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DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-94-13273	89110000107	2/11/11

COMMENTS:

DOES NOT CONTAIN CBI

333094



H.B. Fuller

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FAX COVER SHEET

11 FEB 11 AM 6:05

TO: U.S. EPA
Office of Pollution Prevention and Toxics
Attention: TSCA Declassification Coordinator

FAX NO. (202) 564-8955

FROM: Pam Svedberg

FAX NO. (651) 236-5125

PHONE NO. (651) 236-5184

DATE: February 7, 2011

Number of pages sent (including this cover sheet): 27

RE: Declassification Activity - 8(e) Health & Safety Study, DCN 8895000063

Dear TSCA Declassification Coordinator:

In response to EPA's request and a Freedom of Information Act request, H.B. Fuller is declassifying a primary dermal irritation study originally submitted as an 8(e) study in 1994. Following this cover letter, please find new public versions of two documents:

Final Report: Primary Dermal Irritation Study of WC-0677-A-M-851 in Rabbits
Previously, the only CBI in the study report was the name of the product that was tested. The new public version includes the product name (circled).

Cover Letter and Chemical Composition of Product Tested

- Cover letter. Although it contained no CBI, the original cover letter is being included for reference.
- The former public version of the chemical composition of the tested product. ("Water, Resins, Surfactants")
- The new public version of the chemical composition of the tested product. Disclosed are the CAS numbers and chemical names for the product components (in no particular order). Also disclosed are the percentages of the four components in which the FOIA requester is interested.

Sincerely,

Pam Svedberg

Pam Svedberg

Chemical Control Law Specialist
H.B. Fuller
pam.svedberg@hbfuller.com
Phone: 651-236-5184
Fax: 651-236-5125



DCN 0895000063



PUBLIC
VERSION
(REVISED 2-7-2011)

a CORNING Laboratory Services Company

Sponsor:

H. B. Fuller Company
Vadnais Heights, Minnesota

FINAL REPORT

Study Title:

Primary Dermal Irritation Study of
WC-0677-A-M-851
in Rabbits
(FHSA Regulations)

Author:

Steven M. Glaza

Study Completion Date:

November 4, 1994

Performing Laboratory:

Hazleton Wisconsin, Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704

Laboratory Project Identification:

HWI 40800915

HWI 40800915

COMPLIANCE STATEMENT

Primary Dermal Irritation Study
of WC-0677-A-M-851 in Rabbits
(FHSA Regulations)

This study was conducted in accordance with the U.S. Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 792 (revised September 18, 1989).



Steven M. Glaza
Study Director
Acute Toxicology
Hazleton Wisconsin, Inc.

Date 11-4-94

To the best of my knowledge, the above statement is complete and accurate.

Sponsor's Representative

Date

HWI 40800915

QUALITY ASSURANCE STATEMENT

This report has been reviewed by the Quality Assurance Unit of Hazleton Wisconsin, Inc., in accordance with the Environmental Protection Agency (EPA) Good Laboratory Practice Standards, 40 CFR 792.35 (b) (6) (7). The following inspections were conducted and findings reported to the Study Director and management. Written status reports of inspections and findings are issued to Hazleton management monthly according to standard operating procedures.

<u>Inspection Dates</u>		<u>Phase</u>	<u>Date</u>	<u>Date</u>
<u>From</u>	<u>To</u>		<u>Reported to</u>	<u>to Management</u>
			<u>Study Director</u>	
08/16/94	08/16/94	Protocol Review	08/16/94	09/10/94
09/01/94	09/01/94	Animal Observation	09/01/94	10/10/94
10/25/94	10/25/94	Data/Report Review	10/25/94	11/10/94


 Kori Kong
 Representative, Quality Assurance Unit

11/4/94

 Date

STUDY IDENTIFICATION

Primary Dermal Irritation Study of
WC-0677-A-M-851 in Rabbits
(FHSA Regulations)

Test Material	<u>WC-0677-A-M-851</u>
Sponsor	H. B. Fuller Company 1200 Wolters Blvd. Vadnais Heights, MN 55110
Sponsor's Representative	Anita Boldt H. B. Fuller Company 1200 Wolters Blvd. Vadnais Heights, MN 55110 (612) 481-4895
Study Director	Steven M. Glaza Hazleton Wisconsin, Inc. P.O. Box 7545 Madison, WI 53707-7545 (608) 241-7292
Study Location	Hazleton Wisconsin, Inc. Building No. 3 3802 Packers Avenue Madison, WI 53704
Study Timetable	
In-life Start Date	August 29, 1994
In-life Termination Date	September 14, 1994

KEY PERSONNEL

Acute Toxicology

Steven M. Glaza
Study Director
Manager

Steven R. Sorenson
Study Coordinator

Patricia Padgham
In-life Supervisor

Rose M. Bridge
Report Supervisor

Laboratory Animal Medicine

Cindy J. Cary, DVM
Diplomate, ACLAM
Supervisor

Quality Assurance

Sherry R. W. Petsel
Manager

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SUMMARY

The primary dermal irritation potential of (WC-0677-A-M-85) was evaluated in rabbits under 24-hour occluded conditions. The test material produced well-defined to moderate-severe erythema and very slight to slight edema reactions. Subcutaneous hemorrhaging, desquamation, and denuded areas were also observed. The irritation observed was due, in part, to the mechanical adhesion of the test material and patches to the skin of the rabbits. The primary dermal irritation index (the sum of the 24- and 72-hour scores divided by two) was determined to be 3.6. Irritation continued to be present at the Day 14 observation. Based on these results this test material is not considered to be a primary skin irritant.¹

OBJECTIVE

The objective of this study was to assess the relative level of primary skin irritation of a test material on rabbits under occluded conditions.

All procedures used in this study were in compliance with the Animal Welfare Act Regulations. In the opinion of the Sponsor and study director, the study did not unnecessarily duplicate any previous work.

TEST MATERIAL

Identification

The test material was identified as (WC-0677-A-M-85) and described as a yellow liquid.

Purity and Stability

The Sponsor assumes responsibility for purity and stability determinations (including under test conditions).

Storage and Retention

The test material was stored at room temperature. Any unused test material will be discarded after issuance of the final report according to Hazleton Wisconsin (HWI) Standard Operating Procedure (SOP).

Safety Precautions

The test material handling procedures were according to HWI SOPs and policies.

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TEST SYSTEM

Test Animal

Adult albino rabbits of the Hra:(NZW)SPF strain were procured from HRP, Inc., Kalamazoo, Michigan on August 10, 1994. The animals were maintained at the Hazleton Wisconsin facility at 3802 Packers Avenue, Madison, Wisconsin.

Housing

After receipt, the animals were acclimated for a period of at least 7 days. During acclimation and throughout the study, the animals were individually housed in screen-bottom stainless steel cages in temperature- and humidity-controlled quarters. Environmental controls for the animal room were set to maintain a temperature of 19° to 23°C, a relative humidity of 50% ±20%, and a 12-hour light/12-hour dark lighting cycle. In cases where variations from the required temperature and humidity conditions existed, they were documented and considered to have had no adverse effect on the study outcome. Animal husbandry and housing at HWI complied with the standards outlined in the "Guide for the Care and Use of Laboratory Animals."²

Animal Diet

The animals were provided access to water *ad libitum* and a measured amount of Laboratory Rabbit Diet HF #5326, PMI Feeds, Inc. The feed is routinely analyzed by the manufacturer for nutritional components and environmental contaminants. Samples of the water are periodically analyzed by HWI. There were no known contaminants in the feed or water at levels that would have interfered with or affected the results of the study.

Animal Selection and Preparation of Exposure Area

Three male and three female healthy, acclimated rabbits, weighing from 2,500 to 2,771 g, were selected at random and identified by animal number and corresponding ear tag. On the day before treatment, the back and/or flanks of each animal were clipped free of hair to obtain unblemished skin sites.

Justification for Species Selection

Historically, the New Zealand White albino rabbit has been the animal of choice for evaluating the effect of chemicals on the skin.

PROCEDURES

Preparation of Test Material

The test material was administered as received. The pH of the test material was determined to be 11.4.

Treatment

Just before the test material was applied, epidermal abrasions were made on one exposed area of each rabbit to provide one abraded and one intact test site. The abrasions were sufficiently deep to penetrate the stratum corneum, but not deep enough to penetrate to the dermal layer and cause bleeding.

The test material was applied to the two test sites on each rabbit in the amount of 0.5 mL per site. Each treated area was covered with a 5-cm x 5-cm gauze patch secured with paper tape and overwrapped with Saran Wrap® and Elastoplast® tape to provide an occlusive dressing and maintain the test material in contact with the skin. Collars were used to restrain the test animals during the 24-hour exposure period.

At the end of the 24-hour exposure period, the restraining collars and patches were removed. The test material was removed with Liquid Ivory® soap mixed with warm tap water. Due to patches being firmly adhered to skin, acetone was also used to help remove test material followed by a rinse using tap water and disposable paper towels. The test material was removed from the test sites as thoroughly as possible.

Reason for Route of Administration

Historically, the dermal route has been the route of choice based on the method of Draize.³

Observations

Approximately 30 minutes after removal of the test material, the degree of erythema and edema at each test site was read according to the Draize technique (recorded as the 24-hour score). A second reading was taken at 72 hours to determine the primary dermal irritation index for the test material. Additional observations were made at 96 hours and Days 7 and 14. The untreated skin of each animal was used for comparison.

Animals were weighed just before test material administration and at Days 7 and 14.

Termination

At termination of the experimental phase, all animals were designated to be euthanized and discarded.

Statistical Analyses

No statistical analyses were required by the protocol.

Location of Raw Data, Records, and Final Report

The raw data, records, and an original signed copy of the final report will be retained in the archives of HWI in accordance with HWI SOP.

RESULTS/DISCUSSION

Individual dermal irritation scores are presented in Table 1. Average primary dermal irritation scores and individual body weights are in Tables 2 and 3, respectively.

The primary dermal irritation potential of WC-0677-A-M-851 was evaluated when applied to the skin of rabbits under 24-hour occluded conditions. The test material produced well-defined to moderate-severe erythema and very slight to slight edema reactions. Subcutaneous hemorrhaging, desquamation, and denuded areas were also observed. The irritation observed was due, in part, to the mechanical adhesion of the test material and patches to the skin of the rabbits. The primary dermal irritation index (the sum of the 24- and 72-hour scores divided by two) was determined to be 3.6. Irritation continued to be present at the 14-day observation.

CONCLUSION

Based on the results of this study, this test material, WC-0677-A-M-851 is not considered to be a primary skin irritant under 24-hour occluded conditions.

SIGNATURE



Steven M. Glaza
Study Director
Acute Toxicology

Date 11-4-94

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REFERENCES

1. "Federal Hazardous Substances Act Regulations," *Code of Federal Regulations*, Title 16, Section 1500.3, pp. 325-342 (January 1, 1985).
2. NIH Publication No. 86-23 (revised 1985).
3. Draize, J. H., "Primary Irritation of the Skin," In: *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics - Dermal Toxicity*, Association of Food and Drug Officials of the U.S., pp. 46-47 (1959).

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Table 1

Individual Dermal Irritation Scores

Animal Number	Erythema					Edema				
	Hour			Day		Hour			Day	
	24	72	96	7	14	24	72	96	7	14
<u>Intact Site</u>										
F51884	3 ^a	3 ^a	3 ^a	0	0	1	1	1	0	0
F51885	2	2	2	1	1 ^d	2	1	1	2	1
F51886	2	1	1	1	1 ^c	1	1	1	1	1
F51887	2	2	2	2	1	1	1	1	1	1
F51899	3 ^a	3 ^a	3 ^a	2	0	1	1	1	1	0
F51889	2	2	2	2	0	1	1	1	1	0
<u>Abraded Site</u>										
F51884	3 ^a	3 ^a	3 ^a	0 ^d	0	1	1	1	0	0
F51885	3 ^a	3 ^a	3 ^a	1 ^d	1 ^d	2	1	1	1	1
F51886	3 ^a	2	2	1	0	1	1	1	0	0
F51887	3 ^a	2	2	2	2	1	1	1	1	1
F51899	3 ^a	3 ^a	3 ^a	2 ^d	1 ^d	1	1	1	1	1
F51889	2	1	1	1	0	1	1	1	1	0

a Subcutaneous hemorrhage.

c Desquamation.

d Denuded areas.

Table 2

Average Primary Dermal Irritation Scores

<u>Observation Period</u>	<u>Average Score*</u>
24 Hour	3.8
72 Hour	3.3
96 Hour	3.3
Day 7	2.1
Day 14	1.1
PDII**	3.6

* The average primary dermal irritation score is the total dermal irritation score for all the animals (erythema and edema) divided by the number of test sites (12) at each observation period.

** The primary dermal irritation index (PDII) is the sum of the average 24- and 72-hour primary dermal irritation scores for intact and abraded sites, divided by two and rounded to the nearest tenth.

Table 3

Individual Body Weights (g)

<u>Animal Number</u>	<u>Sex</u>	<u>Initial</u>	<u>Day 7</u>	<u>Day 14</u>
F51884	M	2,500	2,610	2,767
F51885	M	2,581	2,667	2,549
F51886	M	2,771	2,826	2,890
F51887	F	2,617	2,725	2,902
F51899	F	2,603	2,641	2,792
F51889	F	2,671	2,763	2,831

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APPENDIX

Protocol

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CORNING

Sponsor:

H. B. Fuller Company
Vadnais Heights, Minnesota

PROTOCOL TP3208

Study Title:

Primary Dermal Irritation Study of (WC-0677-A-M-851) in Rabbits
(FHSA Regulations)

Date:

August 19, 1994

Performing Laboratory:

Hazleton Wisconsin, Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704

Laboratory Project Identification:

HWI 40800915

STUDY IDENTIFICATION

Primary Dermal Irritation Study of WC-0677-A-M-851 in Rabbits
(FHSA Regulations)

HWI No.	40800915
Test Material	<u>WC-0677-A-M-851</u>
Sponsor	H. B. Fuller Company 1200 Wolters Blvd. Vadnais Heights, MN 55110
Sponsor's Representative	Anita Boldt H. B. Fuller Company 1200 Wolters Blvd. Vadnais Heights, MN 55110 (612) 481-3398
Study Director	Steven M. Glaza Hazleton Wisconsin, Inc. P.O. Box 7545 Madison, WI 53707-7545 (608) 241-7292
Study Location	Hazleton Wisconsin, Inc. Building No. 3 3802 Packers Avenue Madison, WI 53704
Proposed Study Timetable	
Experimental Start Date	Week of August 22, 1994
Experimental Termination Date	Week of September 12, 1994
Final Report Date	Week of October 24, 1994

1. Study
Primary Dermal Irritation Study in Rabbits (FHSA Regulations)
2. Purpose
To assess the relative level of primary skin irritation of a test material on rabbits under occluded conditions
3. Regulatory Compliance
This study will be conducted in accordance with the following Good Laboratory Practice Regulations/Standards/Guidelines:

- Conduct as a Nonregulated Study
- 21 CFR 58 (FDA)
- 40 CFR 160 (EPA-FIFRA)
- 40 CFR 792 (EPA-TSCA)
- C(81)30 (Final) (OECD)
- 59 Nohsan No. 3850 (Japanese MAFF)
- Notification No. 313 (Japanese MOHW)

All procedures in this protocol are in compliance with the Animal Welfare Act Regulations. In the opinion of the Sponsor and study director, the study does not unnecessarily duplicate any previous work.

4. Quality Assurance
The protocol, study conduct, and the final report will be audited by the Quality Assurance Unit in accordance with Hazleton Wisconsin (HWI) Standard Operating Procedures (SOPs) and policies.
5. Test Material
 - A. Identification
WC-0677-A-M-851
 - B. Physical Description
Yellow liquid
 - C. Purity and Stability
The Sponsor assumes responsibility for purity and stability determinations (including under test conditions).
 - D. Storage
Room temperature
 - E. Reserve Samples
Studies of less than 4 weeks in experimental duration will not have reserve samples retained.

Reserve sample(s) of each batch/lot of test material will be taken if this study is more than 4 weeks in experimental duration.

The test material reserve sample will be stored at HWI in a freezer set to maintain a temperature of below 0°C for 10 years per HWI SOP. The Sponsor will be contacted after 10 years for disposition in accordance with the appropriate regulatory Good Laboratory Practices.

F. Retention

Any unused test material will be discarded after issuance of the final report, unless directed otherwise by the Sponsor.

G. Safety Precautions

As required by HWI SOPs and policies

6. Experimental Design

A. Animals

(1) Species
Rabbit

(2) Strain/Source
Hra: (NZW)SPF/HRP, Inc.

(3) Age at Initiation
Adult

(4) Weight at Initiation
2.0 to 3.5 kg

(5) Number and Sex
6 of any sex

(6) Identification
Individual numbered ear tag

(7) Husbandry

(a) Housing
Individually, in screen-bottom stainless steel cages (heavy gauge)

(b) Food
A measured amount of Laboratory Rabbit Diet HF #5326 (PMI Feeds, Inc.). The food is routinely analyzed by the manufacturer for nutritional components and environmental contaminants.

- (c) Water
Ad libitum from an automatic system. Samples of the water are analyzed by HWI for total dissolved solids, hardness, and specified microbiological content and for selected elements, heavy metals, organophosphates, and chlorinated hydrocarbons.
 - (d) Contaminants
There are no known contaminants in the food or water that would interfere with this study.
 - (e) Environment
Environmental controls for the animal room will be set to maintain a temperature of 19 to 23°C, a relative humidity of 50% ±20%, and a 12-hour light/12-hour dark cycle.
 - (f) Acclimation
At least 7 days
- (8) Selection of Test Animals
Based on health and body weight according to HWI SOPs. An adequate number of extra animals will be purchased so that no animal in obviously poor health is placed on test.
 - (9) Justification for Species Selection
Historically, the New Zealand White albino rabbit has been the animal of choice for evaluating the effect of chemicals on the skin.
- B. Dose Administration
- (1) Preparation of Exposure Area
On the day before test material administration, remove the hair from the back and, if necessary (to obtain unblemished skin) the flanks of each animal with an electric clipper. The treatment sites will be inspected for interfering lesions, irritation, or defects that would preclude the use of any of the animals. On the day of treatment, an abraded area will be made on the exposed area of each rabbit to provide one abraded and one intact test site. The abrasions will be deep enough to penetrate the stratum corneum, but not deep enough to penetrate to the dermal layer and cause bleeding. The animals will be clipped as needed throughout the study.

(2) Dose Administration

Before administration of the test material the pH of the material will be determined (if possible). The test material will be applied to the two test areas on each rabbit, in the amount of 0.5 mL/area. The test material will be applied undiluted. The areas of application will be covered with a 5-cm x 5-cm gauze patch secured with paper tape and overwrapped with Saran Wrap[®] and Elastoplast[®] tape to maintain the test material in contact with the skin under occluded conditions. The rabbits will be collared during the 24-hour application period.

(3) Reason for Route of Administration

Historically, the dermal route has been the route of choice based on the method of Draize.

C. Observation of Animals

(1) Reading of Dermal Irritation

Approximately 30 minutes after removing the patches and collars, the degree of erythema and edema will be evaluated according to the Draize technique (Attachment 1) and recorded as the 24-hour score. The untreated skin of each animal will serve as its own control. A second reading will be taken at approximately 72 hours to determine the primary irritation index for the sample. If irritation is present at the 72-hour examination, observations will be made at approximately 96 hours and on Days 7, 14, and 21. Based on the level of irritation observed at any of these time points the study may be terminated at the direction of the study director.

(2) Body Weights

Before test material administration and weekly thereafter (when applicable).

D. Pathology

Any animals dying during the study will be subjected to an abbreviated gross necropsy examination and all abnormalities will be recorded. After necropsy, the animals will be discarded and no tissues will be saved. At termination of the experimental phase, surviving animals will be designated to be sacrificed and discarded.

E. Statistical Analyses

No statistical analyses are required.

7. Report

A final report including those items listed below will be submitted.

Description of the test material
Description of the test system
Procedures
Dates of experimental initiation and termination
Tabulation of irritation data
Primary dermal irritation index

8. Location of Raw Data, Records, and Final Report

Original data, or copies thereof, will be available at HWI to facilitate auditing the study during its progress and before acceptance of the final report. When the final report is completed, all original paper data, including those items listed below will be retained in the archives of HWI according to HWI SOP.

Protocol and protocol amendments
Dose preparation records
In-life records
 Body weights
 Dose administration
 Observations
Anatomical pathology records (if applicable)
Study correspondence
Final report (original signed copy)

The following supporting records will be retained at HWI but will not be archived with the study data.

Animal receipt/acclimation records
Water analysis records
Animal room temperature and humidity records
Refrigerator and freezer temperature records
Instrument calibration and maintenance records

TP3208
Page 8

PROTOCOL APPROVAL

Anita Boldt
Anita Boldt
Sponsor's Representative
H. B. Fuller Company

8-23-94
Date

Steven M. Glaza
Steven M. Glaza
Study Director
Acute Toxicology
Hazleton Wisconsin, Inc.

8-19-94
Date

Jacy Thada
Representative
Quality Assurance Unit
Hazleton Wisconsin, Inc.

8-19-94
Date

(40800915.pr)HD

Attachment 1

Primary Dermal Irritation Scoring Scale
(Draize Technique)

(1) Erythema and Eschar Formation

No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	<u>4</u>
Highest possible erythema score	4

(2) Edema Formation

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges are well defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised approximately 1 mm and extending beyond area of exposure)	<u>4</u>
Highest possible edema score	4

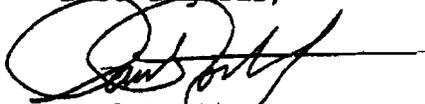
 H.B. Fuller Company
1200 County Road "E" West
Arden Hills, Minnesota 55112-3792
FAX: 612-481-4896
(612) 481-4816

November 18, 1994

Environmental Protection Agency
Chemical Control Division
Chemical Testing Branch, 7405
401 "M" Street
Washington, D.C. 20460

Fuller would like to report under 8(e) the results of a Primary dermal irritation study of one of it's products. Attached is the chemical composition of the product tested. If you have any questions, please feel free to contact me.

Best regards,



Paul Rothweiler
TSCA Compliance Manager

cc: Sarah Oebser
Diane Helland

f:\rothweil\epa\8e0677.pub

From:HB FULLER

02/07/2011 10:17

#016 P.026/027

Water
Resins
Surfactants

DCN 8895 000063

PUBLIC VERSION
(REVISED 2-7-2011)

CAS	7732-18-5		Water
CAS	9010-98-4		1,3-Butadiene, 2-chloro-, homopolymer
CAS	7646-85-7		Zinc chloride (ZnCl ₂)
CAS	1314-13-2		Zinc oxide (ZnO)
CAS	119-47-1		Phenol, 2,2'-methylenebis[6- (1,1-dimethylethyl)-4-methyl-
CAS	34590-94-8	.3850	Propanol, 1(or 2)-(2- methoxymethylethoxy)-
CAS	1310-58-3	.3480	Potassium hydroxide (K(OH))
CAS	126-99-8		1,3-Butadiene, 2-chloro-
CAS	1310-73-2	.1740	Sodium hydroxide (Na(OH))
CAS	11138-66-2		Xanthan gum
CAS	25265-71-8		Propanol, oxybis-
CAS	9084-06-4		Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt
CAS	1336-21-6		Ammonium hydroxide ((NH ₄)(OH))
CAS	2634-33-5		1,2-Benzisothiazol-3(2H)-one
CAS	12199-37-0		Smectite-group minerals
CAS	35691-65-7		Pentanedinitrile, 2-bromo-2- (bromomethyl)-
CAS	7664-41-7		Ammonia
CAS	106-99-0		1,3-Butadiene
CAS	108-88-3		Benzene, methyl-
CAS	7439-92-1		Lead
CAS	7440-38-2		Arsenic
CAS	8052-41-3		Stoddard solvent
CAS	64742-47-8	.6196	Distillates, petroleum, hydrotreated light
CAS	7757-82-6		Sulfuric acid disodium salt
UNK	UNKNOWN		

These lists include impurities and by-products that may be present in the formulations.