

Contains No CBI

1



INDIVIDUAL RECEIPT  
02 NOV 92 11:10:22

RHÔNE-POULENC INC.  
CN 7500, CRANBURY, NJ 08512-7500  
TELEPHONE: (609) 395-8300

8E HQ-92-12065  
INIT  
88920010303

A

October 27, 1992

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED  
P 416 555 368**

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 - 0296

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 MCA  
Chemical Name: 2-Methoxyethyl acrylate  
CAS Registry No: 3121-61-7  
CAS Registry Name: 2-Propenoic acid, 2-methoxyethyl ester

mm  
RECEIVED  
3/10/95

2

The titles of the enclosed reports are:

Defined Oral LD50

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

The oral LD50 was determined to be 0.40 ml/kg. Based on a specific gravity of 1.01 and EPA's criteria for acute toxicity under Section 8(e), this material would be classified as moderately toxic.

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

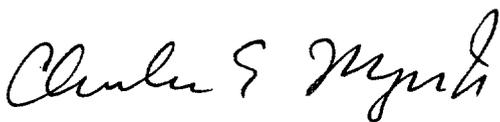
RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

RPI has submitted additional studies on this material under the CAP Agreement; see RP CAP Report No. RPS-0141 and RPS-0142.

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

DEFINED ORAL LD<sub>50</sub>

August 4, 1980

REPORT NO.: T-965  
DATE OF TEST: July 23, 1980  
CLIENT: Mr. George W. Panzer  
ALCOLAC INC.  
3440 Fairfield Road  
Baltimore, Maryland 21226  
PRODUCT IDENTIFICATION: SIPOMER MCA, Lot E169H8  
PRODUCT DESCRIPTION: A clear liquid.  
PSL NO.: E00528-4  
DATE RECEIVED: May 28, 1980  
ANIMALS: Twenty-five male and twenty-five female Sprague Dawley rats, 200-300g from Taconic Farms.  
DIET: Fisher Rat Chow  
QUALITY ASSURANCE REFERENCE: Q.A. 1, 2, 3  
NOTEBOOK NO.: 80-1; pages 518 - 522

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:

Defined Oral LD<sub>50</sub>. Adapted from Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, by the Association of Food and Drug Officials of the United States, 1965.

On arrival, all rats were housed in a quarantine area for a minimum of 7 days. Thereafter, five groups, each consisting of 5 male and 5 female healthy albino rats, weighing 200-300 grams were uniquely identified and fasted for 18 hours. After fasting they were weighed again and individual doses were calculated. Each rat was then individually and singly dosed by gavage.

After dosing the animals, their feed was returned and they were observed daily for mortality and other signs of gross toxicity for 14 days. Gross necropsies were performed on all mortalities. At the end of the test period individual final body weights were recorded. The defined oral LD<sub>50</sub> was calculated by the Litchfield-Wilcoxin method of Probit Analysis (J. Pharmacology and Experimental Therapeutics 96 : 99-115, 1949).

CAP ID No. SCR-BAK-0428  
Reviewed for Sec. 8 (e)  
Compliance Program  
On 9/2/81 By BAJ

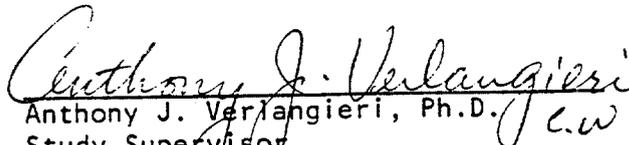
SUMMARY OF RESULTS:

<u>Group</u>	<u>Dose</u> ml/kg	<u>Mortality</u>		<u>Group</u> <u>Mortality</u>
		<u>Male</u>	<u>Female</u>	%
1	0.25	0/5	0/5	0
2	0.35	2/5	2/5	40
3	0.50	2/5	3/5	50
4	0.55	4/5	4/5	80
5	0.60	5/5	5/5	100

OBSERVATIONS: Not remarkable.

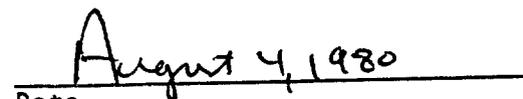
AUTOPSY: See results.

CONCLUSION: The Oral LD<sub>50</sub> of the test material is 0.40 ml/kg  
95% Confidence Levels - Upper - 0.46 ml/kg  
Lower - 0.34 ml/kg

  
Anthony J. Verlangieri, Ph.D. *c.w*  
Study Supervisor  
Toxicologist

  
Ralph Shapiro, Ph.D.  
Director

  
Arlene Stern  
Quality Assurance Unit

  
Date

INDIVIDUAL RESULTS:

Group 1 - Dosage - 0.25 ml/kg

<u>Animal #</u>	<u>Sex</u>	<u>Body Weight</u>		<u>Actual<sup>*</sup> Dose</u>	<u>Mortality</u>	<u>Autopsy</u>
		<u>Initial</u>	<u>g</u> <u>Final</u>			
2637	M	234	274	0.6	---	---
2638	M	226	277	0.6	---	---
2639	M	242	294	0.6	---	---
2640	M	257	335	0.6	---	---
2641	M	262	334	0.7	---	---
2677	F	200	233	0.5	---	---
2678	F	210	246	0.5	---	---
2679	F	200	242	0.5	---	---
2680	F	200	241	0.5	---	---
2681	F	201	239	0.5	---	---

Group 2 - Dosage - 0.35 ml/kg

2597	M	294	342	1.0	---	---
2598	M	277	342	1.0	---	---
2599	M	300	311	1.1	2	UR
2600	M	225	216	0.8	2	UR
2601	M	251	302	0.9	---	---
2672	F	200	226	0.7	---	---
2673	F	204	242	0.7	---	---
2674	F	212	209	0.7	3	PH
2675	F	205	229	0.7	---	---
2676	F	204	205	0.7	3	UR

\* 1.0ml test material diluted to 10.0 ml with water.

Group 3 - Dosage - 0.50 ml/kg

<u>Animal #</u>	<u>Sex</u>	<u>Body Weight</u>		<u>Actual</u> <sup>*</sup>	<u>Mortality</u>	<u>Autopsy</u>	
		<u>Initial</u>	<u>g</u>	<u>Final</u>			<u>Dose</u>
				ml	day		
2532	M	245		325	1.2	---	---
2533	M	256		261	1.3	4	PH
2534	M	239		249	1.2	---	---
2535	M	249		336	1.2	---	---
2536	M	270		274	1.4	3	UR
2667	F	208		226	1.0	2	UR
2668	F	206		245	1.0	---	---
2669	F	200		213	1.0	3	UR
2670	F	204		212	1.0	2	UR
2671	F	208		250	1.0	---	---

Group 4 - Dosage - 0.55 ml/kg

2707	M	275		288	1.5	---	---
2708	M	287		282	1.6	2	PH
2709	M	293		290	1.6	2	PH
2710	M	277		278	1.5	2	PH
2711	M	300		299	1.7	2	PH
2712	F	203		207	1.1	2	UR
2713	F	212		211	1.2	2	PH
2714	F	203		228	1.1	3	PH
2715	F	240		228	1.3	---	---
2716	F	210		228	1.2	2	UR

\* 1.0ml test material diluted to 10.0ml with water.

# product safety labs

a division of nutrition international

Page 5

Report No. T-965

## Group 5 - Dosage - 0.60 ml/kg

<u>Animal #</u>	<u>Sex</u>	<u>Body Weight</u>		<u>Actual</u> <sup>*</sup>	<u>Mortality</u>	<u>Autopsy</u>	
		<u>Initial</u>	<u>g</u>	<u>Final</u>			<u>Dose</u>
				ml	day		
2591	M	213		211	1.3	2	PH
2592	M	300		297	1.8	2	UR
2593	M	295		295	1.8	2	PH
2594	M	212		213	1.3	2	UR
2595	M	280		279	1.7	2	UR
2662	F	200		196	1.2	2	UR
2663	F	207		225	1.2	2	PH
2664	F	200		209	1.2	2	UR
2665	F	205		185	1.2	4	UR
2666	F	200		208	1.2	2	UR

\*1.0ml test material diluted to 10.0ml with water.

### AUTOPSY CODE:

UR                    Unremarkable  
PH                    Pulmonary Hemorrhage



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

Charles E. Moyer, Jr., Ph.D.  
Director, Product Safety  
Rhône-Poulenc Inc.  
CN 7500  
Cranberry, New Jersey 08512-7500

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MAY 08 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

12065A



Recycled/Recyclable  
Printed with Soy/Canola Ink on paper that  
contains at least 50% recycled fiber

**Triage of 8(e) Submissions**

Date sent to triage: MAY 09 1999

NON-CAP

CAP

Submission number: 12065A

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**

<b>For Contractor Use Only</b>	
entire document: <u>0</u> 1 2 pages <u>12</u>	pages <u>12, DMS</u>
Notes:	
Contractor reviewer: <u>PRR</u>	Date: <u>4/26/95</u>

CECATSVIRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHO: 1192-12265 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: Rhone - Palenc 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

OPTIONAL ACTIONS: 0401 NO ACTION REFORMED

0402 STUDIES PLANNED/INITIATED

0403 NOTIFICATION OF WORK RESTARTING

0404 LABEL/MSDS (TRANGL'S)

0405 PROCESSING/ANDLING (TRANGL'S)

0406 AP/USE DISCONTINUED

0407 PRODUCTION DISCONTINUED

0408 CONFIDENTIAL

SUB. DATE: 10/27/92 OTS DATE: 11/02/92 CSRAD DATE: 03/10/95

CHEMICAL NAME: Siporex MCA

CASE# 3121-61-7

11

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 (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 REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/CONF/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	0230 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY ONGOING REVIEW: YES (DROP/REFER) SPECIES: RAT TOXICOLOGICAL CONCERN: LOW USE: \_\_\_\_\_ PRODUCTION: \_\_\_\_\_

YES

CAS SR NO NO (CONTINUE)

IM T R A M I N I R A T T R

MED

HIGH

UNRECD

-CPSS- 0927952113

0 0 0 0 0 0 0 0 0 0 0

> <ID NUMBER>

8(E)-12065A

> <TOX CONCERN>

M

> <COMMENT>

ACUTE ORAL TOXICITY IS MEDIUM CONCERN BASED ON AN LD50 OF 0.40 ML/KG IN RATS. DOSE (ML/KG) AND MORTALITY: 0.25 (0/5 M, 0/5 F), 0.35 (2/5 M, 2/5 F), 0.50 (2/5 M, 3/5 F), 0.55 (4/5 M, 4/5 F), AND 0.60 (5/5 M, 5/5 F). NO CLINICAL SIGNS WERE NOTED. AUTOPSY REVEALED PULMONARY HEMORRHAGES.

\$\$\$\$