

Contains No CBI

1



**TOXICOLOGY DEPARTMENT**

P.O. BOX 12014, 2 T.W. ALEXANDER DRIVE  
RESEARCH TRIANGLE PARK, NC 27709  
(919) 549-2000 TELEFAX (919) 549-8525  
INTERNATIONAL TELEX NUMBER 4999378-ANSWERBACK APC RTP

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88920010426  
8EHQ-92-12204

October 5, 1992

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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

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, 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 MC 2572. The CAS number and name for this chemical are 22787-53-7 and phosphoric acid, dimethyl ester, ester with 4-hydroxy-1,6-dimethyl-2(1H)-pyridone. This chemical was synthesized for pesticide research and development approximately 15 to 20 years ago. To our knowledge, a pesticide application on this chemical has never been submitted to EPA under the Federal Insecticide, Fungicide, and Rodenticide Act.

No claims of confidentiality are made for this submission. The title of the enclosed report is "Acute Oral Toxicity Study in Rats with Mobil Chemical Company's Compound Identified as MC 2572". The following is a summary of the adverse effects observed in this study.

This study is being submitted under Section 8(e) because the oral LD50 was 2.91 mg/kg. According to EPA's criteria under TSCA Section 8(e), this compound would be classified as extremely toxic. Tremors, labored breathing, incoordinated head and body movement, and twitching were seen prior to death.

No previous TSCA Section 8(e) notices have been submitted on this chemical. In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

UC  
RECEIVED  
1/26/95

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

Sincerely,



Glenn S. Simon, PhD, DABT  
Director of Toxicology

**AME Associates**  
BIOLOGICAL RESEARCH

PRINCETON PIKE, P. O. BOX 57

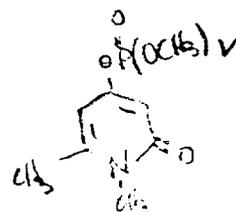
PRINCETON, N. J. 08540

TEL.: (609) 924-9658

Project #20-216

Acute Oral Toxicity Study in Rats with  
Mobil Chemical Company's Compound Identified as MC-2572

GF 77737-1



Conducted for

Mobil Chemical Company  
Metuchen, New Jersey

CC  
C. Dunning  
C. B. B. B.  
A. B. B. B.  
Library  
S. T. B. B. (Original)

Submitted by

AME Associates  
Princeton, New Jersey

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

August 25, 1967

PROJECT #20-216

SPONSOR: MOBIL CHEMICAL COMPANY

SUBJECT: Acute Oral Toxicity Study in Rats with Mobil Chemical Company's Compound Identified as MC-2572

OBJECTIVE

To study the acute oral toxicity in rats of Mobil Chemical Company's compound identified as MC-2572 when administered by means of a stomach catheter.

MATERIAL

Compound MC-2572 supplied by Mobil Chemical Company for use in this study.

PROCEDURE

An approximation of the LD<sub>50</sub> was attained by administering the chemical compound to a number of rats on each of several levels. Following this a group of fifteen young adult, male albino rats of the Sprague-Dawley Strain weighing approximately 200-250 grams was selected for use in this study. The animals were divided into three subgroups of five animals each and fasted for twenty-four hours prior to dosing.

The experimental material was placed in a syringe and introduced through the esophagus into the stomach with a stainless steel catheter.

Five rats were dosed at 6.25 mg/kg with a .5% v/v suspension in corn oil (i.e., .05 ml in 10 ml or .5 ml in 100 ml). Five rats were dosed at 3.125 mg/kg level and five at 1.56 mg/kg level with a .05% v/v suspension in corn oil (i.e., .005 ml in 10 ml or .5 ml in 1000 ml).

Animals on the same dosage level were then placed in a common cage with free access to food and water. The cages employed had wire mesh floors elevated above the droppings and were kept in temperature controlled rooms at 72° F ± 2° F. Light was furnished for eight out of every twenty-four hour period.

The animals were observed for a fourteen day period and deaths were recorded.

The LD<sub>50</sub> was calculated using the Thompson Moving Average Method (Biometrics, September, 1952, Vol. 8, No. 3).

RESULTS

Dosage mg/kg	No. of Animals	<u>Number and Days of Death</u>														<u>Total</u>	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	S*	D**
.78		No deaths assumed at this level														5	0
1.56	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0
3.125	5	3	0	0	0	0	0	0	0	0	0	0	0	0	2	3	
6.25	5	5	0	0	0	0	0	0	0	0	0	0	0	0	0	5	

\*Survivors \*\*Deaths

-3-

OBSERVATIONS

Within ten minutes following dosing the rats on the 6.25 mg/kg level showed tremors of muscles followed by labored breathing. The muscle tremors increased in intensity and duration, and the rats showed increased incoordinated head and body movements followed by death. Some muscular twitching was noted after death. These rats died within one hour of dosing. All dying rats evidenced exophthalmia and injection of the eyes. After death blood was noted around the eyes.

The rats dying on the 3.125 mg/kg level showed similar signs.

The rats on the 1.56 mg/kg level evidenced no clinical signs. Since there were no deaths on the 1.56 mg/kg level, it was assumed there would be no deaths at the .78 mg/kg level.

CONCLUSIONS

The oral LD<sub>50</sub> of Mobil Chemical Company's Compound MC-2572 is 2.91 mg/kg with 95% confidence limits of 2.07 mg/kg to 4.09 mg/kg.

SUBMITTED BY Harry C. Fegley V.M.D.  
AME ASSOCIATES

Harry C. Fegley, V.M.D.

*Associates*  
PHYSIOLOGICAL RESEARCH

PRINCETON PIKE, P. O. BOX 57

PRINCETON, N. J. 08540

TEL.: (609) 924-9658

Mobil Chemical Company  
Metuchen, New Jersey

Invoice Date: August 25, 1967  
Invoice #563

Terms: Net 10 Days

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Project #20-216

Your P. O. #QG-7882

Acute Oral Toxicity Study in Rats with Mobil  
Chemical Company's Compound Identified as MC-2572

\$85.00

*Please pay and*

*Charge to 96201.*

*H. Kaufman*



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

Glenn S. Simon, Ph.D., DABT  
Director of Toxicology  
Rhône-Poulenc  
P.O. Box 12014  
2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

APR 24 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

12204A



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**Triage of 8(e) Submissions**

Date sent to triage: 12/14/95

NON-CAP

CAP

Submission number: 12204A

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: 0 1 2 pages 1, 2 pages 1, 2, tab

Notes:

Contractor reviewer: LPS Date: 4/11/95

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: SELHO-1092-12204 SEQ. A  
 Submission #  
 TYPE: INT. SUPP FLWP  
 SUBMITTER NAME: Rhone-Poulenc, Inc.

INFORMATION REQUESTED: FLWP DATE  
 0591 NO INFO REQUESTED  
 0592 INFO REQUESTED (TECH)  
 0593 INFO REQUESTED (VOL ACTIONS)  
 0594 INFO REQUESTED (REPORTING RATIONALE)  
 DISPOSITION:  
 (R) REFER TO CHEMICAL SCREENING  
 (S) CAP NOTICE

VOLUNTARY ACTIONS:  
 0401 NO ACTION REPORTED  
 0402 STUDIES PLANNED/IN PROGRESS  
 0403 INTERACTION WITH REGULATIONS  
 0404 LABELS/MSDS/CIAM/MS  
 0405 PROCESS/AMEND/INGREDIENTS  
 0406 APP/USE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

SUB. DATE: 10/05/92 OTR DATE: 10/13/92 CSRAD DATE: 01/26/95  
 CHEMICAL NAME: Phosphoric acid, dimethyl ester, ester with 4-hydroxy-1,6-dimethyl-2-(1H)-pyridone  
 CASE: 20787-53-7

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 BARMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 BARMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEMPHYS PROF	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. OCCURENCE/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER ENCI OF ENV CONTAM	01 02 04	0247 DNA DAMAGE/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQ/ST DELAY	01 02 04	0248 PRODUCE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROCOAG/PSYCHEM ID	01 02 04	0251 MEDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0259 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 METAMPHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAMPHARMACO (HUMAN)	01 02 04		

TRACER NAME: NON-CELL INVENTORY YES NO IN PARENT: NO  
 ONCOLOGY REVIEW: YES (DROPPED/REFER) NO (CONTINUE) REF:R  
 SPECIES: RAT TOXICOLOGICAL CONCERN: LOW MED HIGH  
 USE: R&D Pesticide PRODUCTION:  
 CAS SR: NO CAS SR: NO CAS SR: NO  
 I-350213

12204

H

Acute oral toxicity in the rat is of high concern based on an LD<sub>50</sub> of 2.91 mg/kg. Male Sprague-Dawley rats (5/dose) received gavage doses of 1.56, 31.25, and 6.25 mg/kg. Deaths were as follows: 0/5, 3/5, and 5/5. No clinical signs were seen at the lowest dose; at the two highest doses, clinical signs in rats that died included tremors, labored breathing, incoordination, and exophthalmia.