
		12 minutes	5.1492	99.9993%
		15 minutes	5.1492	99.9993%
		20 minutes	5.1492	99.9993%
		30 minutes	5.1492	99.9993%
<i>Bacteroides fragilis</i>	061901Bf2 ^❶	15 seconds	6.6675	99.9999%
		1 minute	6.6675	99.9999%
		3 minutes	6.6675	99.9999%
		6 minutes	6.6675	99.9999%
		9 minutes	6.6675	99.9999%
		12 minutes	6.6675	99.9999%
		15 minutes	6.6675	99.9999%
		20 minutes	6.6675	99.9999%
		30 minutes	6.6675	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Candida albicans</i>	10231	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.0580	12.5000%
		6 minutes	0.4637	65.6250%
		9 minutes	0.7570	82.5000%
		12 minutes	0.8592	86.1719%
		15 minutes	1.0658	91.4063%
		20 minutes	1.5631	97.2656%
		30 minutes	1.9369	98.8438%
<i>Candida albicans</i>	040400Ca2 ^❶	15 seconds	0.2836	47.9508%
		1 minute	0.4580	65.1639%
		3 minutes	0.4143	61.4754%
		6 minutes	0.3343	53.6885%
		9 minutes	0.3155	51.6393%
		12 minutes	0.3746	57.7869%
		15 minutes	0.3267	52.8689%
		20 minutes	0.6202	76.0246%
		30 minutes	0.9117	87.7459%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Candida tropicalis</i>	750	15 seconds	0.3565	56.0000%
		1 minute	0.2632	45.4545%
		3 minutes	0.5585	72.3636%
		6 minutes	0.8058	84.3636%
		9 minutes	1.1008	92.0727%
		12 minutes	1.3674	95.7091%
		15 minutes	1.6100	97.5455%
		20 minutes	1.8008	98.4182%
		30 minutes	2.0719	99.1527%
<i>Candida tropicalis</i>	040400Ct2 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.0196	4.3956%
		3 minutes	0.0707	15.0183%
		6 minutes	0.1690	32.2344%
		9 minutes	0.2932	49.0842%
		12 minutes	0.4276	62.6374%
		15 minutes	0.5759	73.4432%
		20 minutes	1.0383	90.8425%
		30 minutes	1.4868	96.7399%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Enterobacter aerogenes</i>	13048	15 seconds	0.2320	41.3793%
		1 minute	0.0610	13.1034%
		3 minutes	4.0061	99.9901%
		6 minutes	6.1614	99.9999%
		9 minutes	6.1614	99.9999%
		12 minutes	6.1614	99.9999%
		15 minutes	6.1614	99.9999%
		20 minutes	6.1614	99.9999%
		30 minutes	6.1614	99.9999%
<i>Enterobacter aerogenes</i>	040400Ea1 ^❶	15 seconds	0.3260	52.7950%
		1 minute	0.8248	85.0311%
		3 minutes	6.2068	99.9999%
		6 minutes	6.2068	99.9999%
		9 minutes	6.2068	99.9999%
		12 minutes	6.2068	99.9999%
		15 minutes	6.2068	99.9999%
		20 minutes	6.2068	99.9999%
		30 minutes	6.2068	99.9999%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Enterococcus faecalis</i>	29212	15 seconds	0.0000	0.0000%
		1 minute	0.3477	55.0877%
		3 minutes	1.3294	95.3158%
		6 minutes	3.3409	99.9544%
		9 minutes	4.7805	99.9983%
		12 minutes	5.5518	99.9997%
		15 minutes	6.0569	99.9999%
		20 minutes	6.0569	99.9999%
		30 minutes	6.7559	99.9999%
<i>Enterococcus faecalis</i>	040400Esp17 ^❶	15 seconds	0.1826	34.3210%
		1 minute	0.1801	33.9506%
		3 minutes	0.3163	51.7284%
		6 minutes	0.9262	88.1481%
		9 minutes	1.9616	98.9074%
		12 minutes	2.9400	99.8852%
		15 minutes	3.6532	99.9778%
		20 minutes	4.2957	99.9949%
		30 minutes	4.7750	99.9983%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Enterococcus faecium</i>	51559	15 seconds	0.4514	64.6296%
		1 minute	0.0000	0.0000%
		3 minutes	0.0000	0.0000%
		6 minutes	0.0405	8.8889%
		9 minutes	0.1133	22.9630%
		12 minutes	0.3783	58.1481%
		15 minutes	0.6755	78.8889%
		20 minutes	1.3415	95.4444%
		30 minutes	2.5651	99.7278%
<i>Enterococcus faecium</i>	061700Efm1 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.0991	20.4167%
		3 minutes	0.0924	19.1667%
		6 minutes	0.2294	41.0417%
		9 minutes	0.3028	50.2083%
		12 minutes	0.3233	52.5000%
		15 minutes	0.5382	71.0417%
		20 minutes	0.9408	88.5417%
		30 minutes	1.7294	98.1354%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Escherichia coli</i>	11229	15 seconds	0.0641	13.7255%
		1 minute	0.8687	86.4706%
		3 minutes	6.0086	99.9999%
		6 minutes	6.0086	99.9999%
		9 minutes	6.0086	99.9999%
		12 minutes	6.0086	99.9999%
		15 minutes	6.0086	99.9999%
		20 minutes	6.0086	99.9999%
		30 minutes	6.0086	99.9999%
<i>Escherichia coli</i>	051599Ec ^❶	15 seconds	0.7981	84.0796%
		1 minute	0.5668	72.8856%
		3 minutes	3.9667	99.9892%
		6 minutes	6.3032	99.9999%
		9 minutes	6.3032	99.9999%
		12 minutes	6.3032	99.9999%
		15 minutes	6.3032	99.9999%
		20 minutes	6.3032	99.9999%
		30 minutes	6.3032	99.9999%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Escherichia coli</i>	25922	15 seconds	0.4863	67.3611%
		1 minute	1.0345	90.7639%
		3 minutes	6.1584	99.9999%
		6 minutes	6.1584	99.9999%
		9 minutes	6.1584	99.9999%
		12 minutes	6.1584	99.9999%
		15 minutes	6.1584	99.9999%
		20 minutes	6.1584	99.9999%
		30 minutes	6.1584	99.9999%
<i>Escherichia coli</i>	013100Ec1 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.4164	61.6667%
		3 minutes	5.9542	99.9999%
		6 minutes	5.9542	99.9999%
		9 minutes	5.9542	99.9999%
		12 minutes	5.9542	99.9999%
		15 minutes	5.9542	99.9999%
		20 minutes	5.9542	99.9999%
		30 minutes	5.9542	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Haemophilus influenzae</i>	19418	15 seconds	7.0128	99.9999%
		1 minute	7.0128	99.9999%
		3 minutes	7.0128	99.9999%
		6 minutes	7.0128	99.9999%
		9 minutes	7.0128	99.9999%
		12 minutes	7.0128	99.9999%
		15 minutes	7.0128	99.9999%
		20 minutes	7.0128	99.9999%
		30 minutes	7.0128	99.9999%
<i>Haemophilus influenzae</i>	121699Hi1 ^❶	15 seconds	6.9085	99.9999%
		1 minute	6.9085	99.9999%
		3 minutes	6.9085	99.9999%
		6 minutes	6.9085	99.9999%
		9 minutes	6.9085	99.9999%
		12 minutes	6.9085	99.9999%
		15 minutes	6.9085	99.9999%
		20 minutes	6.9085	99.9999%
		30 minutes	6.9085	99.9999%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Klebsiella oxytoca</i>	43165	15 seconds	0.0000	0.0000%
		1 minute	0.7077	80.3968%
		3 minutes	3.4424	99.9639%
		6 minutes	6.1004	99.9999%
		9 minutes	6.1004	99.9999%
		12 minutes	6.1004	99.9999%
		15 minutes	6.1004	99.9999%
		20 minutes	6.1004	99.9999%
		30 minutes	6.1004	99.9999%
<i>Klebsiella oxytoca</i>	061901Ko1 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.2087	38.1579%
		3 minutes	1.9514	98.8816%
		6 minutes	4.2653	99.9946%
		9 minutes	5.1818	99.9993%
		12 minutes	5.7047	99.9998%
		15 minutes	6.1818	99.9999%
		20 minutes	6.1818	99.9999%
		30 minutes	6.1818	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Klebsiella pneumoniae</i>	13883	15 seconds	1.1079	92.1992%
		1 minute	1.7889	98.3741%
		3 minutes	1.6431	97.7256%
		6 minutes	6.7259	99.9999%
		9 minutes	6.7259	99.9999%
		12 minutes	6.7259	99.9999%
		15 minutes	6.7259	99.9999%
		20 minutes	6.7259	99.9999%
		30 minutes	6.7259	99.9999%
<i>Klebsiella pneumoniae</i>	061901Kpn1 ^❶	15 seconds	0.2025	37.2549%
		1 minute	0.6457	77.3856%
		3 minutes	2.1203	99.2418%
		6 minutes	5.2305	99.9994%
		9 minutes	5.8837	99.9999%
		12 minutes	5.8837	99.9999%
		15 minutes	5.8837	99.9999%
		20 minutes	5.8837	99.9999%
		30 minutes	5.8837	99.9999%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Micrococcus luteus</i>	7468	15 seconds	0.1280	25.5319%
		1 minute	0.0000	0.0000%
		3 minutes	0.0593	12.7660%
		6 minutes	0.0000	0.0000%
		9 minutes	0.0000	0.0000%
		12 minutes	0.0000	0.0000%
		15 minutes	0.0000	0.0000%
		20 minutes	0.0000	0.0000%
		30 minutes	0.1738	32.9787%
<i>Micrococcus luteus</i>	061901M11 ^❶	15 seconds	0.9554	88.9189%
		1 minute	1.1043	92.1351%
		3 minutes	1.1043	92.1351%
		6 minutes	1.0896	91.8649%
		9 minutes	1.0754	91.5946%
		12 minutes	1.1532	92.9730%
		15 minutes	1.2987	94.9730%
		20 minutes	1.3129	95.1351%
		30 minutes	1.5229	97.0000%

^❶ = Clinical Isolate 1.5229

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Proteus mirabilis</i>	7002	15 seconds	0.0518	11.2500%
		1 minute	0.6539	77.8125%
		3 minutes	4.7976	99.9984%
		6 minutes	5.5051	99.9997%
		9 minutes	6.2041	99.9999%
		12 minutes	6.2041	99.9999%
		15 minutes	6.2041	99.9999%
		20 minutes	6.2041	99.9999%
		30 minutes	6.2041	99.9999%
<i>Proteus mirabilis</i>	081299Pm ^❶	15 seconds	0.3859	58.8785%
		1 minute	1.0124	90.2804%
		3 minutes	6.0294	99.9999%
		6 minutes	6.0294	99.9999%
		9 minutes	6.0294	99.9999%
		12 minutes	6.0294	99.9999%
		15 minutes	6.0294	99.9999%
		20 minutes	6.0294	99.9999%
		30 minutes	6.0294	99.9999%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Pseudomonas aeruginosa</i>	15442	15 seconds	6.0682	99.9999%
		1 minute	6.0682	99.9999%
		3 minutes	6.0682	99.9999%
		6 minutes	6.0682	99.9999%
		9 minutes	6.0682	99.9999%
		12 minutes	6.0682	99.9999%
		15 minutes	6.0682	99.9999%
		20 minutes	6.0682	99.9999%
		30 minutes	6.0682	99.9999%
<i>Pseudomonas aeruginosa</i>	053099Pa ^❶	15 seconds	3.2395	99.9424%
		1 minute	5.9638	99.9999%
		3 minutes	5.9638	99.9999%
		6 minutes	5.9638	99.9999%
		9 minutes	5.9638	99.9999%
		12 minutes	5.9638	99.9999%
		15 minutes	5.9638	99.9999%
		20 minutes	5.9638	99.9999%
		30 minutes	5.9638	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Pseudomonas aeruginosa</i>	27853	15 seconds	6.1139	99.9999%
		1 minute	6.1139	99.9999%
		3 minutes	6.1139	99.9999%
		6 minutes	6.1139	99.9999%
		9 minutes	6.1139	99.9999%
		12 minutes	6.1139	99.9999%
		15 minutes	6.1139	99.9999%
		20 minutes	6.1139	99.9999%
		30 minutes	6.1139	99.9999%
<i>Pseudomonas aeruginosa</i>	070199Pa ^❶	15 seconds	6.2014	99.9999%
		1 minute	6.2014	99.9999%
		3 minutes	6.2014	99.9999%
		6 minutes	6.2014	99.9999%
		9 minutes	6.2014	99.9999%
		12 minutes	6.2014	99.9999%
		15 minutes	6.2014	99.9999%
		20 minutes	6.2014	99.9999%
		30 minutes	6.2014	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Serratia marcescens</i>	14756	15 seconds	0.0112	2.5478%
		1 minute	0.6277	76.4331%
		3 minutes	3.3698	99.9573%
		6 minutes	5.4969	99.9997%
		9 minutes	6.1959	99.9999%
		12 minutes	6.1959	99.9999%
		15 minutes	6.1959	99.9999%
		20 minutes	6.1959	99.9999%
		30 minutes	6.1959	99.9999%
<i>Serratia marcescens</i>	081499Sm ^❶	15 seconds	0.0414	9.0909%
		1 minute	0.3512	55.4545%
		3 minutes	3.0568	99.9123%
		6 minutes	6.3424	99.9999%
		9 minutes	6.3424	99.9999%
		12 minutes	6.3424	99.9999%
		15 minutes	6.3424	99.9999%
		20 minutes	6.3424	99.9999%
		30 minutes	6.3424	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus aureus</i>	6538	15 seconds	0.0000	0.0000%
		1 minute	0.1909	35.5670%
		3 minutes	0.6366	76.9072%
		6 minutes	1.1607	93.0928%
		9 minutes	1.4305	96.2887%
		12 minutes	1.6157	97.5773%
		15 minutes	1.7315	98.1443%
		20 minutes	1.9004	98.7423%
		30 minutes	1.9415	98.8557%
<i>Staphylococcus aureus</i>	040400Sa1 ^❶	15 seconds	0.0522	11.3333%
		1 minute	0.0827	17.3333%
		3 minutes	0.1849	34.6667%
		6 minutes	0.2703	46.3333%
		9 minutes	0.2785	47.3333%
		12 minutes	0.3279	53.0000%
		15 minutes	0.3500	55.3333%
		20 minutes	0.4643	65.6667%
		30 minutes	0.7368	81.6667%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus aureus</i>	29213	15 seconds	0.0507	11.0294%
		1 minute	0.2643	45.5882%
		3 minutes	0.5260	70.2206%
		6 minutes	0.8368	85.4412%
		9 minutes	1.0129	90.2941%
		12 minutes	1.1769	93.3456%
		15 minutes	1.3590	95.6250%
		20 minutes	1.3342	95.3676%
		30 minutes	1.6637	97.8309%
<i>Staphylococcus aureus</i>	061901Sa1 ^❶	15 seconds	0.0860	17.9641%
		1 minute	0.3535	55.6886%
		3 minutes	0.6812	79.1617%
		6 minutes	1.1088	92.2156%
		9 minutes	1.3419	95.4491%
		12 minutes	1.4730	96.6347%
		15 minutes	1.5832	97.3892%
		20 minutes	1.6887	97.9521%
		30 minutes	1.8648	98.6347%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus epidermidis</i>	12228	15 seconds	0.0000	0.0000%
		1 minute	0.0565	12.1951%
		3 minutes	0.1656	31.7073%
		6 minutes	0.2837	47.9675%
		9 minutes	0.2837	47.9675%
		12 minutes	0.4087	60.9756%
		15 minutes	0.4224	62.1951%
		20 minutes	0.6834	79.2683%
		30 minutes	0.8157	84.7154%
<i>Staphylococcus epidermidis</i>	010500Se2 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.1667	31.8750%
		3 minutes	0.3846	58.7500%
		6 minutes	0.5320	70.6250%
		9 minutes	0.7127	80.6250%
		12 minutes	0.7959	84.0000%
		15 minutes	0.7993	84.1250%
		20 minutes	0.9737	89.3750%
		30 minutes	1.1829	93.4375%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus haemolyticus</i>	29970	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.0235	5.2632%
		6 minutes	0.0000	0.0000%
		9 minutes	0.0955	19.7368%
		12 minutes	0.0955	19.7368%
		15 minutes	0.0420	9.2105%
		20 minutes	0.1996	36.8421%
		30 minutes	0.3080	50.7895%
<i>Staphylococcus haemolyticus</i>	060700Sh1 ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.0535	11.5942%
		6 minutes	0.0000	0.0000%
		9 minutes	0.0259	5.7971%
		12 minutes	0.0313	6.9565%
		15 minutes	0.1433	28.1159%
		20 minutes	0.2753	46.9565%
		30 minutes	0.4306	62.8986%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus hominis</i>	27844	15 seconds	0.0464	10.1266%
		1 minute	0.0403	8.8608%
		3 minutes	0.3224	52.4051%
		6 minutes	0.4760	66.5823%
		9 minutes	0.3898	59.2405%
		12 minutes	0.4599	65.3165%
		15 minutes	0.4505	64.5570%
		20 minutes	0.5672	72.9114%
		30 minutes	0.8257	85.0633%
<i>Staphylococcus hominis</i>	060700Sho2 ^❶	15 seconds	0.1402	27.5862%
		1 minute	0.1299	25.8621%
		3 minutes	0.5816	73.7931%
		6 minutes	0.8068	84.3966%
		9 minutes	1.0350	90.7759%
		12 minutes	1.0152	90.3448%
		15 minutes	1.1613	93.1034%
		20 minutes	1.2748	94.6897%
		30 minutes	1.5731	97.3276%

^❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Staphylococcus saprophyticus</i>	15305	15 seconds	0.0555	12.0000%
		1 minute	0.0416	9.1429%
		3 minutes	0.0583	12.5714%
		6 minutes	0.0612	13.1429%
		9 minutes	0.0555	12.0000%
		12 minutes	0.0757	16.0000%
		15 minutes	0.1095	22.2857%
		20 minutes	0.1567	30.2857%
		30 minutes	0.5042	68.6857%
<i>Staphylococcus saprophyticus</i>	081399Ss ^❶	15 seconds	0.0000	0.0000%
		1 minute	0.0000	0.0000%
		3 minutes	0.0186	4.1916%
		6 minutes	0.0000	0.0000%
		9 minutes	0.0000	0.0000%
		12 minutes	0.0584	12.5749%
		15 minutes	0.0213	4.7904%
		20 minutes	0.1620	31.1377%
		30 minutes	0.2882	48.5030%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Streptococcus pneumoniae</i>	33400	15 seconds	5.3892	99.9996%
		1 minute	5.3892	99.9996%
		3 minutes	5.3892	99.9996%
		6 minutes	5.3892	99.9996%
		9 minutes	5.3892	99.9996%
		12 minutes	5.3892	99.9996%
		15 minutes	5.3892	99.9996%
		20 minutes	5.3892	99.9996%
		30 minutes	5.3892	99.9996%
<i>Streptococcus pneumoniae</i>	081700Spn5 ^❶	15 seconds	6.2148	99.9999%
		1 minute	6.2148	99.9999%
		3 minutes	6.2148	99.9999%
		6 minutes	6.2148	99.9999%
		9 minutes	6.2148	99.9999%
		12 minutes	6.2148	99.9999%
		15 minutes	6.2148	99.9999%
		20 minutes	6.2148	99.9999%
		30 minutes	6.2148	99.9999%

❶ = Clinical Isolate

**Table 7: Product Vehicle – 10% (v/v) concentration 52BSTO Soap with nil TCC
(Continued)**

Microorganism Species	ATCC or BSLI# ^❶	Exposure Time	Log ₁₀ Reduction	Percent Reduction
<i>Streptococcus pyogenes</i>	19615	15 seconds	3.0441	99.9069%
		1 minute	5.3579	99.9996%
		3 minutes	6.0569	99.9999%
		6 minutes	6.0569	99.9999%
		9 minutes	6.0569	99.9999%
		12 minutes	6.0569	99.9999%
		15 minutes	6.0569	99.9999%
		20 minutes	6.0569	99.9999%
		30 minutes	6.0569	99.9999%
<i>Streptococcus pyogenes</i>	061901Spy2 ^❶	15 seconds	5.1865	99.9993%
		1 minute	5.9269	99.9999%
		3 minutes	5.9269	99.9999%
		6 minutes	5.9269	99.9999%
		9 minutes	5.9269	99.9999%
		12 minutes	5.9269	99.9999%
		15 minutes	5.9269	99.9999%
		20 minutes	5.9269	99.9999%
		30 minutes	5.9269	99.9999%

❶ = Clinical Isolate

Bar soap containing 1.5% Triclocarban and a reference product, Hibiclens[®] (4% chlorhexidine gluconate solution), were tested in a general-use handwash procedure. The procedure was comparable to that prescribed in ASTM standard method E 1174-00 with the major variation being that 5 washes rather than 11 were performed. The Bayer study also uses a more conservative hand contamination procedure 5 hand contamination cycles, each with 5 ml of *E. coli* suspension for 45 seconds with 2 minutes of air-drying (as opposed to 3 cycles with 1.5 ml of bacteria suspension for 20 seconds with 30 seconds of air-drying). Statistical summaries of the results of this clinical handwash study (Biosciences report no. 010802-106 dated December 21, 2001) are presented in Tables 8 and 9. The bar soap with 1.5% Triclocarban demonstrated Log₁₀ reductions of 3.01 and 3.11 after washes 1 and 5, respectively. The reference product demonstrated Log₁₀ reductions of 3.34 and 5.21 after washes 1 and 5, respectively. The study report is provided in Attachment 19.

Table 8: Statistical Summary of Sample Data for Test Product – Soap 1.5% (w/w) TCC Lot Number 53BTO-1

Sample	Sample Size	Mean of log ₁₀ Values	Standard Deviation	95% Confidence Intervals	Reduction from Baseline (log ₁₀)	Percent
Baseline	24	8.52	0.25	8.42 to 8.63	N/A	N/A
Wash 1	24	5.51	0.22	5.41 to 5.60	3.01	99.90%
Wash 5	24	5.41	0.30	5.28 to 5.54	3.11	99.92%

Table 9: Statistical Summary of Sample Data for Reference Product - Hibiclens[®] (4% CHG) Lot Number 4597C

Sample	Sample Size	Mean of log ₁₀ Values	Standard Deviation	95% Confidence Intervals	Reduction from Baseline (log ₁₀)	Percent
Baseline	24	8.48	0.22	8.39 to 8.57	N/A	N/A
Wash 1	24	5.14	0.53	4.91 to 5.36	3.34	99.95%
Wash 5	24	3.27	0.19	3.19 to 3.35	5.21	99.99%

ENVIRONMENTAL IMPACT

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

Thank you for your consideration of this petition. If additional information is needed, please contact me at (412) 777-3934 or Dr. J. Michael Kelley of TOXCEL LLC at (703) 335-5670.

Sincerely,

A handwritten signature in black ink that reads "J. Michael Kelley" with a stylized flourish at the end. Below the name, there is a small, less legible signature that appears to be "for".

Kevin I. Ajoku
Market Segment Manager
Bayer Corporation

Attachments

LIST OF ATTACHMENTS

1. Comments dated June 13, 1995, submitted by the CTFA/SDA. Subject: Docket 75N-183H, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monography for Health-Care Antiseptic Drug Products. 59 Federal Register, pp. 31402-31452.
2. Citizens Petition dated April 2, 2001, submitted by the CTFA/SDA to Amend the OTC Labeling in the Tentative Final Monograph for Health-Care Antiseptic Drug Products: Docket 75N-183H.
3. Comments dated December 13, 1995 submitted by The Dial Corporation. Subject: Docket 75N-183H, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products. 59 Federal Register, pp. 31402-31452.
4. Comments dated December 14, 1995, submitted by the CFTA/SDA. Subject: Docket 75N-183H, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products.
5. Comments dated March 7, 1996, submitted by the CTFA/SDA. Subject: Docket 75N-183H, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products.
6. Letter dated August 2, 2000 from the CTFA/SDA to Dr. Charles Ganley of the FDA. Re: Tentative Final Monograph for Health-Care Antiseptic Drug Products; Healthcare Continuum Model; Materials Relating to Test Methods; Docket 75N-183H.
7. Voss, JG 1975. *Effects of an antimicrobial soap on the ecology of aerobic bacterial flora of human skin*. Applied Microbiology 30: 551-556.
8. MacKenzie, Albert R. 1970. *Effectiveness of antimicrobial soaps in a healthy population*. JAMA 211(6):973-976.
9. Bodey, GP, J. Arnett, S. De Salva 1978. *Comparative trial of bacteriostatic soap preparations: hexachlorophene versus triclosan and triclocarban*. Curr. Ther. Res. Clin. Exp. 24: 542-550.
10. Duncan, WC, BG Dodge, JM Knox. 1969. *Prevention of superficial pyogenic skin infections*. Archives of Dermatology. 99:465-468.
11. Gilmore, DS, JZ Mongomerie, IE Graham, DG Schick, and EM Jimenez. 1984. *Effect of antiseptic agents on skin flora of the perineum of men with spinal cord injury*. Infection Control 5(9):431-434.
12. Finkley, MB, NC Corbin, LB Aust, R Aly, HI Maibach. 1984. *In vivo effect of antimicrobial soap bars containing 1.5% and 0.8% trichlorocarbanilide against two strains of pathogenic bacteria*. J. Soc. Cosmet. Chem. 35:351-355.

LIST OF ATTACHMENTS (Continued)

13. Yackovich, F and JE Heinze. 1985. *Evaluation of substantivity and antibacterial activity of soap bars on human skin by an in vivo agar patch test method.* J. Soc. Cosmet. Chem. 36:231-236.
14. Breneman, DL, JM Hanifin, CA Berge, BH Keswick, PB Neumann. 2000. *The effect of antimicrobial soap with 1.5% Triclocarban on Staphylococcus aureus in patients with atopic dermatitis.* CUTIS 66:296-300.
15. Suller MT and AD Russell. 1999. *Antibiotic and biocide resistance in methicillin-resistant Staphylococci aureus and vancomycin-resistant enterococcus.* J. Hosp. Infect. 43:281-291.
16. Hill Top Research, Inc. (1998), HTR Ref. No.97-5467-11, *Summary Report of Test Method for the Assessment of Rapid Germicidal (Time Kill) Activity for Antibacterial Wash Products*, dated March 26, 1998. Sponsored by the Bayer Corporation.
17. Bioscience Laboratories, Inc., Final Report No. 010613-202, dated December 21, 2001 - *Determination of the Minimum Inhibitory Concentrations (MIC) of One Test Product and One Product Vehicle When Challenged With Various Microorganism Strains Using the Macrodilution Broth Method.* Sponsored by the Bayer Corporation.
18. Bioscience Laboratories, Inc., Final Report No. 010612-201, dated December 21, 2001 - *Evaluation of One Test Product and One Product Vehicle for Their Antimicrobial Properties at Nine Exposure Times When Challenged With Various Microorganism Strains Using an In-Vitro Time-Kill Method.* Sponsored by the Bayer Corporation.
19. Bioscience Laboratories, Inc., Final Report No. 010802-106, dated December 21, 2001 - *Determination of the Antimicrobial Efficacy of One Test Product and a Reference Using the General-Use Handwash Procedure.* Sponsored by the Bayer Corporation.