

elf atochem

Contains No CBI

ELF ATOCHEM NORTH AMERICA, INC.

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11/05/92 10:38 AM

September 10, 1992

(A)

SEHG - 92 - 12690

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I. N. E. T.

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

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 sensitization potential in guinea pigs 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 A Dermal Sensitization Study in Guinea Pigs. The following is a summary of the adverse effects observed in this study.

In this study, the sensitization potential of tributyltin oxide was evaluated in 10 Hartley albino guinea pigs, according to a modified Buehler method. On challenge, all ten animals exhibited a positive skin response.

mm
2/8/95

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 mixture.

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

Sincerely,

A handwritten signature in cursive script, appearing to read "C.H. Farr".

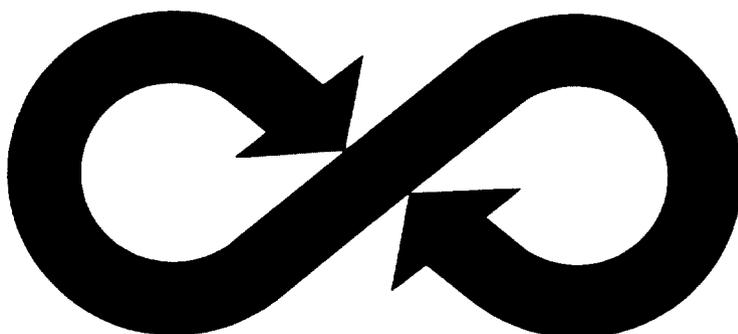
C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosures

FILED: CN00981-85

TR 91-222
237 804

T-106



Bio/dynamics Inc.

Toxicological Resources Unit

PROJECT NO. 5056-78F

A DERMAL SENSITIZATION STUDY IN GUINEA PIGS

COMPOUND: TBTO

Submitted To: M&T Chemicals, Inc.
Rahway, N.J.

Date: June 28, 1978

CAS 56-35-9

I. GENERAL

A guinea pig sensitization study, a modification of that described by Buehler¹, was performed for M&T Chemicals, Inc. to evaluate the sensitization potential of TBTO.

II. MATERIALS

A. Test Substances

1. TBTO - a white powder received from M&T Chemicals, Inc.
2. DNCB - 1-chloro-2,4-dinitrobenzene (Aldrich Chemical Company; Metuchen, New Jersey)
3. Acetone
4. Elastoplast Bandage^R (Beiersdorf, Inc.; South Norwalk, Connecticut)
5. Elastopatch^R (Beiersdorf, Inc.; South Norwalk, Connecticut)
6. Neet^R Creme Depilatory (Whitehall Laboratories; New York, New York)

B. Test Animals

Thirty (15/sex) Hartley albino guinea pigs (Dutchland Breeding Farms; Denver, Pennsylvania) were individually housed and equilibrated in this laboratory. Food (Purina Guinea Pig Chow) and water were provided ad libitum. Fresh greens (spinach) were used to supplement the diet.

¹Buehler, E.V. Arch. Dermatol., 91: 171 (1965).

III. METHODS

A. Experimental Design

<u>Group</u>	<u>Number Animals</u>	<u>Treatment</u>	<u>Concentration</u>	<u>Dose</u>
I	10	Acetone	100%	0.2 ml
II*	10	DNCB	0.1% w/v in acetone	0.2 ml
III	10	TBTO	5.0% w/v in acetone	0.2 ml

*This control group used for Bio/dynamics project nos. 5056-78 A, B, C conducted concurrently.

B. Treatment

1. Sensitizing Period

Twenty-four hours before the initial treatment the back of each animal was clipped free of hair. Clipping was repeated as necessary throughout the study.

All animals in all groups received 0.2 ml of the appropriate test mixture applied to the back on the right side of the spinal column beneath an Elastopatch^R, with a 3/4" x 1" Webril pad. The trunk of each animal was then wrapped in Elastoplast Bandage^R to occlude and secure the patches. Following treatment the animals were returned to their cages. Six hours after treatment the bandages and patches were removed.

The above sensitizing procedure was repeated three times a week for three weeks, for a total of nine sensitizing exposures. During this period the animals were observed daily for mortality and signs of systemic toxicity.

III. METHODS (cont.)

2. Challenge Period

On the thirteenth day following the last sensitizing treatment, the treatment area of each animal was again clipped free of hair and depilated with Neet^R. On the following day all animals received the first challenge dose of their respective treatments following the procedure described for the sensitizing period except that in the challenge phase two sites, one on either side of the spinal column were treated.

After six hours the dams were removed and both sites were examined and scored for erythema and edema². Observations for dermal response were repeated at twenty-four and forty-eight hours.

If the first challenge produced negative or doubtful results, a second challenge was performed seventy-two hours following the first, repeating the above procedure.

Animals receiving erythema scores of 2 or higher at both left and right sites at any observation interval were considered sensitized. Animals with erythema scores of 2 or higher at only one site at any observation were considered questionable

Sensitization potentials were assigned as follows:

Potential	Non-sensitized
Minimal	0
Slight	1 - 2
Moderate	3 - 5
Strong	6 - 10

²Draize, John H. et al. Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes. J. Pharm. Exp. Ther., 82: 337 (1944).

(7)

IV. RESULTS

A summary of dermal responses is presented in Table I. Individual dermal responses are presented in Table II.

Ten of ten animals treated with TBTO were considered sensitized. No significant dermal responses were noted in animals treated with acetone (control). Ten of ten animals treated with DNCB (positive control) were found to be sensitized.

TBTO is found to be a strong sensitizing agent (dermal response equivalent to that for DNCB) under the conditions of this study.


Pamela R. Heenehan, B.S.
Staff Supervisor


William G. Braun, M.S.
Manager

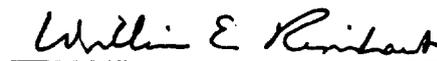

William E. Rinehart, Sc.D.
Director, Division of Biology
and Safety Evaluation

TABLE I

A DERMAL SENSITIZATION STUDY IN GUINEA PIGS

COMPOUND: TBTO

Summary of Dermal Responses

Group	Time Interval (Hours)	Challenge I						Challenge II									
		Left Side			Right Side ^a			Left Side			Right Side ^a						
		0	S	M	E	0	S	M	E	0	S	M	E				
I (Acetone)	6	8	2	0	0	7	3	0	0	8	2	0	0	9	1	1	0
	24	10	0	0	0	10	0	0	0	9	1	0	0	7	3	0	0
	48	10	0	0	0	10	0	0	0	9	1	0	0	9	1	0	0
II (DNCB)	6	1	4	5	0	1	0	7	2	Challenge II not performed							
	24	0	0	6	4	0	0	3	7	Challenge II not performed							
	48	0	0	5	5	0	0	2	8	Challenge II not performed							
III (TBTO)	6	1	0	9	0	0	0	10	0	Challenge II not performed							
	24	0	0	2	8	0	0	1	9	Challenge II not performed							
	48	0	0	1	9	0	0	1	9	Challenge II not performed							

Key to Degree of Response:

0 = No irritation (dermal score for both erythema and edema = 0)

S = Slight irritation (highest score for either erythema or edema = 1)

M = Moderate irritation (highest score for either erythema or edema = 2 or 3)

E = Extreme irritation (highest score for either erythema or edema = 4)

^aRight side treated during sensitization phase.

TABLE II
A DERMAL SENSITIZATION STUDY IN GUINEA PIGS

COMPOUND: TBTO

Individual Dermal Responses

Group	Animal Number	Challenge I						Challenge II						
		6 hr.		24 hr.		48 hr.		6 hr.		24 hr.		48 hr.		
		L	R ^a	L	R ^a	L	R ^a	L	R ^a	L	R ^a	L	R ^a	
I Acetone	1018M	ER	0	1	0	0	0	0	1	0	0	0	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1024M	ER	0	0	0	0	0	0	0	0	0	0	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1030M	ER	0	0	0	0	0	0	0	0	0	0	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1007M	ER	0	0	0	0	0	0	0	0	1	1	1	1
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1013M	ER	0	0	0	0	0	0	0	0	0	0	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1078F	ER	1	1	0	0	0	0	0	0	0	0	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1052F	ER	0	0	0	0	0	0	1	2	0	1	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1058F	ER	0	0	0	0	0	0	0	1	0	0	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1064F	ER	0	0	0	0	0	0	0	0	0	0	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0
	1070F	ER	1	1	0	0	0	0	0	0	0	1	0	0
		ED	0	0	0	0	0	0	0	0	0	0	0	0

^aRight side treated during sensitization phase.

ER - Erythema; ED - Edema

L - Left; R - Right

TABLE II (cont.)

A DERMAL SENSITIZATION STUDY IN GUINEA PIGS

COMPOUND: TBTO

Individual Dermal Responses

Group	Animal Number	Challenge I						Challenge II						
		6 hr.		24 hr.		48 hr.		6 hr.		24 hr.		48 hr.		
		L	R ^a	L	R ^a	L	R ^a	L	R	L	R	L	R	
II DNCB	1016M	ER	0	0	4*	4*	4*	4*	Challenge II not performed					
		ED	0	0	2	2	2	2						
	1022M	ER	1	4*	4*	4*	4*	4*						
		ED	1	2	2	2	2	2						
	1027M	ER	1	4*	4	4*	4	4*						
		ED	1	2	2	2	2	2*						
	1005M	ER	1	3	2	4*	4	4*						
		ED	2	3	2	3	2	2						
	1011M	ER	1	2	2	4	3	3						
		ED	2	3	2	2	1	2						
	1080F	ER	1	2	4	4	4	4*						
		ED	2	3	2	2	2	2						
	1054F	ER	1	2	2	3	2	2						
		ED	2	2	1	1	1	1						
	1060F	ER	0	1	2	3	2	4						
		ED	1	2	1	1	1	1						
	1066F	ER	1	3	2	3	3	4*						
		ED	1	2	1	2	1	1						
	1072F	ER	1	3	3	4*	2	4						
		ED	2	2	1	2	1	1						

^aRight side treated during sensitization phase

ER - Erythema; ED - Edema

L - Left; R - Right

* - Eschar

TABLE II (cont.)
A DERMAL SENSITIZATION STUDY IN GUINEA PIGS

COMPOUND: TBTO

Individual Dermal Responses

Group	Animal Number	Challenge I						Challenge II						
		6 hr.		24 hr.		48 hr.		6 hr.		24 hr.		48 hr.		
		L	R ^a	L	R ^a	L	R ^a	L	R	L	R	L	R	
III TBTO	1037M	ER	0	2	3	4	4	4	Challenge II not performed					
		ED	0	1	2	2	2	2						
	1043M	ER	2	2	4	4	4	4						
		ED	0	1	3	2	2	2						
	1049M	ER	2	3	4	4	4*	4						
		ED	1	2	2	2	2	2						
	1001M	ER	2	2	4	4	4	4						
		ED	1	1	2	2	1	2						
	1008M	ER	2	3	4	4	4*	4*						
		ED	1	2	2	2	2	2						
1089F	ER	2	3	2	3	2	4*							
	ED	1	2	2	1	1	1							
1095F	ER	2	3	4	4*	4*	4*							
	ED	1	2	2	2	1	1							
1082F	ER	2	3	4	4*	4*	4*							
	ED	1	2	2	2	2	2							
1088F	ER	2	3	4	4	4	2*							
	ED	1	2	2	2	2	1							
1094F	ER	2	3	4	4	4*	4*							
	ED	1	2	2	2	2	2							

ER - Erythema; ED - Edema
L - Left; R - Right
a - Right side treated during sensitization phase



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

C. H. Farr, PhD, DABT
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Atochem North America, Inc.
900 First Avenue
P.O. Box 1536
King of Prussia, Pennsylvania 19406-0018

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

12690A



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Triage of 8(e) Submissions

Date sent to triage: MAY 10 1995

NON-CAP

CAP
Y N D

Submission number: 12690A
~~12690A~~

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

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entire document: <u>0</u> 1 2	pages <u>1, 2</u> pages <u>1, 2, 7</u>
Notes:	
Contractor reviewer: <u>FOR</u>	Date: <u>2/22/95</u>

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ-1092-12690 SEQ. A

TYPE: (INT) SUPP FLWP
 SUBMITTER NAME: Elf Atochem North America, Inc.

SUB. DATE: 09/09/92 OTS DATE: 10/06/92 CSRAD DATE: 02/09/95
 CHEMICAL NAME: TBTO CAS# 56-35-9

UNPLANNED ACTIONS:
 0401 NO ACTION REPORT ID
 0402 STUDIES PLANNED IN DIHWAY
 0403 NOTIFICATION OF WORK IN PROGRESS
 0404 LABEL/MSDS CHANGES
 0405 PROCESS/HANDLING CHANGES
 0406 APP/PAUSE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

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

INFORMATION TYPE	P F C	INFORMATION TYPE	P F C	INFORMATION TYPE	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIM)	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-CHI INVENTORY (YES) NO
 Ongoing Review: YES (DROP/REFER) NO (CONTINUE)
 CAS SR: NO
 TOXICOLOGICAL CONCERN: LOW MED HIGH
 USE: PRODUCTION

UNPLANNED

-CPSS- 1004951453

0 0 0 0 0 0 0 0 0 0 0

> <ID NUMBER>

8(e)-12690A

> <TOX CONCERN>

H

> <COMMENT>

SKIN SENSITIZATION IN GUINEA PIGS IS HIGH CONCERN. 10 ANIMALS WERE EXPOSED TO 0.2 ML OF TEST MATERIAL AND ALL HAD A POSITIVE REACTION. ERYTHEMA AND EDEMA WAS NOTED IN ALL ANIMALS.

\$\$\$\$