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Submitting Organization		
MONSANTO CO		
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Contractor		
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Document Title		
PRIMARY SKIN IRRITATION OF P-NITROPHENOL TO RABBITS WITH ATTACHMENTS AND COVER LETTER DATED 060889		
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Chemical Category		
P-NITROPHENOL (100-02-7)		

86-890000361

Monsanto

CONTAINS NO C...

ENVIRONMENT, SAFETY & HEALTH

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone (314) 694-1000

June 8, 1989

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Document Control Officer (TS-790)
Room L-100
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Room 201, East Tower
Washington, D. C. 20460

Attention 8(d) Health and Safety Reporting Rule

The enclosed submission is made in response to final rules published in the February 28, 1989 Federal Register Volume 54, No. 38, p. 8484. The rule deals with the addition of certain pesticide inert ingredients to the list requiring reporting under 40 CFR 716, Health and Safety Data Reporting.

Attachment 1 lists the chemicals that Monsanto manufactures, imports or processes, for which our file search identified health and safety studies subject to submission. The individual studies are indexed by chemical on the enclosed F/1 forms. Covered studies that are underway are indexed by chemical on enclosed F/2 forms.

Since these studies may be used for activities regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), they may be subject to financial compensation provisions of Section 3 of FIFRA. We do not waive any rights to such compensation with this submission.

Sincerely,



J. R. Condray
Director, Regulatory Management

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Enc.

Table 1

Chemicals Included In This Submission

54 FR 8484

<u>Chemical</u>	<u>CAS No.</u>
Diphenyl Oxide	101-84-8
1-Methoxy-2-Propane	107-98-2
p-nitrophenol	100-02-7
Dimethylformamide	68-12-2
o-Benzyl-p-chlorophenol	120-32-1
Triethanolamine	102-71-6

Date June 9, 1989

CONTAINS NO CBI

HEALTH AND SAFETY STUDIES - TSCA 8(d)

101-84-8

CAS Number

Diphenyl Oxide

Chemical Name

Monsanto Study Number

Study Title

Y-77-72

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Eye Irritation
Primary Skin Irritation

LF-78-168

Salmonella Mutagenicity Assay

BN-80-241

Toxicity of DPO to the freshwater alga
Selenastrum capricornutum

AB-80-242

Acute Toxicity of DPO to Daphnia magna

AB-80-243

Acute Toxicity of DPO to Rainbow Trout
(Salmo gairdneri)

AB-80-244

Acute Toxicity of DPO to Fathead Minnow
(Pimephales promelas)

PK-86-421

CHO/HGPRT Mammalian Cell Forward Gene
Mutation Assay

SR-86-422

Evaluation of the Potential of DPO to Induce
Unscheduled DNA Synthesis in Primary Rat
Hepatocyte Cultures

PK-86-423

In Vitro Chromosome Abberation Analysis in
Chinese Hamster Ovary (CHO) Cells

BD-88-65

Primary Dermal Irritation Study in Rabbits
(4-Hour Exposure/Semi-Occlusive Covering)

ES8388023

Biodegradation Screening of Biphenyl,
Diphenyl Oxide and VP-1

*Indicates a study of a mixture

F/1
Rev.

40CFR 716

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

101-84-8

CAS Number

Diphenyl Oxide

Chemical Name

Monsanto Study Number

Study Title

BN-79-204*

Toxicity of Therminol VPI to the freshwater alga Selenastrum capricornutum

AB-79-205*

Acute Toxicity of Therminol VPI to Rainbow Trout (Salmo gairdneri)

AB-79-206*

Acute Toxicity of Therminol VPI to Daphnia magna

SR-86-424*

Evaluation of the Potential of Therminol VP-1 to Induce Unscheduled DNA Synthesis in Primary Rat Hepatocyte Cultures

BD-86-378*

Range-Finding Study to Evaluate the Toxicity of Therminol VP-1 Heat Transfer Fluid in the Pregnant Rat

BD-86-379*

Developmental Toxicity Study in Rats with Therminol VP-1 Heat Transfer Fluid

ML-84-0196*

Three-month Inhalation Study of Therminol VP-1 in Rats

*Indicates a study of a mixture

F/1
Rev.

40CFR 716

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

107-98-2

CAS Number

1-Methoxy-2-Propane

Chemical Name

Monsanto Study Number

Study Title

AB-87-9191

Acute Toxicity of Dowanol (R) PH Glycol Ether
to Fathead Minnow (Pimephales promelas)

*Indicates a study of a mixture

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40CFR 716

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

100-02-7

CAS Number

p-Nitrophenol

Chemical Name

Monsanto Study Number

Study Title

Y-61-65

Skin Absorption MLD (Rabbits)

Y-56-56

Oral LD₅₀ in Rats
Minimum Lethal Oral Dose for Rabbits
Toxicity by Skin Absorption in Rabbits
Skin Irritation in Rabbits
Eye Irritation in Rabbits

BN-77-126

Acute (96-Hour) Toxicity to Bluegill

ML-82-131-A

Acute Oral Toxicity to Rats

ML-82-131-B

Acute Dermal Toxicity to Rabbits

ML-82-131-C

Primary Eye Irritation to Rabbits

ML-82-131-D

Primary Skin Irritation to Rabbits

HL-82-242

Subacute Dust Inhalation Toxicity Study in Rats

ML-83-047

Primary Skin Irritancy and Department of
Transportation (DOT) Skin Corrosivity Test in
Rabbits

*Indicates a study of a mixture

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40CFR 716

Date June 9, 1989

ONGOING HEALTH AND SAFETY STUDIES - TSCA 8(d)

100-02-7

CAS Number

p-nitrophenol

Chemical Name

Is the study on a mixture?

Yes/No

Study Number:

ML88-0372

Study Name:

3-month oral toxicity in rats

Date Study Initiated:

November 1988

Purpose:

In compliance with Section 4 Test Rule

Data to be Collected:

-

Estimated Completion:

August 1989

Name and address of laboratory conducting study.

Monsanto Company
Environmental Health Laboratory
645 S. Newstead
St. Louis, MO 63110

F/2
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40CFR 716

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

68-12-2

CAS Number

Dimethylformamide

Chemical Name

Monsanto Study Number

Study Title

BTL-71-30-1

Teratogenic Study with DMF in Albino Rats

BTL-71-30-1A

One-Generation Reproduction and Teratology
Study with DMF in Albino Rats

BTL-71-30-1B

Mutagenic Study with DMF in Albino Mice

BTL-71-30-1C

Mutagenic Study with DMF in Albino Mice

*Indicates a study of a mixture

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Rev.

40CFR 716

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

120-32-1
CAS Number

o-Benzyl-p-Chlorophenol
Chemical Name

Monsanto Study Number

Study Title

KE-48-0038	Report on the Toxicity of o-Benzyl p-Chlorophenol Designated as Santophen 1
MO-76-345	Effect of Santophen 1 on Algae
ML-79-023	Acute Toxicity Report
ML-79-051	Projected Identification of Santophen 1 Metabolites
BTL-72-108	Mutagenic Study with Santophen 1 in Albino Mice
BTL-72-113	21-Day Subacute Dermal Toxicity Study with Santophen 1 in Albino Rabbits
BTL-72-114	Depigmentation Bioassay - Experiment IV
BTL-72-115	90-Day Subacute Oral Toxicity Study with Santophen 1 in Albino Rats
BTL-72-116A	Teratogenic Study with Santophen 1 in Albino Rats
BTL-72-116B	Reproduction Study with Santophen 1 in Albino Rats
BTL-72-116C	Perinatal and Lactation Performance Study with Santophen 1 in Albino Rats
BTL-72-117	21-Day Subacute Oral Toxicity Study with Santophen 1 in Newborn Beagle Pups
BTL-72-118	90-Day Subacute Oral Toxicity Study with Santophen 1 in Beagle Dogs

*Indicates a study of a mixture

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

120-32-1
CAS Number

o-Benzyl-p-Chlorophenol
Chemical Name

Monsanto Study Number

Study Title

HL-78-336

Study of the Metabolism of ¹⁴C-Santophen 1 in Male Sprague-Dawley Rats

AB-80-335

Acute Toxicity of CP-1 (Santophen 1) to Daphnia magna

AB-80-338

Acute Toxicity of CP-1 (Santophen 1) to Rainbow Trout (Salmo gairdneri)

AB-80-339

Acute Toxicity of CP-1 (Santophen 1) to Bluegill Sunfish (Lepomis macrochirus)

AB-80-340

Acute Toxicity of CP-1 (Santophen 1) to Fathead Minnow (Pimephales promelas)

AB-80-342

Determination of Santophen 1 (CP-1) in Bluegill Sunfish (Lepomis macrochirus)

Y-78-276

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Eye Irritation
Primary Skin Irritation
Inhalation Toxicity

Y-72-169

Skin Irritation in Rabbits after Application of Santophen 1

Y-72-170

Skin Irritation in Rabbits after Application of Santophen 1

Y-74-8

Acute Dermal Toxicity
Acute Eye Irritation
Primary Skin Irritation

*Indicates a study of a mixture

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Rev.

40CFR 716

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

<u>120-32-1</u> CAS Number	<u>o-Benzyl-p-Chlorophenol</u> Chemical Name
<u>Monsanto Study Number</u>	<u>Study Title</u>
Y-75-46	Acute Eye Irritation
Y-75-47	Acute Eye Irritation
Y-75-174	Acute Eye Irritation
BN-80-334	Acute Toxicity of CP-1 to mysid shrimp (<u>Mysidopsis bahia</u>)
LN-80-333	Toxicity of CP-1 to the freshwater alga <u>Selenastrum capricornutum</u>
BN-80-335	Acute Toxicity of CP-1 to sheephead minnows (<u>Cyprinodon variegatus</u>)
AB-81-253	Acute Toxicity of Santophen 1 to Hidge (<u>Paratanytarsus parthenogenetica</u>)
BTL-72-14	Four-Day Static Fish Toxicity Study in Bluegills
SH-65-7	Patch Test Study
Y-71-138	Toxicological Investigation
AB-80-337	Dynamic Toxicity of CP-1 (Santophen 1) to Fathead Minnows (<u>Pimephales promelas</u>)
AB-80-341	Preliminary Investigation of the Uptake, Depuration and Bioconcentration of ¹⁴ C-CP-1 (Santophen 1) by Bluegill Sunfish (<u>Lepomis macrochirus</u>)

*Indicates a study of a mixture

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

<u>120-32-1</u> <u>CAS Number</u>	<u>o-Benzyl-p-Chlorophenol</u> <u>Chemical Name</u>
<u>Monsanto Study Number</u>	<u>Study Title</u>
AB-80-343	Investigation of the Bioconcentration and Distribution of ^{14}C -CP-1 (Santophen I) by Bluegill Sunfish (<u>Lepomis macrochirus</u>)
AB-80-345	Early Life Stage Toxicity of CP-1 (Santophen I) to Fathead Minnows (<u>Pimephales promelas</u>) in a Flow-Through System
AB-78-218	Acute Toxicity of Santophen I to Rainbow Trout
BD-78-230	Pilot Study of Santophen I in Pregnant Rabbits
BD-78-231	Teratology Study with Santophen I in Rabbits

*Indicates a study of a mixture

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40CFR 716

Date June 9, 1989

HEALTH AND SAFETY STUDIES - TSCA 8(d)

102-71-6

CAS Number

Triethanolamine

Chemical Name

Monsanto Study Number

Study Title

BI650026

Acute Oral LD₅₀ - Male Albino Rats
Acute Dermal LD₅₀ - Albino Rabbits
Primary Skin Irritation - Rabbits
Acute Eye Irritation - Rabbits
Subacute Feeding (28 Days) - Male Albino Rats

*Indicates a study of a mixture

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40CFR 716

JUL 21 1983

MONSANTO COMPANY
ENVIRONMENTAL HEALTH LABORATORY
645 S. NEWSTEAD
ST. LOUIS, MISSOURI 63110

CONTAINS NO CBI

100-02-7

Primary Skin Irritation of p-Nitrophenol
to Rabbits

Study Number: 820091
DMEH Project Number: ML-82-131-D

Submitted to: Monsanto Agricultural Products Company

(Sponsor)

Through: ~~_____ Toxicologist~~

Author and Study Director: D. K. Branch

DK Branch 7/14/83
D. K. Branch, Study Director Date

L. D. Stout 7/19/83
L. D. Stout, Group Leader Date

R. M. Folk 7/19/83
R. M. Folk, Director EHL Date

Date Report Issued: July 14, 1983

Number of Pages: Seven

EPA-OTS



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SUMMARY

One-half gram of p-nitrophenol was applied to each of two intact and two abraded sites on each of six albino rabbits. Scarring had occurred on at least one exposed site of four of these animals by the fourteenth day after exposure. Some signs of dermal irritation were still evident in one of the two remaining rabbits on the twenty-first day after exposure, at which time the study was terminated. The skin of the sixth animal had regained a normal appearance by the seventh day after test material administration.

EXPERIMENTAL

p-Nitrophenol, lot AC PN 04 093, received as a yellow granular solid, was topically applied to albino rabbits to assess potential skin irritation resulting from dermal contact with the product. Six (6) young adult New Zealand White rabbits (Isf: (NZW), Isaacs' Rabbitry, Litchfield, Illinois) weighing 2.49-2.95 kilograms on the day of exposure were randomly assigned to this study. Each animal was identified by ear tag and bar coded cage card. The skin on the dorsal surface of each animal was shaved with an electric clipper prior to the administration of the test material. A mass of $0.5 \pm .007$ grams of the test material, moistened with physiological saline, was applied to each of two intact and two abraded sites on each animal. The abrasions, made with a hypodermic needle, were sufficiently deep to penetrate the stratum corneum, but not deep enough to produce bleeding. The test material was applied to the skin under one inch square gauze patches and held in contact with the skin by means of an occlusive wrap of latex rubber secured by bandaging and elastic tape. The occlusive wrap and gauze patches were removed after approximately 24 hours, and the excess material was wiped from the treated sites of the animals.

Each animal was individually housed and provided food and water ad libitum. The initial (day one) observation for skin irritation was made approximately one hour after the removal of the wrappings. Dermal irritation was scored by the method of Draize (1944), and results were recorded on the first, third, and seventh days after topical application. Additional observations for signs of irritation in individual animals were conducted as outlined in Table 1.

RESULTS AND DISCUSSION

The daily individual Draize scores and additional clinical observations for the six rabbits are summarized in Table 1. By the first day after test material administration, the skin on all four treated sites of all six animals was stained yellow. In numerous instances, this staining made assessment of erythema difficult. Examinations during which such difficulties were encountered are footnoted in Table 1. By the seventh day after exposure, scabbing had occurred on at least one exposed site of each of five rabbits. In four of these animals, scarring had occurred on at least one site by the fourteenth day after dosing. In three of these four animals, dark brown discoloration of the skin on at least one site had also occurred prior to observation of scabs or scars. In the remaining rabbit that had scabs by the seventh day after exposure, the skin on both affected sites was thickened by day fourteen. This effect subsequently subsided, but neither of these two sites had regained a normal appearance by the termination of the study.

REFERENCE

Draize, J. H., Woodard, G., and Calvery, H. O. (1944). Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes. J. Pharmacol. Exp. Therap. 82: 377-390.

GENERAL INFORMATION

The testing facility was the Environmental Health Laboratory, Monsanto Company, 645 South Newstead, St. Louis, Missouri 63110.

The protocol, raw data, and final report for this study are located in the archives of the Environmental Health Laboratory.

The protocol was signed by the study director on August 4, 1982.

The in vivo portion of this study was initiated on August 17, 1982, and completed on September 7, 1982.

Daily observations for mortality, while not required by protocol, were conducted and data were recorded on the fourth, fifth, eleventh, twelfth, eighteenth, nineteenth, and twentieth days after exposure.

The stated purity of the test material was 99.5%. It has also been stated to be stable indefinitely at 80 degrees F.

1c/4805A-3

Table 1

**p-Nitrophenol: Primary Skin Irritation to Rabbits
Individual Irritation Scores**

Animal Number	Period (Days)	ERYTHEMA				EDEMA			
		RFI	LBI	LFA	RBA	RFI	LBI	LFA	RBA
01M01	1	2a	2a	2a	2a	4	4	4	4
01M02	1	2a	2a	2a	4a	4	2	4	4
01M03	1	2a	2a	2a	2a	4	4	4	4
01F01	1	2a	2a	2a	2a	4	4	4	4
01F02	1	2a	2a	2a	2a	4	4	4	4
01F03	1	2a	2a	2a	4a	4	4	4	4
01M01	3	2a	2a	4a,b	2a	1	0	4	4
01M02	3	2a	2a	2a	4a,b	2	0	0	3
01M03	3	2a	2a	2a	2a	0	0	0	0
01F01	3	2a	2a	2a	2a	0	0	0	0
01F02	3	2a	2a	2a	2a	0	0	4	4
01F03	3	4a,b	2a	2a	4a,b	4	0	0	2
01M01	7	4c,d	1a,d	4c,d	2a,d	0	0	0	0
01M02	7	4c	0	2a,d	4c	0	0	0	0
01M03	7	2a	2a	4c	4c	0	0	0	0
01F01	7	0	0	0	0	0	0	0	0
01F02	7	2a	2a	2a	4c	0	0	0	0
01F03	7	4c	2a	4c	4c	0	0	0	0
01M01	10	4c	1a,d	4c	2a	0	0	0	0
01M02	10	SCARS ON THE RFI, LFA, AND RBA SITES							
01M03	10	2a	2a	4c	4c	0	0	0	0
01F02	10	2a	2a	2a	4c	0	0	0	0
01F03	10	4c	2a	4c	4c	0	0	0	0
01M01	14	SCARS ON THE RFI AND LFA SITES							
01M03	14	2a	2a	2a,e	2a,e	0	0	0	0
01F02	14	SCAR ON THE RBA SITE							
01F03	14	SCARS ON THE RFI, RBA, AND LFA SITES							

(Table 1 - Cont.)

Table 1 (Cont.)

p-Nitrophenol: Primary Skin Irritation to Rabbits
Individual Irritation Scores

Animal Number	Period (Days)	ERYTHEMA				EDEMA			
		RFI	LBI	LFA	RBA	RFI	LBI	LFA	RBA
01M03	17	2a	2a	2a,e	2a,e	0	0	0	0
01M03	21	0a	0a	1a	1a	0	0	0	0

RFI - Right Front Intact Site

LFA - Left Front Abraded Site

LBI - Left Back Intact Site

RBA - Right Back Abraded Site

^aSkin stained yellow; degree of erythema difficult to assess.

^bDark brown discoloration of the skin.

^cScab(s) evident.

^dEpidermal desquamation.

^eThickened skin.

DMEH QUALITY ASSURANCE AUDIT STATEMENT

Study Number: 820091
ML-82-131

Protocol Amendments: None

Study Title: Primary Skin Irritation of p-Nitrophenol
to Rabbits

Communication of Findings: August 16, 19, 1982
December 1, 1982

Quality Assurance Review Conducted by: S. M. Haag
C. K. Russell

Results: The Quality Assurance review indicates the final report accurately presents the raw data as developed during the study. There were no significant deviations from Good Laboratory Practice regulations which affected study quality or integrity. The study appears to have been conducted in general compliance with 21 CFR Part 58, Monsanto Standard Operating Procedures and study protocol.

Arthur F. Helms
Manager, Quality Assurance

December 14, 1982
Date

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH
SAMPLE SUBMISSIONSTUDY NO. ML-82-131

PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S) <u>Para Nitrophenol</u>		CHEMICAL NAME <u>4-nitro phenol</u>	
CP NO. <u>5442</u>	CHEM. ABSTRACTS REG. NO. <u>100-02-7</u>	LOT OR I.D. NO., NOTE BOOK REF. <u>AC PN 04 093</u>	
SAMPLE SIZE <u>250 g</u>	PURITY <u>99.5</u>	SAMPLE DISPOSITION <input checked="" type="checkbox"/> DISCARD <input type="checkbox"/> RETURN	<input type="checkbox"/> HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

STRUCTURAL FORMULA (COMPOSITION OF MIXTURE)



EMPIRICAL FORMULA <u>C₆H₅NO₃</u>	MOLECULAR WEIGHT <u>139</u>	COLOR/PHYSICAL STATE <u>slightly yellow granules</u>	
MELTING POINT <u>112-2°C</u>	BOILING POINT <u>--</u>	VAPOR PRESSURE <u>--</u>	SPECIFIC GRAVITY <u>--</u>
SOLUBILITY: WATER <u>moderately soluble</u>	ORGANIC SOLVENTS (SPECIFY) <u>alcohol, chloroform</u>	OTHER	
PHYSICAL/CHEMICAL HAZARDS			
<input type="checkbox"/> FLAMMABLE	<input type="checkbox"/> UNSTABLE TO LIGHT	<input type="checkbox"/> POLYMERIZES READILY	<input checked="" type="checkbox"/> NO SPECIAL PRECAUTIONS
<input type="checkbox"/> EXPLOSIVE	<input type="checkbox"/> UNSTABLE TO HEAT	<input type="checkbox"/> HYGROSCOPIC	<input type="checkbox"/> OTHER (SPECIFY)
<input type="checkbox"/> OXIDIZER	<input type="checkbox"/> UNSTABLE TO WATER	<input type="checkbox"/> REACTS WITH _____	

OTHER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)

Stable indefinitely at 80°F. Store in a cool, dry area 60-80°F.

III. TOXICITY INFORMATION

ORAL LD ₅₀ <u>350 mg/kg</u>	NO INFORMATION AVAILABLE
DERMAL LD ₅₀ <u>21500 mg/kg (25% in corn oil) >6000 (40% aqueous)</u>	SEE ATTACHMENT
EYE IRRITATION <u>AVG MAX = 21.0/110</u>	OTHER (SPECIFY)
SKIN IRRITATION <u>AVG MAX = 1.6/3.0</u>	
SINGLE VAPOR INHALATION <u>--</u>	

4-56-56 4-61-65

IV. DOCUMENTATION

COMPOSITION & PURITY <input type="checkbox"/> STATED ABOVE <input type="checkbox"/> SEE ATTACHMENT <input checked="" type="checkbox"/> STAFF TOXICOLOGY FILE	METHOD OF SYNTHESIS <input type="checkbox"/> SEE ATTACHMENT <input type="checkbox"/> STAFF TOXICOLOGY FILE <input checked="" type="checkbox"/> OPERATING CO. FILE
SUBMITTED BY: (Name, Location, Phone No., Date) <u>Lydia A. Suba - C2SL - 4-3095</u>	DMEH CONTACT: (Name, Location, Phone No., Date) <u>J. M. Kronenberg - G2ND - 4-8832</u>

V. EHL USE

STUDY NUMBER(S)	SUBSTANCE IDENTIFICATION CODE
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WHITE COPY—LABORATORY COPY; YELLOW COPY—DMEH FILE COPY; PINK COPY—REQUESTOR'S COPY