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Submitting Organization	ATOCHM NORTH AMERICA INC		
Contractor	AME ASSC BIOLOGICAL RESEARCH		
Document Title	INITIAL SUBMISSION: EVALUATION OF HEXAMETHYL DI-TIN BY DRAIZE SKIN IRRITATION TECHNIQUE IN RABBITS WITH COVER LETTER DATED 07/24/92		
Chemical Category	HEXAMETHYL DI-TIN		

8(e)

CAP

(COMPLIANCE AUDIT PROGRAM)

TSCA CONFIDENTIAL BUSINESS INFORMATION

ORIGINAL - DCO (Jeff/Eric)
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19410

COMPANY SANITIZED

ORIGINAL - PINS
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elf aquitaine

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92 AUG -4 PM 1:55

July 24, 1992

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 final reports on a study to establish skin irritation potential of hexamethyl di-tin in albino rabbits 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 hexamethyl di-tin. Its exact chemical name is hexamethyldistannane and its CAS number is 661-69-8.

The title of the enclosed study is Evaluation of Hexamethyl Di-Tin by Draize Skin Irritation Technique. The following is a summary of the adverse effects observed in study reports.

One-half (0.5) ml hexamethyl di-tin was applied to the intact and abraded skin of three male and three female albino rabbits. All six rabbits died within six hours. One-half (0.5) ml of hexamethyl di-tin applied to the intact and abraded skin of a second group of six rabbits for five minutes resulted in death of the six animals within 48 hours of test material application.

TSCA CAP
Hexamethyl Di-Tin
July 24, 1992
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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,



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

Enclosures

FILED, CNO3947-85

TR 91-124

T-24

AME Associates
BIOLOGICAL RESEARCH

PRINCETON PIKE, P. O. BOX 57

PRINCETON, N. J. 08540

TEL.: (609) 924-9658

Project #20-196

Evaluation of Hexamethyl Di-Tin
by Draize Skin Irritation Technique

Conducted for

M & T Chemicals, Inc.
Rahway, New Jersey

Submitted by

AME Associates
Princeton, New Jersey

CAS Registry Number 661-69-8

A. M. E. ASSOCIATES P.O. BOX 57 PRINCETON, N. J. 08540

May 23, 1967

PROJECT #20-196

SPONSOR: M & T CHEMICALS, INC.

SUBJECT: Evaluation of Hexamethyl Di-Tin by Draize Skin
Irritation Technique

OBJECTIVE

Evaluation of the irritant capacity of Hexamethyl Di-Tin based on the application on abraded and intact skin of the albino rabbit for a 5 minute exposure period followed by a 15 minute washing.

MATERIAL

Hexamethyl Di-Tin supplied by M & T Chemicals, Inc., for use in this study.

PROCEDURE

A group of six (three males and three females) healthy albino rabbits was employed in this project to study the experimental material. The hair was clipped from about the sixth thoracic vertebrae to the sacral region and about 10 cm from the vertebral column on each side using an electric clipper. Two areas, approximately 10 cm apart, on the back of each rabbit were selected as application sites. One site was abraded by making four epidermal incisions in a cross hatch pattern on this site.

Then 0.5 ml of the experimental material was applied to each intact and abraded site. After a contact period of 5 minutes, the sites were washed using Zest soap. The sites were washed for a 15 minute period alternating lathering and rinsing. After the washing was completed, the animals were dried. The sites were examined and evaluated 24 hours after application of the test material.

The scoring method employed was that of Draize, Woodard, and Calvery as described by Draize on page 48 of "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" published by the Association of Food and Drug Officials of the United States.

Evaluation of Skin Reactions

(1) Erythema and Eschar Formation

No erythema.....	0
Very slight erythema (barely perceptible).....	1
Well defined erythema.....	2
Moderate to severe erythema.....	3
Severe erythema (beet red) to slight eschar formation (injuries in depth).....	4

Total possible erythema score.....	4

(2) Edema Formation

No edema.....	0
Very slight edema (barely perceptible).....	1

Slight edema (edges of area well defined by definite raising).....	2
Moderate edema (raised approximately 1 mm).....	3
Severe edema (raised more than 1 mm and extending beyond area of exposure).....	4
Total possible edema score.....	<u>4</u>

RESULTS

Three (all females) of the six rabbits treated died within 24 hours of application of the test material. Twenty-four hours following application, one of the remaining rabbits demonstrated a slight unsteadiness; another demonstrated twitching of the upper eye lids and a head tilt to the right; the last rabbit demonstrated twitching of the nose, legs, tail (essentially intermittent twitching of all areas of the body) and lay flat on its right side within the cage. Outside the cage it was unable to right itself or stand; there was increased twitching of the entire body characterized by multiple muscle contractions in different areas at the same or different times. Nystagmus was also evident. The three male rabbits died within 48 hours after application of the test material.

A. M. E. ASSOCIATES P.O. BOX 57 PRINCETON, N. J. 08540

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CONCLUSIONS

The skin irritation potential of M & T Chemicals, Inc., Hexamethyl Di-Tin could not be calculated due to the death of the rabbits before the observation period was complete.

SUBMITTED BY Harry C. Fegley VMD
AME ASSOCIATES

Harry C. Fegley, V.M.D.

Project #20-196

TABLE 1

Primary Skin Irritation Study
5 Minute Exposure - 15 Minute Wash

Compound - Hexamethyl Di-Tin

Test Method - Draize, Woodard and Calvery

Rabbit No.	<u>Erythema and Eschar Formation</u>				<u>Edema Formation</u>			
	<u>Intact</u>		<u>Abraded</u>		<u>Intact</u>		<u>Abraded</u>	
	<u>24</u>	<u>72</u>	<u>24</u>	<u>72</u>	<u>24</u>	<u>72</u>	<u>24</u>	<u>72</u>
1M	0	Dead	1	Dead	0	Dead	4	Dead
2F	Died within 24 hours after application							
3M	0	Dead	1	Dead	0	Dead	1	Dead
4F	Died within 24 hours after application							
5M	1	Dead	1	Dead	0	Dead	4	Dead
6F	Died within 24 hours after application							

✓ FILED: CNO3947-85

TR 91-12

T-25

AME Associates
BIOLOGICAL RESEARCH

PRINCETON PIKE, P. O. BOX 57

PRINCETON, N. J. 08540

TEL.: (609) 924-9658

NO 39-1

Project #20-196

Evaluation of Hexamethyl di-tin
by Draize Skin Irritation Technique

Conducted for

M & T Chemicals, Inc.
Rahway, New Jersey

Submitted by

AME Associates
Princeton, New Jersey

CAS 661-69-8

A. M. E. ASSOCIATES P.O. BOX 57 PRINCETON, N. J. 08540

March 28, 1967

PROJECT #20-196

SPONSOR: M & T CHEMICALS, INC.

SUBJECT: Evaluation of Hexamethyl di-tin by Draize Skin
Irritation Technique

OBJECTIVE

Evaluation of the irritant capacity of Hexamethyl di-tin based on the application on abraded and intact skin of the albino rabbit.

MATERIAL

Hexamethyl di-tin supplied by M & T Chemicals, Inc., for use in this study.

PROCEDURE

A group of six (three males and three females) healthy albino rabbits was employed in this project to study the experimental material. The hair was clipped from about the sixth thoracic vertebrae to the sacral region and about 4 inches from the vertebral column on each side using an electric clipper. Two areas, approximately 10 cm apart, on the back of each rabbit were selected as application sites. One site was abraded by making four epidermal incisions in a cross hatch pattern on this site. Then 0.5 ml of the experimental material was applied

to each site and patches consisting of two layers of light gauze cut into squares were secured to the selected areas by strips of 1-inch wide adhesive tape. The trunk of each rabbit was then wrapped in polyethylene sheeting and taped at both ends.

The experimental material was left in contact with the skin for twenty-four hours after which the trunk bands were removed and the sites examined and evaluated. The sites were again examined seventy-two hours after application.

The scoring method employed was that of Draize, Woodard and Calvery as described by Draize on page 48 of "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" published by the Association of Food and Drug Officials of the United States.

Evaluation of Skin Reactions

(1) Erythema and Eschar Formation

No erythema.....	0
Very slight erythema (barely perceptible).....	1
Well defined erythema.....	2
Moderate to severe erythema.....	3
Severe erythema (beet red) to slight eschar formation (injuries in depth).....	4
Total possible erythema score.....	<u>4</u>

(2) Edema Formation

No edema.....	0
Very slight edema (barely perceptible).....	1
Slight edema (edges of area well defined by definite raising).....	2
Moderate edema (raised approximately 1 mm).....	3
Severe edema (raised more than 1 mm and extending beyond area of exposure).....	4
Total possible edema score.....	<u>4</u>

RESULTS

Employing the procedure for conducting primary skin irritation studies utilizing albino rabbits as the test animal, M & T Chemicals, Inc., Hexamethyl di-tin sample caused death in all animals within six hours. During the period of time preceding death, general observation showed deep depression, muscular weakness and incoordination, and CNS excitation emphasized by tremors.

CONCLUSION

Due to the very acute deaths of all rabbits with the Hexamethyl di-tin sample, conclusions based on the usual parameters for evaluation of skin irritation could not be made.

SUBMITTED BY

Harry C. Fegley
AME ASSOCIATES

HARRY C. FEGLEY, V.M.D.

CERTIFICATE OF AUTHENTICITY

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