

# elf atochem

ELF ATOCHEM NORTH AMERICA, INC.

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Tel: 215-337-6500

September 10, 1992

A

**Contains No CBI**

**CERTIFIED MAIL**

**RETURN RECEIPT REQUESTED**

Document Processing Center (TS-790)  
Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 M St., S.W.  
Washington, D.C. 20460

8E11Q-92-12689

58920010868

INIT

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e)  
Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed study to establish skin irritation potential in rabbits for tributyltin oxide to the EPA. This study does not involve effects in humans.

Nothing in this letter or the enclosed study is considered confidential business information of Atochem.

The enclosed study provides information on the chemical tributyltin oxide. Its exact chemical name is hexabutyldistannoxane and its CAS number is 56-35-9.

The title of the enclosed study is Primary Skin Irritation of Tributyltin Oxide. The following is a summary of the adverse effects observed in this study.

Application of one-half (0.5) ml of tributyltin oxide to the intact and abraded skin of a group of six New Zealand white rabbits for 24 hours was corrosive to rabbit skin. Continuous washing and rinsing with water for 15 minutes after a five minute application of the test material to the intact and abraded skin of a second group of six rabbits for five minutes failed to reverse the skin effects and was again corrosive to rabbit skin.

2/9/95

TSCA CAP  
Tributyltin Oxide  
September 10, 1992  
Page Two

To our knowledge, Atochem has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on the subject chemical.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,



C.H. Farr, PhD, DABT  
Manager, Product Safety  
and Toxicology

Enclosures

CONFIDENTIAL REPORT  
TO  
M&T CHEMICALS INC.

PRIMARY SKIN IRRITATION  
OF  
TRIBUTYLTIN OXIDE

THE HINE LABORATORIES, INC.

DECEMBER 1966

CAS Number 56-35-9

## I. INTRODUCTION

This study was carried out to determine the skin irritation potential and the efficacy of water lavage following exposure to tributyltin oxide according to the standard methods of the Food and Drug Administration.

## II. MATERIALS AND METHODS

### A. Materials:

1. Test Animals: All rabbits used in these experiments were male New Zealand Whites and weighed between 2 and 3 kilograms.

2. Test Compound: Tributyltin oxide is a clear non-viscous liquid with a characteristic and irritating odor. The tributyltin oxide (TBTO) used in these experiments was supplied by M&T Chemicals Inc. and bore the code 15 RDO-3.

### B. Methods:

1. Primary Skin Irritation Study: The backs of each of six rabbits were clipped and one side abraded by making a series of cross-hatched incisions through the epidermis. TBTO was placed in contact with the skin on both intact and abraded sides in the amount of 0.5 ml per side. The area was covered with a gauze patch and the animal restrained. After 24 hours, the patches were removed, the excess material wiped off and the degree of irritation estimated according to the method of Draize. A second reading was made at 72 hours.

2. Skin Washoff Study: The backs of each of six rabbits were prepared as above and 0.5 ml of TBTO was placed in contact with the skin on both intact and abraded sides. The areas were covered with gauze patches and the animal restrained. After a period of five minutes,

the patches were removed and the excess TBTO wiped off. The skin was immediately washed thoroughly with Zest soap and water for a period of 2.5 minutes, after which it was rinsed with tap water through a spray nozzle for a period of 2.5 minutes. Two more series of soaping and rinsing were carried out for a total washing time of 15 minutes. Readings were made according to the method of Draize at 24 and 72 hours.

### III. RESULTS

A. Primary Skin Irritation Study: At 24 hours, there were varying degrees of erythema on abraded skin. There was no erythema or edema on intact skin. At 72 hours, there was slight edema on abraded skin and a slight erythema in the center of a large ischemic area. The areas of application on the intact skin had become ischemic, and one animal showed a slight erythema in the center of the ischemic area. The average score at 24 hours was 1.3. The average score at 72 hours was 1.6. The combined average score was 1.5. The areas of application of both intact and abraded skin were necrotic by seven days and were replaced with scar tissue. Table 1 gives supporting data.

B. Skin Washoff Study: At 24 hours, there was again noted varying degrees of erythema, ranging from 1 to 4 on abraded skin. On intact skin, four out of the six animals showed erythema. The average score at 24 hours was 2.5. At 72 hours, three out of the six animals showed a slight edema of abraded skin, and similar erythema as at 24 hours. In addition, skin around the edges of the area of application was becoming ischemic. On intact skin, the areas of application were ischemic, though there was no evidence of erythema or edema. The average score at 72 hours was again 2.5. The combined average score was 2.5. Table 2 gives supporting data.

#### IV. SUMMARY

A. Tributyltin oxide causes severe skin damage, the area of application becoming ischemic and necrotic, rather than particularly erythematous or edematous.

B. Water lavage did not significantly reduce the local intensity of effects of tributyltin oxide and may enhance these effects.

Table 1: Results of Primary Skin Irritation Study with Tributyltin Oxide

Time of Reading	Animal Number	Abraded Skin		Intact Skin	
		Edema	Erythema	Edema	Erythema
24 hrs.	J-75	0	1	0	Ischemic
	J-76	0	1	0	Ischemic
	K- 3	0	2	0	Ischemic
	K- 4	0	2	0	Ischemic
	K- 5	0	2	0	Ischemic
	K- 7	0	0	0	Ischemic
72 hrs.	J-75	1	1	0	Ischemic
	J-76	1	1	0	Ischemic
	K- 3	0	1	0	Ischemic
	K- 4	1	2	0	Ischemic
	K- 5	1	1	0	Ischemic
	K- 7	1	1	0	Ischemic
Combined Average: 1.5					

Table 2: Results of Skin Washoff Study with Tributyltin Oxide (5-Minute Exposure, 15-Minute Lavage)

Time of Reading	Animal Number	Abraded Skin		Intact Skin	
		Edema	Erythema	Edema	Erythema
24 hrs.	J-77	0	1	0	Ischemic
	J-78	0	1	0	Ischemic
	J-79	0	2	0	1
	J-80	0	1	0	1
	J-81	0	1	0	1
	J-82	0	4	0	2
72 hrs.	J-77	1	2	0	Ischemic
	J-78	1	1	0	Ischemic
	J-79	1	1	0	Ischemic
	J-80	1	2	0	Ischemic
	J-81	0	1	0	Ischemic
	J-82	0	4	0	Ischemic
		Combined Average: 2.5			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MAR 30 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

*Terry R. O'Bryan*  
Terry R. O'Bryan  
Risk Analysis Branch

Enclosure

12689A



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**Triage of 8(e) Submissions**

Date sent to triage: MAY 10 1995

NON-CAP

CAP

Submission number: 12689A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

**For Contractor Use Only**

entire document: 0 1 2

pages 112

pages 42,6

Notes:

Contractor reviewer: POK

Date:

2/22/95

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ: 1092-12689 SEQ. A  
 TYPE: (INT) SUPP FLWP  
 SUBMITTER NAME: Elf Atochem Nor  
America, Inc.

INFORMATION REQUESTED: FLWP DATE:  
 0501 NO INFO REQUESTED  
 0502 INFO REQUESTED (TECH)  
 0503 INFO REQUESTED (VOL ACTIONS)  
 0504 INFO REQUESTED (REPORTING RATIONALE)  
 DISPOSITION:  
(0639) REFER TO CHEMICAL SCREENING  
(0678) CAP NOTICE

EXEMPTARY ACTIONS:  
 0401 NO ACTION REPORTED  
 0402 STUDIES PLANNED/IN PROGRESS  
 0403 NOTIFICATION OF WORK PROGRESS  
 0404 LABEL/MSDS CHANGES  
 0405 PROCESS/ANALYSIS CHANGES  
 0406 APP/USE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

SUB. DATE: 09/16/12 OTS DATE: 10/06/92 CSRAD DATE: 02/09/95  
 CHEMICAL NAME: TOTO CASE# 56-35-9

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPI/CLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAJE DATA: NON-CBI INVENTORY YES NO Ongoing REVIEW YES (DROP/REFER) NO (CONTINUE) REF:R  
 CAS SR YES NO IN HUMANI  
 SPECIES RET TOXICOLOGICAL CONCERN: LOW MED HIGH  
 USE: \_\_\_\_\_ PRODUCTION: \_\_\_\_\_

-CPSS- 0929951235

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> <ID NUMBER>

8(e)-12689A

> <TOX CONCERN>

H

> <COMMENT>

PRIMARY SKIN IRRITATION IN RABBITS IS HIGH CONCERN DUE TO THE CORROSIVITY OF THE TEST MATERIAL. 12 ANIMALS (6 UNWASHED, 6 WASHED) WERE EXPOSED TO 0.5 ML OF TEST MATERIAL TO INTACT AND ABRADED SKIN. THE TEST MATERIAL CAUSED SEVERE SKIN DAMAGE AND AREAS OF APPLICATION BECAME ISCHEMIC AND NECROTIC RATHER THAN EDEMATOUS OR ERYTHEMATOUS. THE COMBINE AVERAGE SKIN IRRITATION SCORE WAS 1.5 AND 2.5 FOR UNWASHED AND WASHED SKIN, RESPECTIVELY.

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