

ORIGINAL

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

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October 6, 1992

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Washington, D.C. 20460

8EHQ-92-13201  
82920011004s

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

CAP

Dear Coordinator:

RECAP- [ ]

On behalf of the Regulatee and pursuant to Units II B.1.b; II C and II D of the [ ] CAP Agreement, [ ] hereby submits (in triplicate) the attached information. Submission of the information in this letter is made voluntarily under a recently published TSCA §8(e) reporting Q/A, June 1991 TSCA 8(e) Reporting Guide ("Reporting Guide") and is not to be construed as a waiver of due process rights, or as an admission of TSCA violation or that Regulatee's activities with the study compound(s) reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which was not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide" states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due process issues and



clouds the appropriate reporting standard by which regulated persons can assure TSCA §8(e) compliance.

Regulatee is claiming certain bracketed "[ ]" information in this submission as Confidential Business Information and has provided substantiation and a redacted copy for the public file.

For Regulatee,

{

}

**Attachment 1**

**Substantiation of Confidential Business Information Claims**

SUBSTANTIATING CLAIMS OF CONFIDENTIALITY

Information claimed as CBI: Submitter identity (including internal codes, personnel); mixture proportions; use.

1. For what period of time do you assert this confidentiality claim? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why the information should remain confidential until such event or time.

Indefinitely. Since the composition is not patented, we would have no means of stopping a competitor from using this composition to duplicate our product. It was developed at considerable expense in R&D in both time and dollars, estimated at [ ] A competitor would use this information and seriously jeopardize our business interest.

2. Have there been any confidentiality determinations made by EPA, other Federal agencies, or courts in connection with this information? If so, please enclose copies.

No.

3. Has any information that you are claiming as confidential been disclosed to any individuals or entities (including governmental agencies) outside your company? If so, explain the circumstances of such disclosure. Will the information be disclosed to such persons or entities in the future? If so, what restrictions, if any, apply to the use of further disclosure of the information?

No. The information has not been disclosed outside of [ ] and we have no current intent to disclose it.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming as confidential. What other steps, if any, have you taken to prevent undesired disclosure of the information during its use or when an employee leaves your company?

We have taken all measures practical to prevent disclosure of the information. It has never been disclosed publicly, and is disclosed within [ ] only on a "need to know" basis. Documents related to this information are classified as "Confidential" and

treated according to corporate practices protecting proprietary information. For example, such documents are stored in locked files and handled by intra-company mail in special sealed confidential envelopes. All employees are periodically trained in the need to avoid either purposeful or inadvertent disclosures of such information. Periodically, management audits conformance to CBI policies and initiates corrective or disciplinary action where failure to comply is detected. All [ ] employees, when they first join the company and as a condition of employment, sign an agreement not to divulge confidential information during their employment or after departure.

5. Does the information claimed as confidential appear or is it referred to in any of items listed below:
- advertising or promotional materials for the chemical or the end product containing it;
  - safety data sheets or other similar materials for the chemical or the end product containing it;
  - professional or trade publications; or
  - any other media available to the public or to your competitors

No. The test mixture proportions claimed as confidential do not appear in the items listed above. Company name and end use do appear on MSDSs, but there is no connection to or disclosure of confidential trade secret compositional information.

6. Would disclosure of this information be likely to result in substantial harm to your competitive position? If so, you must specifically describe the alleged harmful effects and indicate why they should be considered to be substantial. Also, you must describe how disclosure of the information would cause the harm.

The information would provide our competitors with important insight into the technology we use to make [ ] coatings. We know our competitors are actively seeking to duplicate our products. In these very competitive markets, we would lose our competitive edge and never recoup the time and money invested in R&D in developing this technology.

7. If the information in question is "health and safety data" pursuant to 40 CFR Part 2.306(e)(i), do you assert that disclosure of the information you are claiming as confidential would reveal:

- a) confidential process information;
- b) confidential proportions of a mixture; or
- c) information unrelated to the effects of the substance on human health or the environment?

If your answer to any of the above questions is yes, you must explain how such information would be revealed.

Submitter does not assert that confidential information/trade secret information claimed as CBI herein is "health and safety data" pursuant to 40 CFR Part 2.306(e)(i). Notwithstanding this claim and the inapplicability of this subpart to the information claimed as CBI, submitter states as follows:

- a) No.
- b) Yes. Part of information deleted is itself the confidential proportions of a mixture.
- c) Yes. Information such as [ ] is unrelated to the effects of the substance on human health or the environment, but would provide a competitor with important information about our technical strategy in these product areas.

CAS #see below  
Chem: Polyamide resin 37189-83-6  
Xylene 1330-20-7  
Tris(dimethylaminomethyl)phenol 90-72-2  
Isophorone diamine 2855-13-2  
Methyl ethyl ketone 78-93-3  
butyl cellosolve 111-76-2  
toluene 108-88-3  
VM&P Naphtia 64742-89-8  
butyl acetate 123-86-4  
mineral spirits 64742-88-7  
aromatic hydrocarbons 64742-95-6  
Title: Dermal Sensitization Study in Guinea Pigs  
Date: 3-21-88  
Summary of Effects: Skin sensitization

[ ] [ ]

Study Title

[ Dermal Sensitization Study with ]  
[ ] in Guinea Pigs

Author

[ ]

Study Completed On

March 21, 1988

Performing Laboratory

[ ]

Medical Research No.

[ ]

Laboratory Project ID

[ ]

[ ]

GENERAL INFORMATION

Test Material

Material Tested:

[ ]

Medical Research No.:

[ ]

[ ]

[ ]

Physical Form:

Clear liquid

Composition:

[ ]

- Polyamide
- Xylene
- Tri(dimethylaminomethyl)phenol
- Isophoronediamine
- Methyl ethyl ketone
- Butyl Cellosolve
- Toluene
- VM&P Naphtha
- Butyl acetate
- Mineral spirits
- Aromatic hydrocarbons

Other Code:

[ ] (10/22/87)

Stability:

The test material was assumed to be stable under the conditions of administration.

Positive Control Material

Material Tested:

1,4-Benzenediamine

Synonyms:

- 1,4-Phenylenediamine
- p-Phenylenediamine

Other Codes:

- EM Science Co., Catalog No. PX0730-3
- EM Science Co., Lot No. 6175

CAS Registry No.:

106-50-3

Stability:

The material was assumed to be stable under the conditions of administration.

[ ]

GENERAL INFORMATION (Cont'd)

Sponsor:

Material Submitted By:

In-Life Phase  
Initiated - Completed:

1/6/88 - 2/19/88

Notebooks:

E-54758, pp. 28-43 (Main Study)  
E-45996, pp. 1, 3 and 126-140 (Positive  
Control)

There are 22 pages in this report.

Distribution:

[ ]

Dermal Sensitization Study with

[ ] in Guinea Pigs

SUMMARY

[ ] as 100% and 10% (v/v) emulsions in dimethyl phthalate was tested on the shaved, intact skin of male and female guinea pigs. p-Phenylenediamine as 30% and 3% (w/v) suspensions in acetone:dimethyl phthalate (1:9) was used to demonstrate the ability of the test system to detect a skin sensitizer (positive control group). Vehicle control animals were treated with dimethyl phthalate.

Mild erythema was observed in 3 test animals at 24 hours and in 6 test animals at 48 hours after treatment in the 100% concentration site during the primary irritation phase. No dermal irritation was observed in the test animals in the 10% concentration site. No dermal irritation was observed in the vehicle control or positive control animals.

During the challenge phase, mild erythema to necrosis was observed in the 100% concentration site by 48 hours after treatment in the test animals. Mild erythema was observed in 2 test animals and moderate erythema was observed in 1 test animal at 48 hours in the 10% concentration site. No to moderate erythema was observed in the vehicle control animals in the 100% concentration site. No dermal irritation was observed in the 10% concentration site in the vehicle control animals. Mild erythema to necrosis was observed in the positive control animals in the 30% concentration site. No to moderate erythema was observed in the 3% concentration site. Under the conditions of this study, [ ] produced strong delayed hypersensitivity or allergic reactions in guinea pigs.

Work by

Study Director:

WJB:smk:HLR88.9

[ ]

QUALITY ASSURANCE DOCUMENTATION

STUDY: [ ] [ Dermal Sensitization Study with ] in Guinea Pigs

Because short-term studies are numerous and routine in nature, representative studies from this test type are audited quarterly to ensure the studies are designed and conducted in compliance with the Good Laboratory Practice Standards.

Reported by: [ ] 3/18/88  
Date

## INTRODUCTION

The purpose of this study was to evaluate the potential of [redacted] to produce delayed hypersensitivity or allergic reactions when applied to the skin of guinea pigs. Sensitization was defined as a significant score increase at challenge over the response observed after the primary application of the test material to the test guinea pigs, or the response observed in the vehicle controls. A significant score increase was defined as a 2-or-more step increase (e.g., from 0 to 2, from 1 to 3, etc.) in irritation scores. The experimental procedure described in this report has been used at [redacted] for its ability to identify compounds that are sensitizers. The sensitivity of the test system and procedure to detect chemical sensitizers was evaluated with p-phenylenediamine. This study was conducted according to the EPA Good Laboratory Practice Regulations. Areas of noncompliance are documented in the study records. No deviations existed that significantly affected the validity of the study.

## MATERIALS AND METHODS

### A. Animal Husbandry

Male and female Duncan Hartley albino guinea pigs were received from Charles River Breeding Laboratories, Stone Ridge, New York. The guinea pigs were housed singly in suspended, stainless steel, wire-mesh cages with dimensions of 8" x 14" x 8". Each guinea pig was assigned a unique identification number which was recorded on a card affixed to the cage. Purina Certified Guinea Pig Chow® #5026 and water were available ad libitum. Guinea pigs were weighed and observed for general health during a quarantine period of approximately one week. Animal rooms were maintained on a timer-controlled, 12-hour light/12-hour dark cycle. Environmental conditions of the rooms were targeted for a temperature of 23° + 2°C and relative humidity of 50% + 10%. Any excursions outside these ranges were of small magnitude and/or brief duration and did not adversely affect the validity of the study.

### B. Protocol

A preliminary rangefinding test was conducted to estimate the primary irritation potential of the test material. The results of the rangefinding study were used to select the exposure concentrations for the main study. The main sensitization study consisted of 3 phases: a primary irritation phase, an induction phase and a challenge phase. During each phase, skin responses were scored according to the system presented in Table I. During the study, body weights were recorded weekly.

[ ]

The rangefinding test was conducted on 3 female guinea pigs ranging in weight from 537 to 673 grams. Aliquots (approximately 0.05 mL) of the neat test material and 50%, 25% and 10% (v/v) emulsions of the test material in dimethyl phthalate were applied and lightly rubbed onto separate test sites on the shaved, intact skin of each animal's back. Irritation responses were scored approximately 24 and 48 hours after treatment.

The primary irritation phase was conducted in 10 guinea pigs (5 males and 5 females), weighing from 483 to 608 grams, by applying and lightly rubbing in 1 drop (approximately 0.05 mL) of 100% and 10% (v/v) emulsions of the test material in dimethyl phthalate onto separate sites of shaved, intact skin of each animal. Ten vehicle control guinea pigs (5 males and 5 females), weighing from 499 to 624 grams, were also treated by applying and lightly rubbing in 1 drop (approximately 0.05 mL) of dimethyl phthalate onto separate sites of shaved, intact skin of each animal. In addition, 10 positive control guinea pigs (5 males and 5 females), weighing from 496 to 617 grams, were treated by applying and lightly rubbing in 1 drop of 30% and 3% (w/v) suspensions of p-phenylenediamine in acetone:dimethyl phthalate (1:9 ratio) onto separate sites of shaved, intact shoulder skin of each animal. Dermal responses were scored approximately 24 and 48 hours after application of the test material.

Two days after the primary dermal application phase, the induction phase of the study was initiated using the same 10 test guinea pigs in which primary irritation had been evaluated. Induction consisted of a series of 4 sacral intradermal injections (1 each week) of 0.1 mL of a 1.0% (v/v) emulsion of [ ] in dimethyl phthalate. The same injection procedure was followed for the 10 vehicle control guinea pigs using dimethyl phthalate and for the 10 positive control guinea pigs using 0.1 mL of a 1.0% (w/v) suspension of p-phenylenediamine in acetone:dimethyl phthalate (1:9). Skin responses were evaluated approximately 24 hours after each injection.

Two weeks after the last induction treatment, the test guinea pigs were challenged for sensitization by applying and lightly rubbing in 1 drop of 100% and 10% (v/v) emulsions of the test material in dimethyl phthalate onto separate sites of shaved, intact shoulder skin. The 10 vehicle control guinea pigs received identical topical applications of [ ] The positive control animals were challenged for sensitization by applying and lightly rubbing in 1 drop of 30% and 3% (w/v) suspensions of p-phenylenediamine in acetone:dimethyl phthalate (1:9) onto separate sites of shaved, intact skin. Responses were scored approximately 24 and 48 hours after application of the test material.

[ ]

**C. Records Retention**

[ All raw data and the final report will be stored in the archives of

**RESULTS AND CONCLUSIONS**

Initial and final body weights are presented in Appendix A.

In the rangefinding test, mild erythema was observed in the 100% and 50% concentration sites. No dermal irritation was observed in the 25% or 10% concentration test sites. Based on the results of the rangefinding study, 100% and 10% emulsions were used for the primary irritation phase.

During the primary irritation phase, mild erythema was observed in 3 test animals at 24 hours and in 6 test animals at 48 hours after treatment in the 100% concentration site. No dermal irritation was observed in the vehicle control or positive control animals. Individual animal data are presented in Table II.

During the induction phase, moderate erythema to necrosis was observed in the vehicle control, positive control and test animals. Blanching was also observed in these animals after each injection. Individual animal data from the induction phase are presented in Table III.

During the challenge phase, mild erythema to necrosis was observed in the test animals at 48 hours after treatment in the 100% concentration site. Mild or moderate erythema was observed in 3 test animals at 48 hours in the 10% concentration site. In the vehicle control animals, mild or moderate erythema was observed in 6 animals at 48 hours in the 100% concentration site; no dermal irritation was observed in the 10% concentration site. Mild erythema to necrosis was observed in the positive control animals by 24 and 48 hours after treatment in the 30% concentration sites. No to moderate erythema was observed in the positive control animals in the 3% concentration site. Dermal responses observed during the challenge phase are summarized in the following table. Individual animal data are presented in Table IV.



[ ]

**TABLE I**  
**SCORING SYSTEM USED TO EVALUATE SKIN RESPONSES**

<b><u>Skin Reaction</u></b>	<b><u>Score</u></b>
No Erythema or Edema	0
Mild Erythema	1
Moderate Erythema	2
Strong Erythema	3
Erythema and Edema	4
Necrosis or Vesicles	5



[ 7

TABLE II (Cont'd)

PRIMARY IRRITATION PHASE

SKIN RESPONSES OBSERVED IN VEHICLE CONTROL  
GUINEA PIGS FOLLOWING TOPICAL EXPOSURE TO DIMETHYL PHTHALATE

GUINEA PIG NUMBER	LEFT FRONT	
	24 hr	48 hr
61608	0	0
61609	0	0
61610	0	0
61611	0	0
61612	0	0
61668	0	0
61669	0	0
61670	0	0
61671	0	0
61672	0	0

[ ]

TABLE II (Cont'd)

PRIMARY IRRITATION PHASE

SKIN RESPONSES OBSERVED IN POSITIVE CONTROL  
GUINEA PIGS FOLLOWING TOPICAL EXPOSURE TO p-PHENYLENEDIAMINE

GUINEA PIG NUMBER	LEFT FRONT 30%		RIGHT FRONT 3%	
	24 hr.	48 hr	24 hr	48 hr
61633	0	0	0	0
61634	0	0	0	0
61635	0	0	0	0
61636	0	0	0	0
61637	0	0	0	0
61697	0	0	0	0
61698	0	0	0	0
61700	0	0	0	0
61701	0	0	0	0
61702	0	0	0	0

[ ]

TABLE III

INDUCTION PHASE

SKIN RESPONSES OBSERVED IN TEST GUINEA PIGS  
FOLLOWING INTRADERMAL INJECTIONS OF [ ]

<u>GUINEA PIG NUMBER</u>	<u>ID1 (LEFT)</u>	<u>ID2 (RIGHT)</u>	<u>ID3 (LEFT)</u>	<u>ID4 (RIGHT)</u>
61613	5B	3B	3B	3B
61614	2B	5B	4B	3B
61615	5B	5B	5B	3B
61616	2B	3B	4B	3B
61617	2B	3B	4B	3B
61673	2B	2B	4B	2B
61674	2B	2B	5B	3B
61675	3B	3B	4B	3B
61676	3B	3B	4B	3B
61677	3B	3B	4B	3B

B = Blanching

[ ]

TABLE III (Cont'd)

INDUCTION PHASE

SKIN RESPONSES OBSERVED IN VEHICLE CONTROL  
GUINEA PIGS FOLLOWING INTRADERMAL INJECTIONS OF DIMETHYL PHTHALATE

<u>GUINEA PIG NUMBER</u>	<u>101 (LEFT)</u>	<u>102 (RIGHT)</u>	<u>103 (LEFT)</u>	<u>104 (RIGHT)</u>
61608	3B	3B	3B	3B
61609	2B	3B	3B	2B
61610	2B	3B	3B	3B
61611	2B	3B	4B	2B
61612	3B	3B	3B	3B
61668	5B	5B	3B	3B
61669	2B	2B	3B	3B
61670	2B	2B	3B	2B
61671	3B	3B	3B	2B
61672	3B	3B	5B	2B

B = Blanching

[ ]

TABLE III (Cont'd)

INDUCTION PHASE

SKIN RESPONSES OBSERVED IN POSITIVE CONTROL  
GUINEA PIGS FOLLOWING INTRADERMAL INJECTIONS OF P-PHENYLENEDIAMINE

<u>GUINEA PIG NUMBER</u>	<u>ID1 (LEFT)</u>	<u>ID2 (RIGHT)</u>	<u>ID3 (LEFT)</u>	<u>ID4 (RIGHT)</u>
61633	3B	3B	2B	3B
61634	3B	3B	4B	3B
61635	3B	3B	3B	3B
61636	3B	3B	5B	3B
61637	3B	3B	4B	3B
61697	3B	3B	3B	2B
61698	3B	5B	3B	3B
61700	3B	5B	5B	5B
61701	3B	3B	5B	5B
61702	5B	5B	3B	3B

B = Blanching



TABLE IV (Cont'd)

CHALLENGE PHASE

SKIN RESPONSES OBSERVED IN POSITIVE CONTROL GROUP  
GUINEA PIGS FOLLOWING TOPICAL APPLICATION OF p-PHENYLENEDIAMINE

GUINEA PIG NUMBER	LEFT FRONT 30%		RIGHT FRONT 3%	
	24 hr	48 hr	24 hr	48 hr
61633	1	1	0	1
61634	3	2	1	1
61635	1	1	0	0
61636	2	1	0	0
61637	1	2	1	1
61697	1	1	0	0
61698	1	1	0	0
61700	5	5	2	1
61701	1	1	1	0
61702	2	3	0	1

[ ]

APPENDIX A

INITIAL AND FINAL BODY WEIGHTS (g)

[ ]  
INITIAL AND FINAL BODY WEIGHTS (g)

<u>Animal Number</u>	<u>Sex</u>	<u>Initial Body Weight</u>	<u>Final Body Weight</u>
Test Group			
61613	Male	485	657
61614	Male	500	680
61615	Male	592	799
61616	Male	586	810
61617	Male	567	728
61673	Female	608	759
61674	Female	523	619
61675	Female	545	681
61676	Female	505	644
61677	Female	483	568

[ ]

INITIAL AND FINAL BODY WEIGHTS (g)

<u>Animal Number</u>	<u>Sex</u>	<u>Initial Body Weight</u>	<u>Final Body Weight</u>
<b>Vehicle Control Group</b>			
61608	Male	617	779
61609	Male	624	874
61610	Male	553	726
61611	Male	532	682
61612	Male	543	750
61668	Female	538	688
61669	Female	499	606
61670	Female	527	621
61671	Female	565	675
61672	Female	519	617

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