Contains NO CBI

(1)

RHÔNE-POULENC

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

October 5, 1992

(A)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

8EHQ-92-12598

8892001078 2

INIT

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 7783 or MCTR 171-78. The CAS number and name for this chemical are 53775-55-6 and 5-(2,4-dichlorophenoxy)-2-nitrobenzoic acid, sodium salt. This chemical was synthesized for pesticide research and development approximately 10 to 15 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; Acute Dermal Toxicity in Rabbits; Acute Inhalation Toxicity; Ocular Irritation; Primary Dermal Irritation". The following is a summary of the adverse effects observed in this study.

This study is being submitted under Section 8(e) because moderate irritation with blanching and formation of fibrovascular connective tissue was observed in the eye irritation study. No evidence of reversibility was observed for the eye irritation.

No previous TSCA Section 8(e) notices have been submitted on this chemical, and this is the only notice to be submitted under the CAP.

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

MM
3/15/95

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

Sincerely,

Glenn S. Simon, PhD, DABT
Director of Toxicology

(3)

Mobil Oil Corporation

P.O BOX 1026
PRINCETON, NEW JERSEY 08540
TELEPHONE (609) 737-3000

ENVIRONMENTAL AFFAIRS
AND TOXICOLOGY DEPARTMENT

MCTR-171-78
MOBIL 7783
LOT 234338

DATE 2-28-79

ACUTE TOXICITY CLASSIFICATION				
TOXICITY			IRRITATION	
ORAL	DERMAL	INHAL.	EYE	SKIN
2	1	3*	4	0

Acute oral toxicity (LD_{50}, rat): > 500 mg/kg (no deaths)
< 5 g/kg (10/10 deaths)
moderately Toxic

Acute dermal toxicity (LD_{50}, rabbit): > 2 g/kg (no deaths)
Slightly Toxic

Acute inhalation (1 hour, rat): > 2 mg/l (no deaths)
moderately Toxic

Eye irritation (rabbit): 46/1, 62/2, 44/3, 67/4, 41/7 Day
Corrosive

Skin irritation (rabbit): 0.10/8.0

Ames Assay: Negative.

T. Ellison

Final Report Summary

DATE: February 1, 1979
CLIENT: Mobil Oil Corporation
STUDY NO.: 78474
REFERENCE NO.: T. Ellison, Ph.D.
MATERIAL: 4. MCTR-171-78

Acute Oral Toxicity

Method: Albino rats in groups of ten (5M:5F), 202 - 220 g, single dosed orally, observed fourteen days. Material used as a 25% gravimetric suspension in corn oil.

Result: LD_{50} : > 500 mg/kg

Dose Level (mg/kg)	Sex	#dead/#dosed	%
500	5M:5F	0/5:0/5	0

Consumer Product Testing Company, Inc.

Final Report Summary

DATE: February 1, 1979
CLIENT: Mobil Oil Corporation
STUDY NO.: 78474
REFERENCE NO.: T. Ellsion, Ph.D.
MATERIAL: 4. MCTR-171-78

Acute Oral Toxicity

Method: Albino rats in groups of ten (5M:5F), 198 - 232 g, single dosed orally, observed fourteen days. Material used as a 25% gravimetric suspension in corn oil.

Result: LD_{50} : < 5 g/kg

Dose Level (g/kg)	Sex	#dead/#dosed	%
5.0	5M:5F	5/5:5/5	100

Consumer Product Testing Company, Inc.

Table 19

Acute Oral Toxicity

MCTR-171-78

Dose mg/kg	Animal Number and Sex	Bodyweight (grams)	Hours: 1	3	6	24	Days: 2	3	4	5	6	7--14	Bodyweight (grams)
500	1 M	202	N	N	N	SD	N	N	N	N	N	N	N	324
	2 M	212	N	N	N	N	N	N	N	N	N	N	SD	220
	3 M	220	N	N	N	N	N	N	N	N	N	N	N	330
	4 M	212	N	N	N	N	N	N	N	N	N	N	N	368
	5 M	202	N	N	N	N	N	N	N	N	N	N	N	320
	6 F	205	N	N	N	N	N	N	N	N	N	N	N	266
	7 F	208	N	N	N	N	N	N	N	N	N	N	N	280
	8 F	212	N	N	N	N	N	N	N	N	N	N	N	270
	9 F	220	N	N	N	N	N	N	N	N	N	N	N	282
	10 F	218	N	N	N	N	N	N	N	N	N	N	N	270

N = Normal
D = Depression
SD = Slight Depression
XD = Severe Depression
+ = Animal Death

Comments: Animal #1 - #10: No gross changes observed.

Table 14

Acute Oral Toxicity

MCTR-171-78

Dose g/kg	Animal Number and Sex	Bodyweight (grams)	Hours: 1	3	6	24	Days: 2	3	4	5	6	7--14	Bodyweight (grams)
5.0	1 M	232	+	-	-	-	-	-	-	-	-	-	234
	2 M	206	SD	SD	+	-	-	-	-	-	-	-	210
	3 M	200	+	-	-	-	-	-	-	-	-	-	204
	4 M	218	+	-	-	-	-	-	-	-	-	-	218
	5 M	206	+	-	-	-	-	-	-	-	-	-	204
	6 F	212	XD	+	-	-	-	-	-	-	-	-	208
	7 F	200	+	-	-	-	-	-	-	-	-	-	200
	8 F	198	SD	+	-	-	-	-	-	-	-	-	196
	9 F	210	+	-	-	-	-	-	-	-	-	-	210
	10 F	198	+	-	-	-	-	-	-	-	-	-	196

N = Normal
D = Depression
SD = Slight Depression
XD = Severe Depression
+ = Animal Death

Comments: Animal #1, #3 - #5, #7, #9, and #10: Pyloric and intestinal mucosae severely reddened.

Animal #2: Pyloric and intestinal mucosa severely reddened.

Animal #6 and #8: Test material in stomach and intestines; pyloric mucosa severely reddened.

Final Report Summary

DATE: February 1, 1979
CLIENT: Mobil Oil Corporation
STUDY NO.: 78474
REFERENCE NO.: T. Ellison, Ph.D.
MATERIAL: 4. MCTR-171-78

Dermal Toxicity

Method: Six rabbits, 1/2 male, 1/2 female, 1/2 abraded and 1/2 non-abraded, 2 g/kg single application under occluded patch, 14 day observation. Material used as received.

Result: LD_{50} : > 2 g/kg

Dose Level (g/kg)	Sex	# dead/ # dosed	%
2.0	3M:3F	0/3:0/3	0

Table 29

Acute Dermal Toxicity in Rabbits

MCTR-171-78

Dose g/kg	Animal Number and Sex	Bodyweight (kg)	Hours: 1	3	6	24	Days: 2	3	4	5	6	7--14	Bodyweight (kg)
2.0	1 M a	1.66	N	N	N	N	N	N	N	N	N	N N	2.03
	2 M a	1.63	N										2.10
	3 M	1.89	N										1.90
	4 F	1.67	N		NO CHANGES OBSERVED								2.16
	5 F a	1.69	N										2.30
	6 F	2.15	N										2.36

a = abraded skin

N = Normal
D = Depression
SD =Slight Depression
XD = Severe Depression
+ = Animal Death

Comments: Animal #1 - #6: Skin pliable and non-irritated. No gross changes observed.

Draize Scores at 24 Hours:

Animal #1	3/2
Animal #2	1/0
Animal #3	1/2
Animal #4	2/0
Animal #5	3/3
Animal #6	0/0

Final Report Summary

DATE: February 1, 1979
CLIENT: Mobil Oil Corporation
STUDY NO.: 78474
REFERENCE NO.: T. Ellison, Ph.D.
MATERIAL: 4. MCTR-171-78

Acute Inhalation Toxicity

Method: Albino rats in groups of ten (5M:5F), 212 - 266 g, exposed to concentrations of 2 mg/liter for one hour, observed two weeks. Material used as received.

Result: LC_{50} : > 2 mg/l

Dose Level (mg/l)	Sex	# dead/ # dosed	%
2.0	5M:5F	0/5:0/5	0

Consumer Product Testing Company, Inc.

Table 24

Acute Inhalation Toxicity

MCTR-171-78

Dose mg/1	Animal Number and Sex	Bodyweight (grams)	Hours: 1	3	6	24	Days: 2	3	4	5	6	7--14	Bodyweight (grams)
2.0	1 M	226	N	N	N	N	N	N	N	N	N	N	N	340
	2 M	226	N											316
	3 M	266	N											384
	4 M	226	N											348
	5 M	236	N		NO CHANGES OBSERVED									350
	6 F	216	N											236
	7 F	232	N											280
	8 F	212	N											236
	9 F	220	N											244
	10 F	226	N											262

N = Normal
D = Depression
SD = Slight Depression
XD = Severe Depression
+ = Animal Death

Comments: Animal #1 - #10: No gross changes observed.

Final Report Summary

DATE: February 1, 1979
CLIENT: Mobil Oil Corporation
STUDY NO.: 78474
REFERENCE NO.: T. Ellison, Ph.D.
MATERIAL: 4. MCTR-171-78

Ocular Irritation

Method: Six rabbits, mixed sex, 1.8 - 2.4 kg, 0.1 g single administration, all with no wash for 24 hours and up to seven day observation. Material used as received.

Result:

	Draize Score				
	----------Day----------				
Group	1	2	3	4	7
No Wash	46.0	62.3	43.5	67.0	41.3

Table 9

Primary Eye Irritation - Rabbits
SUMMARY OF EYE IRRITATION

MCTR-171-78

Rabbit Number	Day	Cornea: A x B x 5 +	Iris: A x 5 +	Conjunctivae: (A + B + C) x 2 =	Total Scores*
		----------No Wash Group----------			
1	1	2 1	1	2 2 1	25
	2	2 4	0	2 4 2	56
	3	3 2	1	2 2 1	45
	4	3 3	1	2 2 1	60
	7	2 1	0	1 1 0	14
2	1	3 3	1	3 3 2 (B)	66
	2	3 4	1	3 4 2 (B)	83
	3	2 4	1	3 3 2	61
	4	3 4	0	2 2 1	70
	7	3 3	0	1 2 1	53
3	1	3 2	1	2 3 1	47
	2	3 4	1	3 4 1	81
	3	3 1	1	3 3 1	34
	4	3 4	1	1 2 1	73 FVCN
	7	4 1	1	1 1 1	31 FVCN
4	1	2 1	1	2 3 1 (B)	27
	2	4 2	1	2 4 2 (B)	61
	3	3 1	1	3 2 1	32
	4	3 4	1	2 2 1	75 FVCN
	7	4 1	1	2 2 1	35 FVCN
5	1	3 4	1	2 3 1 (B)	77
	2	2 2	1	3 4 2	43
	3	4 2	1	2 4 2 (B)	61
	4	4 2	2	2 4 1	64
	7	4 2	2	2 2 1	60
6	1	1 4	0	2 3 2 (B)	34
	2	2 4	0	2 2 1 (B)	50
	3	3 1	1	1 2 1 (B)	28
	4	3 3	1	2 2 1 (B)	60
	7	3 3	0	2 2 1 (B)	55
Average	1				46.0
	2				62.3
	3				43.5
	4				67.0
	7				41.3

*Total score possible/animal/observation interval = 110
B = Blanched
FVCN = Fibrovascular Connective Tissue

Final Report Summary

DATE: February 1, 1979
CLIENT: Mobil Oil Corporation
STUDY NO.: 78474
REFERENCE NO.: T. Ellison, Ph.D.
MATERIAL: 4. MCTR-171-78

Primary Dermal Irritation

Method: Six rabbits, mixed sex, each abraded and non-abraded, 0.5 g single application under occluded patch, 24 and 72 hour observation. Material used as received.

Result: Primary Irritation Index:*

0.10

* See Table 1A for evaluation.

Table 4

Primary Skin Irritation - Rabbits
SUMMARY OF SCORES FOR SKIN IRRITATION

MCTR-171-78

Rabbit Number	Skin	Hours: 24 E[1] / Ed	72 E / Ed
1	NA[2]	0 / 0	0 / 0
	A[3]	0 / 0	0 / 0
2	NA	0 / 0	0 / 0
	A	0 / 0	0 / 0
3	NA	0 / 0	0 / 0
	A	0 / 0	0 / 0
4	NA	0 / 0	0 / 0
	A	0 / 0	0 / 0
5	NA	0 / 0	0 / 0
	A	0 / 0	0 / 0
6	NA	1 / 0	0 / 0
	A	1 / 0	0 / 0
Average	NA	0.2 / 0.0	0.0 / 0.0
	A	0.2 / 0.0	0.0 / 0.0

Combined Averages: 0.4
Primary Irritation Index: 0.10

[1] E/Ed= Erythema and Edema

[2] NA = Non-abraded skin

[3] A = Abraded Skin

Triage of 8(e) Submissions

Date sent to triage: 2/5/96

NON-CAP CAP

Submission number: 12598A

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** 1,2,3

Notes:

Contractor reviewer : LPS **Date:** 5/11

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092 -12598 SEQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: Rhone-Poulenc 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

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/USERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/05/92 OTS DATE: 10/13/92 CSRAD DATE: 03/15/95

CHEMICAL NAME:
2-Nitrobenzoic acid, 5-(2,4-dichlorophenoxy)-,
sodium salt
MGTR-171-78

CAS#
53775-55-6
11 ← Mobil 7783

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:

NON-CBI INVENTORY	ONGOING REVIEW	SPECIES
YES	YES (DROP/REFER)	RBT
CAS SR	NO (CONTINUE)	RAT
NO	REFER	IN VITRO
IN TRANSITIONI		

TOXICOLOGICAL CONCERN:
LOW Acute Oral Toxicity, Acute Dermal Toxicity, Dermal Irritation, Acute Inhalation Toxicity
MED
HIGH ~~Ocular Irritation~~

USE: R&D pesticide

PRODUCTION:

COMMENTS

#12598A

~~M~~ H high

Ocular irritation is of ~~medium~~ concern based on persistent moderate to severe irritation (corneal, iridal and conjunctival) in 6 rabbits over a 7 day observation period.

L

Acute oral toxicity is of low concern based on 0/10 deaths in rats (5/sex) dosed at 500 mg/kg, and 10/10 deaths at 5000 mg/kg. Clinical signs included slight (≥500) to severe (5000) depression. Abnormalities were observed in the stomach and intestines.

L

Acute dermal toxicity is of low concern based on no mortality (0/6) in rats (3/sex) dosed at 2000 mg/kg.

L

Dermal irritation is of low concern based on no irritation in 6 rabbits exposed to 2000 mg/kg (acute dermal toxicity study). There was no or minimal irritation in 6 rabbits from the primary dermal study.

L

Acute inhalation toxicity is of low concern based on no mortality (0/10) in rats (5/sex) exposed to 2 g/m^3 for 1 hour.

11) √ 8EHQ-92-12598: Rank - low.

Chemical: 5-(2,4-dichlorophenoxy)-2-nitrobenzoic acid, sodium salt (MC 7783; MCTR 171-78; CAS# 53775-55-6).

Letter from Rhone-Poulenc, Research Triangle Park NC, dated October 22, 1992: Negative for gene mutations in Salmonella typhimurium. <no data>