



Contains No CBI

TOXICOLOGY DEPARTMENT
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INTERNATIONAL TELEX NUMBER 4999378-ANSWERBACK APC RTP

30 OCT 21 AM 9:22

October 12, 1992

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

8EHQ-92-12010
INIT 10-21-92
88920010252

Document Processing Center (TS-790)
Office of Toxic Substances
US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

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

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

CAP ID No.: 8ECAP - 0004

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN 5266, Princeton, NJ 08543-5266) and its subsidiary Rhône-Poulenc Ag Company (RPAC), the attached study report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for a TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA.

The enclosed study report provides information on MCTR-131-78. We have diligently searched our files and have not been able to determine the chemical identity of this compound. This chemical was synthesized 10 to 20 years ago for pesticide research and development purposes.

No claims of confidentiality are made for this submission. The title of the enclosed report is "Report on Primary Dermal Irritation Study in Rabbits". The following is a summary of the adverse effects observed in this study.

This report is being submitted under Section 8(e) because of systemic toxicity observed in the dermal irritation study. Two of six rabbits died within 24 hours of dermal application of 0.5 ml of test material. These deaths were considered to be treatment-related.

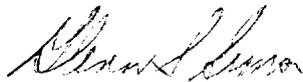
No previous TSCA Section 8(e) notices have been submitted on this chemical, but several will be submitted under the CAP.

Three copies of the report and this cover letter are provided, i.e. one original and two copies.

2/21/95

Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

A handwritten signature in cursive script, appearing to read "Glenn S. Simon".

Glenn S. Simon, PhD, DABT
Director of Toxicology

Cannon Laboratories, Inc.

P. O. Box 3627, Reading, Pa. 19605 (215) 375-4536

REPORT ON PRIMARY DERMAL IRRITATION STUDY IN RABBITS

SUBMITTED TO: MOBIL OIL COMPANY
ENVIRONMENTAL AFFAIRS & TOXICOLOGY
POST OFFICE BOX 1026
PRINCETON, NEW JERSEY 08540

REFERENCE: Notebook MOB-002 Pages 46-47

MOBIL SAMPLE: MCTR-131-78 (a clear liquid)

LABORATORY NUMBER: 8E-2479

DATE RECEIVED: 8/2/78

DATE COMPLETED: 8/10/78

PROCEDURE: Six New Zealand albino rabbits, 2 to 2.2 kg, were closely clipped over the back and sides with an Oster electric clipper. A one inch square site was abraded to the left of the spinal column, while a one inch square site on the right was left intact. The abrasions were minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma or produce bleeding. A 0.5 ml portion of the test material was introduced under a one inch square surgical gauze and placed directly on each test site and secured with Dermicel tape. The rabbits were wrapped with rubber damming to keep the gauze in place for 24 hours. Observations for signs of dermal irritation were recorded after this interval and again 72 hours after application. At each observation, all treated sites were graded for edema, erythema and eschar formation in a range 0-4 in accordance with section 1500.41 of the Federal Hazardous Substance Act.

RESULTS:

	RABBIT NUMBER						MEAN SCORE
	3968	3967	3763	3945	3949	3954	
Erythema and Eschar Formation							
Intact Skin.....24 hours	2	*	2	2	2	*	2.0
Intact Skin.....72 hours	0	*	1	0	0	*	0.3
Abraded Skin....24 hours	2	*	2	2	2	*	2.0
Abraded Skin....72 hours	0	*	1	1	0	*	0.5
Edema							
Intact Skin.....24 hours	1	*	0	0	0	*	0.3
Intact Skin.....72 hours	0	*	0	0	0	*	0.0
Abraded Skin....24 hours	1	*	0	0	0	*	0.3
Abraded Skin....72 hours	0	*	0	0	0	*	0.0
Sum of Mean Score							5.4
Primary Dermal Irritation Index - Sum of Mean Scores/4 =							1.35

RESULTS: When tested in accordance with the Federal Hazardous Substance Labeling Act, 'MCTR-131-78' produced an irritation index of 1.35 which was calculated on only four surviving animals. Two rabbits died prior to the 24-hour observation period. The gross findings for both animals revealed clear fluid in the peritoneal cavity, the lungs were injected and irregularly hemorrhagic, the heart was dilated in all chambers and the distal cecum and colon contained liquid material. Both of these deaths were deemed compound related according to the staff pathologist.

* DEATH

Cannon Laboratories, Inc.

Mobil - 'MCTR-131-78'

8E-2479

Performed By: Luann Seaman
Luann Seaman
Technician

Supervised By: Patricia E Doyle
Patricia E. Doyle
Biologist

Approved By: Geoffrey St. E. Parke
Geoffrey St. E. Parke
Director of Biological Services

Reviewed By: Samuel J. Charles III
Samuel J. Charles III
Compliance Officer

Herbert L. Ratcliffe
Herbert L. Ratcliffe, Sc.D., H.D.V.M.
Staff Pathologist

Cannon Laboratories, Inc.

TABLE I: SCALE FOR GRADING SKIN REACTIONS

<u>Skin Reaction</u>	<u>Value</u>
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

Method for Determining Primary Dermal Irritation Index*

The Primary Dermal Irritation Index is calculated by adding the values for erythema and eschar formation at 24 hours and at 72 hours for intact skin to the values on abraded skin at 24 hours and at 72 hours. Similarly, the values for edema formation at 24 hours and at 72 hours for intact skin and for abraded skin are added. The total of the 8 values is divided by 4 to give the Primary Dermal Irritation Index.

*Federal Register, Vol. 38, No. 187, September 27, 1973

8(E)-12010A

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ACUTE DERMAL TOXICITY IN NEW ZEALAND ALBINO RABBITS (ORIGINALLY A DERMAL IRRITATION STUDY) IS OF MEDIUM CONCERN DUE TO LETHALITY. DOSAGE (24-HOURS) AND MORTALITY DATA ARE AS FOLLOWS: 0.25 ML/KG (2/6). DERMAL RESPONSES IN SURVIVORS INCLUDED NO TO VERY SLIGHT EDEMA AND NO TO WELL-DEFINED ERYTHEMA. PATHOLOGY REVEALED IN ANIMALS THAT DIED CLEAR FLUID IN THE PERITONEAL CAVITY, INJECTED AND HEMORRHAGIC LUNGS, AND DILATED HEART CHAMBERS.



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

Glenn S. Simon, Ph.D., DABT
Director of Toxicology
Rhône-Poulenc
P.O. Box 1
2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 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

12010A



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contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: APR 20 1995

NON-CAP

CAP

Submission number: 12010A

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: <u>0</u> 1 2 pages <u>12</u>	pages <u>1, 2, 3</u>
Notes:	
Contractor reviewer: <u>PR</u>	Date: <u>3/29/95</u>

CECATS/STRAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ 1092-12010 SEQ A

TYPE: INT SUPP FLWP

SUBMITTER NAME: Rhone-Poulenc Inc.

INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED

0502 INFO REQUESTED (TECI)

0503 INFO REQUESTED (VOL ACTIONS)

0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
 REFER TO CHEMICAL SCREENING
 CAP NOTICE

VOLUNTARY ACTIONS:

0401 NO ACTION REPORTED

0402 STUDIES PLANNED/IN PROGRESS

0403 NOTIFICATION OF WORKING WITHIN 60 DAYS

0404 LABELING/STUDY IN PROGRESS

0405 PROCESSING/IN PROGRESS

0406 APPROUSE DISCONTINUED

0407 PRODUCTION DISCONTINUED

SUB DATE: 10/12/92 OTS DATE: 10/21/92 CSRAD DATE: 02/21/95

CHEMICAL NAME:

MCCTR-131-78

CAS#

Unknown

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPIGLIN	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. OCCUREL/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	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		

TRAGE DATA: NON-CBI INVENTORY

ONGOING REVIEW

SPECIES

TOXICOLOGICAL CONCERN:

USE:

PRODUCTION:

YES

YES (DROP/REFER)

RST

LOW

Resicides

CAS SR

NO

NO (CONTINUE)

REFER

IN REMAIN

MED
~~TOX~~

UNCLASSIFIED