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MONSANTO CO		
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Contractor		
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Document Title		
PRIMARY SKIN IRRITANCY AND DEPARTMENT OF TRANSPORTATION (DOT) SKIN CORROSIVITY TEST OF P-NITROPHENOL IN RABBITS WITH ATTACHMENTS AND COVER LETTER DATED 060889		
[Hatched separator]		
Chemical Category		
P-NITROPHENOL (100-02-7)		

86-890000363

# Monsanto

CONTAINS NO CB

ENVIRONMENT, SAFETY & HEALTH

Monsanto Company  
800 N. Lindbergh Boulevard  
St. Louis, Missouri 63167  
Phone: (314) 684-1000

June 8, 1989

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U.S. Environmental Protection Agency  
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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	<u>Salmonella Mutagenicity Assay</u>
BN-80-241	Toxicity of DPO to the freshwater alga <u>Selenastrum capricornutum</u>
AB-80-242	Acute Toxicity of DPO to <u>Daphnia magna</u>
AB-80-243	Acute Toxicity of DPO to Rainbow Trout ( <u>Salmo gairdneri</u> )
AB-80-244	Acute Toxicity of DPO to Fathead Minnows ( <u>Pimephales promelas</u> )
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	<u>In Vitro Chromosome Abberation Analysis in Chinese Hamster Ovary (CHO) Cells</u>
BD-88-65	Primary Dermal Irritation Study in Rabbits (4-Hour Exposure/Semi-Occlusive Covering)
ES83SS023	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

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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) PM Glycol Ether  
to Fathead Minnow (Pimephales promelas)

\*Indicates a study of a mixture

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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 LD <sub>50</sub> 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?

Y/N/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  
Rev.

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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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 <u>o</u> -Benzyl <u>p</u> -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

ML-78-336	Study of the Metabolism of 14C-Santophen 1 in Male Sprague-Dawley Rats
AB-80-336	Acute Toxicity of CP-1 (Santophen 1) to <u>Daphnia magna</u>
AB-80-338	Acute Toxicity of CP-1 (Santophen 1) to Rainbow Trout ( <u>Salmo gairdneri</u> )
AB-80-339	Acute Toxicity of CP-1 (Santophen 1) to Bluegill Sunfish ( <u>Lepomis macrochirus</u> )
AB-80-340	Acute Toxicity of CP-1 (Santophen 1) to Fathead Minnows ( <u>Pimephales promelas</u> )
AB-80-342	Determination of Santophen 1 (CP-1) in Bluegill Sunfish ( <u>Lepomis macrochirus</u> )
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

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

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> )
BN-80-333	Toxicity of CP-1 to the freshwater alga <u>Selenastrum capricornutum</u>
BN-80-335	Acute Toxicity of CP-1 to sheepshead minnows ( <u>Cyprinodon variegatus</u> )
AB-81-253	Acute Toxicity of Santophen 1 to Midge ( <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 <sup>14</sup> 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 - TECA 8(d)

120-32-1

CAS Number

o-Benzyl-p-Chlorophenol

Chemical Name

Monsanto Study Number

Study Title

AB-80-343	Investigation of the Bioconcentration and Distribution of $^{14}\text{C}$ -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 LD<sub>50</sub> - Male Albino Rats  
Acute Dermal LD<sub>50</sub> - 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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Rev.

40CFR 716

MASTER FILE  
PROJECT NO. ML-83-047

Feb 29 1984

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

CONTAINS NO CBI

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

100-02-7

Study Number: 830120  
DMEH Project Number: ML-83-047

Submitted to: Monsanto Industrial Chemicals  
Through: R. S. Nair, Product Toxicologist

Author and Study Director: D. K. Branch

DK Branch 2/21/84  
D. K. Branch, Study Director Date

L. D. Stout 2/24/84  
L. D. Stout, Group Leader Date

RM Folk 2/24/84  
R. M. Folk, Director EHL Date

Date Report Issued: February 21, 1984

Number of Pages: Seven

EPA-OTS



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## SUMMARY

One-half gram of p-nitrophenol was held in continuous contact with each of two sites on the shaved dorsal surface of six albino rabbits for four hours under a semioclusive wrapping. Prior to application to one site on each animal, the test material was moistened with physiological saline; it was applied to the other site as received. In the sites exposed to the dry material, no ulceration, necrosis, or scarring were observed, so the substance was not considered to be a (DOT) corrosive material. Slight to mild irritation occurred in five of the sites exposed to the moistened material, but all erythema and edema in these sites had subsided by the seventh day after dosing.

## EXPERIMENTAL

p-Nitrophenol, lot ADPN 09043, received as a yellow/orange granular solid, was topically applied to rabbits to assess potential skin irritation and (DOT) skin corrosion resulting from dermal contact with the product. Six (6) young adult New Zealand White rabbits obtained from Lomax Small Animal Farm, Opdyke, IL, weighing 3.00-3.76 kilograms on the day of exposure were randomly assigned to this study. Each animal was identified by ear tag and corresponding cage card. The skin on the dorsal surface of each animal was shaved with an electric clipper on the day prior to the administration of the test material. A mass of  $0.5 \pm .002$  grams of the test material was applied to each of two sites on each animal under one inch square gauze patches. Prior to administration to one site on each animal, the test material was moistened with physiological saline; it was applied to the other site as received. The gauze patches were then covered by a semioclusive wrap which was secured with elastic tape. The wrappings and gauze patches were removed after approximately four 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. In the sites exposed to the unmoistened material, examinations for signs of corrosivity were conducted at the time of removal of the wrappings and 44 hours later. These sites were washed with tap water after the initial examination. In the sites exposed to the moistened material, dermal irritation was scored by the method of Draize (1944), and results were recorded at approximately 1, 24, 48, and 72 hours after removal of the wrappings. The two animals that had irritation evident during the 72 hour examination were also observed for signs of irritation on the seventh day after exposure.

EHL 830120

PAGE 2

## RESULTS AND DISCUSSION

Results of the examinations for subepidermal necrosis, dermal ulceration, and dermal scarring in sites exposed to unmoistened p-nitrophenol are in Table 1. None of these effects were observed in any of the rabbits, so the test substance was not considered to be a (DOT) corrosive material. Daily individual irritation scores and additional clinical observations for the six sites exposed to the moistened material are in Table 2; mean scores for observations made on the first four days of the study are in Table 3. During the examination approximately one hour after removal of the wrappings, irritation ranged from none to mild, and was slight overall. After that time, improvement steadily occurred, and all erythema and edema had subsided by the seventh day after exposure. All of these sites were stained bright yellow throughout the study. In the sites exposed to the unmoistened test material, similar, though less intense, staining was observed in one rabbit during the examination at the time of removal of the wrappings and in all six animals two days later. In most instances, this was considered to result from the rabbit licking his (her) stained site, followed by licking elsewhere on the dorsum.

## 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 October 12, 1983.

The in vivo portion of this study was initiated on November 1, 1983 and completed on November 8, 1983.

The stated purity of the test material was 99.53%. It has been stated to be stable indefinitely at 80 degrees F.

cmn/6323A-1

Table 1

Incidence Summary of Corrosive Effects After  
Topical Application of Unmoistened p-Nitrophenol  
to Albino Rabbits

Animal Number	Observation Period (Hours after Dosing)	Subepidermal Necrosis	Dermal Ulceration	Dermal Scarring
01M01	4	-	-	-
01M02	4	-	-	-
01M03	4 <sup>a</sup>	-	-	-
01F01	4	-	-	-
01F02	4	-	-	-
01F03	4	-	-	-
01M01	48 <sup>a</sup>	-	-	-
01M02	48 <sup>a</sup>	-	-	-
01M03	48 <sup>a</sup>	-	-	-
01F01	48 <sup>a</sup>	-	-	-
01F02	48 <sup>a</sup>	-	-	-
01F03	48 <sup>a</sup>	-	-	-

+ indicates that the effect was observed during a given examination.

- indicates that the effect was not observed during a given examination.

<sup>a</sup> Yellow staining of skin.

Table 2

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

Animal Number	Period (Days)	Erythema	Edema
01M01	0a, b	1	0
01M02	0a, b	1	0
01M03	0a, b	1	0
01F01	0a, b	2	1
01F02	0a, b	0	0
01F03	0a, b	1	0
01M01	1b	1	0
01M02	1b	1	0
01M03	1b	0	0
01F01	1b	0	0
01F02	1b	0	0
01F03	1b	1	0
01M01	2b	1	0
01M02	2b	1	0
01M03	2b	0	0
01F01	2b	0	0
01F02	2b	0	0
01F03	2b	0	0
01M01	3b	1	0
01M02	3b	1	0
01M03	3b	0	0
01F01	3b	0	0
01F02	3b	0	0
01F03	3b	0	0
01M01	7b	0	0
01M02	7b	0	0

<sup>a</sup>Day 0 observations were conducted between 30 and 60 minutes after removal of the wrappings.

<sup>b</sup>Bright yellow staining of skin.

Table 3

**p-Nitrophenol: Primary Skin Irritation to Rabbits  
Primary Skin Irritation Score Summary**

<b>Period (Days)</b>	<b>Erythema</b>	<b>Edema</b>	<b>Irritation Score</b>
0a	1.0	0.2	1.2
1	0.5	0.0	0.5
2	0.3	0.0	0.3
3	0.3	0.0	0.3

<sup>a</sup>Day 0 observations were conducted between 30 and 60 minutes after removal of the wrappings.

DMEH QUALITY ASSURANCE AUDIT STATEMENT

Study Number: 830120  
ML-83-047

Protocol Amendments: none

Study Title: Primary Skin Irritancy and Department of  
Transportation (DOT) Skin Corrosivity  
Test of p-Nitrophenol in Rabbits

Communication of Findings: October 20, 1983  
November 1, 1983  
February 2, 1984

Quality Assurance Review Conducted by: M. G. T. Chatel  
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.

Steven M. Huss  
for - Manager, Quality Assurance

February 6, 1984  
Date

MONSANTO COMPANY  
ENVIRONMENTAL HEALTH LABORATORY  
St. Louis, Missouri 63110

ISSUE DATE: October 12, 1983  
NO. OF PAGES: Six

Title: Evaluation of Primary Skin Irritation and (DOT) Skin  
Corrosivity of p-Nitrophenol in Rabbits

Project Number: ML-83-047  
EHL Study Number: 830120

Sponsor: Monsanto Fibers and Intermediates Company

Submitted by  
Study Director: Signed DK Branch Title Res Tox  
DB 10/7/83 Dated 10/12/83

Approved by  
Product  
Toxicologist: Signed ~~R. J. ...~~ Title Sen. Prod. Toxicologist  
Dated 10/11/83

Approved by  
Laboratory  
Director: Signed RM Folk  
Dated 10/7/83

Proposed Starting Date: October, 1983

Proposed Completion Date: October, 1983

Proposed Report Completion Date: December, 1983

Record of Amendments

NO.	DATE	TYPE/DESCRIPTION

## PROTOCOL

### 1. Introduction

#### 1.1 Purposes:

1.1.1 To determine whether, according to DOT regulations (49 CFR subpart F, section 173.240), p-nitrophenol is corrosive when held in contact with rabbit skin for four hours.

1.1.2 To assess primary skin irritation resulting from dermal contact with the material.

1.2 Reason for Route of Administration: This study is designed to determine the dermal irritation/(DOT) corrosion potential of the test compound; as such the dermal route was chosen.

1.3 Justification of Test System: The albino rabbit is the species specified for this test.

### 2. Materials and Methods:

2.1 Test Material: p-Nitrophenol. Information on the physicochemical characteristics of this material and/or the location of this information will be maintained in the study records.

#### 2.2 Animals:

2.2.1 Strain and Species: New Zealand White rabbit.

2.2.2 Source: Lomax Small Animal Farm, Opdyke, IL.

2.2.3 Age and Weight on the Day of Exposure: Adult animals; at least 2.0 kg.

2.2.4 Number Required: Six animals.

2.3 Animal Husbandry:

2.3.1 Identification of Test System: Individual ear tag and corresponding cage card.

2.3.2 Housing: One animal per stainless steel cage.

2.3.3 Pretest Examination and Acclimation: Animals will be quarantined for at least seven days. Only animals considered healthy by a staff veterinarian will be released for testing. Any or all animals may be rejected by the Study Director if considered unsuitable for testing.

2.3.4 Food and Water: Ad libitum.

2.3.5 Dietary Control: Purina Certified (5322) Laboratory Rabbit Chow® (Registered Trademark of the Ralston-Purina Company, St. Louis, Missouri) will be used. This diet has been determined to be nutritionally acceptable for the maintenance of laboratory rabbits and has been tested by the manufacturer for contaminants likely to interfere with the study. No food will be used that has been reported to contain unacceptable levels of such contaminants. All water will be furnished by the City of St. Louis, Missouri. This water meets human drinking water standards.

2.4 Bias Control: Animals will be assigned to test groups by random numbers generated by computer. In instances where computer facilities are unavailable, animals will be assigned to the study manually and the method of randomization will be documented in the study records.

2.5 Exposure: The skin will be exposed to the test material under a semi-occlusive wrapping for four hours.

2.6 Measurement of Absorption Into the Body: Determination of the degree of absorption of the test article is not necessary to achieve the objectives of the study and will not be performed.

## 2.7 Treatment:

2.7.1 Preparation of Test Animals: On the day prior to exposure, the fur on the dorsal surface of each rabbit will be shaved with an electric clipper. Only animals with healthy, intact skin will be used.

2.7.2 Application of Test Material: The test material will be applied under each of two gauze patches approximately one square inch in area. A mass of 0.5 g of the material, which will be powdered if practical, will be applied to each site. On one site, the material will be applied without the addition of a solvent; on the other site, it will be moistened with physiological saline. The gauze patches will be held in place with non-irritating tape and covered with a suitable semi-occlusive material. The patches and covering will be secured with bandaging and elastic tape to prevent ingestion. The test material will be kept in contact with the skin for four hours.

2.8 Post Exposure Observation Period: Sites exposed to the dry test material will be observed for 48 hours or until criteria in section 2.9.3 are met, whichever occurs first. Sites exposed to the saline moistened material will be observed for 14 days or until criteria in sections 2.9.2 or 2.9.3 are met, whichever occurs first.

## 2.9 Scoring of Results and Observations:

2.9.1 At the end of the exposure, the wrappings and gauze patches will be removed and the resulting skin reactions on the sites exposed to the dry test material will be evaluated for corrosion as specified in section 2.9.3. After these examinations, each treated site will be washed with an appropriate solvent in an attempt to remove the residual test material and thus prevent further exposure. On the sites exposed to the saline-moistened test material, signs of irritation will be recorded between 30 and 60 minutes and approximately 24, 48, and 72 hours after removal of the wrappings; these signs of irritation will be scored by the procedure of Draize<sup>1</sup>.

2.9.2 The sites that have not been moistened with saline and have not shown signs of corrosion during the initial examination will be observed for corrosive reactions 48 hours after test material administration. No further observations will normally be conducted on these sites. Sites exposed to the saline moistened material that have irritation evident on the third day after exposure will be observed for signs of irritation on the seventh and (if irritation is still present) fourteenth days after dosing or until conditions in section 2.9.3 are met. The observation period for these sites may be extended if the presence of a scab precludes determination of whether scarring has occurred.

2.9.3 Exposure to the test material resulting in ulceration, scarring, or subepidermal necrosis will be considered evidence of corrosion. If any of these effects are observed on a site, the material will be considered corrosive to that site and no further observations will be conducted on that site. If such effects occur in at least three dry sites, the test material will be considered a (DOT) corrosive material and no further observations will be conducted on those sites. If such effects occur in at least three moistened sites, the material will be considered corrosive under moistened conditions and no further observations will be conducted on those sites.

2.9.4 Signs of systemic intoxication will be recorded if noted.

3. Report: The report will include: Species and strain of animals used, body weight range on the day of exposure, dose and condition of the test material, methodology, a description of corrosive reactions or a statement that such reactions were not observed in the sites exposed to the dry material, irritation scores and (if any) other dermal reactions recorded in the sites exposed to the moistened test material, and if noted, signs of systemic intoxication.

4. Records: The protocol, original data, and final report for the study will be maintained in the EHL archives.
5. Reference: <sup>1</sup>Draize et al, (1944) J. Pharmacol. Exp. Therap., 82: 377-390.
6. General Information: The testing facility is the Environmental Health Laboratory, Monsanto Company, 645 South Newstead, St. Louis, Missouri 63110.

1c/6006A-2

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH  
SAMPLE SUBMISSION

STUDY NO. ML-83-047

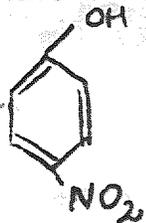
PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S) Paranitrophenol (PNP)		CHEMICAL NAME Paranitrophenol	
CP NO. 5442	CHEM. ABSTRACTS REG. NO. 100-02-7	LOT OR I.D. NO., NOTE BOOK REF. ADPN 09043	
SAMPLE SIZE 500 g	PURITY 99.53%	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 C <sub>6</sub> H <sub>5</sub> NO <sub>3</sub>	MOLECULAR WEIGHT 139	COLOR/PHYSICAL STATE slightly yellow granules	
MELTING POINT 113-2°C	BOILING POINT --	VAPOR PRESSURE	SPECIFIC GRAVITY
SOLUBILITY: WATER Moderately soluble	ORGANIC SOLVENTS (SPECIFY) alcohol, chloroform		OTHER

PHYSICAL/CHEMICAL HAZARDS

<input type="checkbox"/> FLAMMABLE	<input type="checkbox"/> UNSTABLE TO LIGHT	<input type="checkbox"/> POLYMERIZES READILY	<input 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<sub>50</sub> 350 mg/kg - moderate 230 mg/kg NO INFORMATION AVAILABLE

DERMAL LD<sub>50</sub> > 5000 mg/kg SEE ATTACHMENT

EYE IRRITATION severe to corrosive OTHER (SPECIFY)

SKIN IRRITATION corrosive (24 hour application)

SINGLE VAPOR INHALATION \_\_\_\_\_

ML-82-131

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>Lynna A. Suba - C2SL - 4-3095</u> <u>9/29/83</u>	DMEH CONTACT: (Name, Location, Phone No., Date) <u>Rashmi S. Nair</u> <u>10/11/83</u> <u>Rashmi Nair - G2ND, - 4-8817</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