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88-920002907		BEHQ-0592-4265
		
Date Produced	Date Received	TSCA section
12/12/79	5/26/92	BECP
		
Submitting Organization		
RHONE-POULENC INC		
		
Contractor		
PRODUCT SAFETY LABS		
		
Document Title		
INITIAL SUBMISSION: PRIMARY SKIN IRRITATION AND CORROSION STUDIES WITH DIMETHYL MALEATE MONOMER IN RABBITS WITH COVER LETTER DATED 051592		
		
Chemical Category		
DIMETHYL MALEATE MONOMER		

8(e)

4265

CAP

(COMPLIANCE AUDIT PROGRAM)

TSCA CONFIDENTIAL BUSINESS INFORMATION

ORIGINAL - DCO (Jeff/Eric)
COPY # 1 - CBIC
COPY # 2 - Scott Sherlock

COMPANY SANITIZED

ORIGINAL - PINS
COPY # 1 - PINS
COPY # 2 - ECAD

CONTAINS NO CBI

ORIGINAL - PINS
COPY # 1 - PINS
COPY # 2 - ECAD (Dave Williams)

CONTAINS NO CBI



11:02

RHÔNE-POULENC INC.

CN 5266, PRINCETON, NJ 08543-5266
TELEPHONE: (908) 297-0100 TELEX: 211056

May 15, 1992

8EHQ-0592-4265 init

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 513 377 979



88920002907

Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator (CAP Agreement)
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

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

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0084

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed reports provide information on the following chemical substance:

Product Name: Sipomer DMM
Identity: Dimethyl maleate monomer >99%

CAS Registry No: 624-48-6

CAS Registry Name: 2-Butenedioic acid (Z)-dimethyl ester

The titles of the enclosed reports are:

Primary Skin Irritation and DOT Skin Corrosion

The following is a summary of the adverse effects observed in these reports.

The material was found to be a severe irreversible primary skin irritant and to be corrosive at 4 hours and 48 hours. pH = N/A

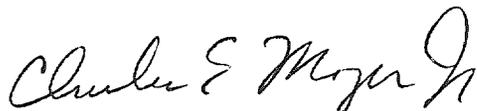
RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

In total, RPI is submitting three copies of each of the enclosed reports and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,



Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(609)860-3589

CEMjr/mm
Enclosures

product safety labs

is a division of nutrition international inc

340 Commercial Avenue
New Brunswick, N.J. 08901
201-545-1704

DOT SKIN CORROSION

December 12, 1979

REPORT NO.: T-703
DATE OF TEST: November 27, 1979
CLIENT: Mr. George W. Panzer
ALCOLAC INC.
3440 Fairfield Road
Baltimore, Maryland 21226
PRODUCT IDENTIFICATION: Sipomer DMM Lot B518B8
PRODUCT DESCRIPTION: A clear liquid
PSL NO.: 91106-7
DATE RECEIVED: November 6, 1979
ANIMALS: Six New Zealand Albino Rabbits
(Skippack Farms, Pa.)
DIET: Fisher Rabbit Chow.
QUALITY ASSURANCE REFERENCE: QA-1; page 7
NOTEBOOK NO.: 79-3; page 144

ENVIRONMENTAL CONDITIONS:

During the test period the animals were housed in individual stainless steel wire bottomed cages in an environmentally controlled room. The temperature was kept at 68° - 72°F at a relative humidity of 45 - 55%. They were exposed to 12 hours of fluorescent light (8 A.M. - 8 P.M.) and 12 hours of darkness (8 P.M. - 8 A.M.) daily. The animals were housed 1 per cage. Feed and water were provided ad-libitum after dosing.

PROCEDURE:

DOT Skin Corrosion, Department of Transportation CFR Title 49, 173, 1200. Six healthy rabbits were each uniquely identified and then prepared by clipping the trunk free of hair. A 2.5 cm² gauze was placed over intact skin on each rabbit. 0.5 ml of the test material was placed under each patch. The patches were secured in place with adhesive tape. The entire trunk of each animal was wrapped with a rubberized elastic cloth to retard evaporation (in the case of volatile substances) and as an aid in maintaining test patch position. The rabbits were then immobilized in head stocks for 4 hours after which time the patches were removed. All test sites were washed to prevent further exposure. Corrosion readings were made at 4 hours and 48 hours after exposure. Corrosion was considered to have resulted if the test substance caused destruction or irreversible alteration of the tissue. Tissue destruction was considered to have occurred if, at any of the readings, there was ulceration or necrosis. Epidermal sloughing, erythema, edema or fissuring were not considered tissue destruction.

CAP ID No. SUC-BAK-0398
Reviewed for Sec. 8 (e)
Compliance Program
On 9/12/91 By BAK

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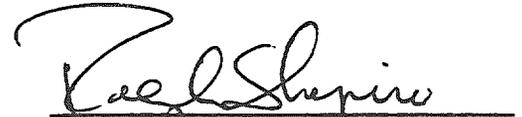
Page 2
Report No. T-703

SUMMARY OF RESULTS:

OBSERVATIONS: Not remarkable.

CONCLUSION: The test material is a corrosive agent.


Anthony J. Verlangieri, Ph.D.
Study Supervisor


Ralph Shapiro, Ph.D.
Director


Arlene Stern
Quality Assurance Unit

RESULTS:

<u>Animal No.</u>	<u>Corrosion</u>	
	<u>4 hrs.</u>	<u>48 hrs.</u>
1	-	+
2	-	+
3	-	-
4	-	-
5	-	-
6	+	+

product safety labs

a division of nutrition international inc.

CAP ID No. S-12-BAK-0397
Reviewed for Sec. 8 (c)
Compliance Program
On 5/12/91 By GAK

340 Commercial Avenue
New Brunswick, N.J. 08901
201-545-1704

PRIMARY SKIN IRRITATION

December 12, 1979

REPORT NO.: T-709
DATE OF TEST: November 27, 1979
CLIENT: Mr. George W. Panzer
ALCOLAC INC.
3440 Fairfield Road
Baltimore, Maryland 21226
PRODUCT IDENTIFICATION: Sipomer DMM Lot B518B8
PRODUCT DESCRIPTION: A clear liquid
PSL NO.: 91106-7
DATE RECEIVED: November 6, 1979
ANIMALS: Six New Zealand Albino Rabbits
(Skippack Farms, Pa.)
DIET: Fisher Rabbit Chow
QUALITY ASSURANCE REFERENCE: Q.A.-1; page 7
NOTEBOOK NO.: 79-3; page 144

ENVIRONMENTAL CONDITIONS:

During the test period the animals were housed in individual stainless steel wire bottomed cages in an environmentally controlled room. The temperature was kept at 68° - 78°F at a relative humidity of 45 - 55%. They were exposed to 12 hours of fluorescent light (8 A.M. - 8 P.M.) and 12 hours of darkness (8 P.M. - 8 A.M.) daily. The animals were housed 1 per cage. Feed and water were provided ad-libitum after dosing.

PROCEDURE:

Primary Skin Irritation. FHSLA 16 CFR 1500. Six healthy rabbits were each uniquely identified and then prepared by clipping the trunk free of hair. Two 2.5 cm² gauze patches were placed over intact skin and abraded skin on each rabbit. 0.5 ml of the test material was placed under each patch. The patches were secured in place with adhesive tape. The entire trunk of each animal was wrapped with a rubberized elastic cloth to retard evaporation (in the case of volatile substances) and as an aid in maintaining test patch position. The rabbits were then immobilized in head stocks for 24 hours, after which time the patches were removed. All test sites were washed to prevent further exposure. Skin lesions were evaluated at 24 and 72 hours and scored in accordance with FHSLA 16 CFR 1500.

FHSA PRIMARY SKIN IRRITATION

Evaluation of Skin Reactions

Value¹

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 redness) to slight eschar formation (injuries in depth)	4

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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure ...	4

¹ The "value" recorded for each reading is the average value of the six or more animals subject to the test.

SUMMARY OF RESULTS:

OBSERVATIONS: Not remarkable.

CONCLUSION: The test material is a severe primary skin irritant.


Anthony J. Verlangieri, Ph.D.
Study Supervisor


Ralph Shapiro, Ph.D.
Director


Ariene Stern
Quality Assurance Unit

RESULTS:

	<u>Exposure Time</u> hours	<u>Average Exposure Unit</u> value
<u>Erythema and Eschar Formation</u>		
<u>Intact Skin</u>	24	2.88
<u>Do</u>	72	3.67
<u>Abraded Skin</u>	24	4.00
<u>Do</u>	72	4.00
	<u>Subtotal</u>	<u>14.55</u>
<u>Edema Formation</u>		
<u>Intact Skin</u>	24	0.67
<u>Do</u>	72	2.17
<u>Abraded Skin</u>	24	1.50
<u>Do</u>	72	3.00
	<u>Subtotal</u>	<u>7.34</u>
	<u>Total</u>	<u>21.89</u>
	<u>Primary Irritation Score</u>	<u>5.47</u>

Primary Skin Irritation Score

- 0.5 - non-primary irritant
- 0.6 - 2.0 - mild primary irritant
- 2.1 - 5.0 - moderate primary irritant
- > 5.1 - severe primary irritant

CERTIFICATE OF AUTHENTICITY

THIS IS TO CERTIFY that the microimages appearing on this microfiche are accurate and complete reproductions of the records of U.S. Environmental Protection Agency documents as delivered in the regular course of business for microfilming.

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