UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

009265

FEB 18 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: Review of Toxicology Studies with Bora-Care™ (sodium octaborate decahydrate) to support registration (label revision) of test substance. (Toxchem No. 406B; HED Project No. 1-2434; Barcode: D168914)

FROM: Steven L. Malish, Ph.D., Toxicologist S.L. Malish 2/12/92
Tox. Branch II, Review Section IV
HED (H7509C)

TO: Susan Lewis, Product Manager (21)
Registration Division
(H7505C)

THRU: Elizabeth Doyle, Ph.D., Section Head E.A. Doyle 2/12/92
Tox. Branch II, Review Section IV
HED (H7509C)

and

Marcia van Gemert, Ph.D., Branch Chief
Tox Branch II
HED (H7509C) Mvangemert 2/12/92

ACTION REQUESTED: Review of toxicology studies

Overview of Studies:

The oral LD_{50} of the test substance, sodium octaborate tetrahydrate, was > (greater than) 5.0 gm/kg; the dermal LD_{50} was >2.0 gm/kg and the 4 hour inhalation LC_{50} was >5.1 mg/L.

The test material was not considered a primary irritant or dermal sensitizer. The primary eye irritation study produced only mild, transient irritation.

1 of 19

Studies Summarized

1. MRID 419668-01 Acute Oral Toxicity Study (81-1) - rat; Core - guideline (limit test).

The LD_{50} was calculated to be >5 gm/kg (Toxicity Category IV).

2. MRID 419668-02 Acute Dermal Toxicity Study (81-2); Core - guideline (limit test).

The LD_{50} in the rabbit was calculated to be >2.0 gm/kg (Toxicity Category III).

3. MRID 419668-03 Acute Inhalation Toxicity Study (81-3) - rat; Core - guideline.

The four (4) hour LC_{50} was calculated to be >5.1 mg/L (Toxicity Category IV).

4. MRID 419668-04 Primary Eye Irritation Study (81-4) - rabbit; Core - guideline.

Transient, mild primary irritation occurred (Toxicity Category III).

5. MRID 419668-05 Primary Dermal Irritation Study (81-5); Core - guideline.

The test material was not considered to be a dermal irritant (Toxicity Category IV).

6. MRID 419668-6; Dermal Sensitization - guinea pig; Core - guideline.

The test material was not considered to be a dermal sensitizer.

009265

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Secondary Reviewer: Elizabeth Doyle, Ph.D. E.A. Doyle 2/12/92
Tox. Branch II, Section IV (H7509C)

DATA EVALUATION REPORT

STUDY TYPE:	Acute Oral Toxicity Study - Rat (81-1)
MRID:	419668-01
TEST MATERIAL:	Bora-Care
SYNONYMS:	disodium octaborate decahydrate
SUBMITTING COMPANY:	Nisus Corporation Cherokee Place 101 Concord Street North Knoxville, TN 37919
SPONSOR:	Perma-Chink Systems, Inc. 1605 Prosser Rd. Knoxville, TN 37914
AGENT for SPONSOR:	RegWest Co. P.O. Box 2220 Greeley, CO 80632-2220
TESTING FACILITY:	Tox Monitor Laboratories, Inc 33 West Chicago Ave. Oak Park, IL 60302
TITLE OF REPORT:	Acute Oral Toxicity Study
REPORT NO.:	90-166-1
AUTHORS:	Michael Kukulinski, B.S., L.A.T.G.
REPORT ISSUED:	August 1, 1990
QUALITY ASSURANCE:	Quality assurance documentation was provided.
CONCLUSIONS:	The acute oral LD_{50} was greater than 5 gm/kg.
CLASSIFICATION:	Core - guideline (limit test) This study satisfies the guideline requirements 81-1 for an "Acute Oral Toxicity Study."
TOXICITY CATEGORY:	-IV- (LD_{50} greater than 5.0 gm/kg (40 CFR 156.10, p.79, 7/1/89).

A. Materials:

1. Test Compound:	Chemical:	disodium octaborate tetrahydrate
	Label:	Bora-Care
	Lot No.	1022
	Description:	clear liquid
	Purity:	40% active ingredient
	Stability:	stable
2. Test Animal:	Species:	Rat
	Strain:	Sprague-Dawley derived
	Groups:	One (1) group of 10 animals/sex
	Weight:	200 - 300 gms
	Age:	6 - 10 weeks old
	Source:	Bio-Lab, St. Paul, MN

Study Design:

Rats were acclimated at least 4 days prior to treatment. Purina Rat Chow and water were available ad libitum. All test animals were fasted overnight prior to dosing.

All animals were dosed, neat, by oral gavage with the test material at a dose of 5 gm/kg of body weight. After dosing, the test animals were observed frequently during the day of dosing and once daily for 14 days following dosing for any toxic or deleterious effects. The weight of each animal was determined prior to dosing and at 7 and 14 days.

All test animals were sacrificed by CO_2 asphyxiation at the end of the observation period. A complete gross necropsy was performed.

RESULTS:

Weight: All animals gained weight throughout the 14 day study.

Table 1

Mean Body Weight Data
(gm)

Day	Males	Females
0	235	225
7	277	245
14	331	251

Observation and Gross Necropsy:

Animals were considered to be unremarkable throughout the 14 day observation period and at the gross necropsy examination.

SUMMARY:

The administration of the test substance by oral gavage at a dose level of 5 gm/kg of body weight to male and female rats produced no mortality.

CONCLUSIONS:

The acute oral LD_{50} was greater than 5 gm/kg.

009265

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Tox. Branch II, Section IV (H7509C)

DATA EVALUATION REPORT

STUDY TYPE:	Acute Dermal Toxicity Study - Rat (81-2)
MRID:	419668-02
TEST MATERIAL:	Bora-Care
SYNONYMS:	disodium octaborate decahydrate
SUBMITTING COMPANY:	Nisus Corporation Cherokee Place 101 Concord Street North Knoxville, TN 37919
SPONSOR:	Perma-Chink Systems, Inc. 1505 Prosser Rd. Knoxville, TN 37914
AGENT for SPONSOR:	RegWest Co. P.O. Box 2220 Greeley, CO 80632-2220
TESTING FACILITY:	Tox Monitor Laboratories, Inc. 33 West Chicago Ave. Oak Park, IL 60302
REPORT NO.:	90-166-2
TITLE OF REPORT:	Acute Dermal Toxicity Study of TM 90-166
AUTHORS:	Michael Kukulinski, B.S., L.A.T.G.
REPORT ISSUED:	August 1, 1990
QUALITY ASSURANCE:	Quality assurance documentation was provided.
CONCLUSION:	The acute dermal LD_{50} of the test article was greater than 2.0 gm/kg.
CLASSIFICATION:	Core - guideline (limit test) This study satisfies the guidelines requirements 81-2 for an "Acute Dermal Toxicity Study."

TOXICITY CATEGORY: - III- (Dermal LD_{50} 2 thru 20 gm/kg) as per 40 CFR 156.10, p.79, 7/1/89.

A. MATERIALS:

1. Test Compound:

Chemical:	disodium octaborate tetrahydrate
Label:	Bora-Care
Lot No.	1022
Description:	clear liquid
Purity:	40% active ingredient
Stability:	Stable

2. Test Animals:

Species:	white rabbit
Strain:	New Zealand White
Groups:	One (1) group of 5 animals/sex
Weight:	2 - 3 Kg
Age:	8 - 12 weeks old
Source:	Scientific Small Animals Laboratory, Arlington Hgts. Il

Study Design:

All animals were acclimated for a minimum of 5 days. Rabbits were given Purina Rabbit Chow and water ad libitum.

Twenty-four hours before application of the test material, the trunk of the rabbits were shaved with electric clippers.

Body weights were determined prior to dosing and on days 7 and 14, the end of the study. The test material was applied neat at 2 gm/kg of body weight. A sleeve of plastic sheeting was fitted over the shaven trunk of the animal and secured with surgical tape. The test material remained in contact with the skin for a 24 hour period after which time the wrap was removed and any remaining test article wiped off.

The animals were observed on the day of dosing and once daily for 14 days following dosing for any toxic or deleterious effects.

All test animals at the end of the observation period were sacrificed by an injection of T-61 euthanasia solution. A complete gross necropsy was performed.

RESULTS:

Weight

Animals of both sexes gained weight during the 14 day observation period (Table 1).

Table 1

Mean Body Weight Data
(Kg)

Day	Males	Females
0	2.14	2.27
7	2.26	2.41
14	2.52	2.63

Observations and Necropsy

Animals were considered to be unremarkable throughout the 14 day observation period and at the gross necropsy examination.

SUMMARY:

The administration of the test substance by dermal administration at a dose of 2 gm/kg of body weight to male and female animals produced no mortality. The dermal LD_{50} of the test substance was greater than 2 gm/kg of body weight.

CONCLUSION:

The acute dermal LD_{50} of the test article was greater than 2.0 gm/kg.

009265

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Tox. Branch II, Section IV (H7509C)

DATA EVALUATION REPORT

STUDY TYPE:	Acute Inhalation Toxicity Study (81-3)
MRID NO.:	419668-03
TEST MATERIAL:	Bora-Care
SYNONYMS:	disodium octaborate decahydrate
COMPANY:	Nisus Corporation Cherokee Place 101 Concord Street North Knoxville, TN 37919
SPONSOR:	Perma-Chink Systems, Inc. 1605 Prosser Rd. Knoxville, TN 37914
AGENT:	RegWest Co. P.O. Box 2220 Greeley, CO 80632-2220
TESTING FACILITY:	Tox Monitor Laboratories, Inc. 33 West Chicago Ave. Oak Park, Ill 60302
REPORT NUMBER:	90-166-3
TITLE OF REPORT:	EPA/FIFRA Acute Inhalation Toxicity Study of TM 90-166-3
AUTHORS:	Michael Kukulinski, B.S., L.A.T.G.
REPORT ISSUED:	August 8, 1990
QUALITY ASSURANCE:	Quality assurance documentation was provided
CONCLUSIONS:	The LC_{50} (4 hours) > 5.06 mg/L
CLASSIFICATION:	Core - guideline (limit test) This study satisfies the guideline requirements (81-3) for an "Acute Inhalation Toxicity Study".

9

TOXICITY CATEGORY: -IV- as per 40 CFR 156.10 p. 79, 7/1/89.

A. MATERIALS

1. Test Compound:	Chemical:	disodium octaborate tetrahydrate
	Label:	Bora-Care
	Lot No.	1022
	Description:	clear liquid
	Purity:	40% active ingredient
	Stability:	stable
2. Test Animal:	Animal:	albino rat
	Strain:	Sprague-Dawley derived
	Groups:	One (1) group of 5 animals/sex
	Weight:	males 223 - 260 gm females 200 - 216 gm
	Age:	not available
	Source:	Bio-Lab, Inc. St. Paul, MN

Rats were conditioned for a least 4 days prior to the study initiation. All animals received Purina Lab Chow and water ad libitum.

B. STUDY DESIGN:

Sample Preparation and Generation:

The test material was diluted to a 50/50 mixture by weight in tap water and the aerosol generated by using a Spraying System Co. Model 1/4K-SS air atomizing nozzle assembly. The nozzle siphoned the test article from a reservoir.

The exposure was conducted in a 400 L stainless steel chamber. Room air entered at the top of the chamber and exited through the bottom. The aerosol entered the chamber through a hole in the rear of the chamber.

Exposure duration was for 4 hours (total of 265 minutes of which 25 minutes was for chamber equilibration).

Concentration Measurements:

The actual concentration was determined by gravimetric analysis based on samples taken at 30 minute intervals from the breathing zone of the test animals. The time weighted gravimetric concentration was 5.06 mg/L of air for both male and female animals.

Particle Size Determination

Particle size distribution of the test material aerosol was determined at 120 minutes during the exposure period using an Anderson 1 ACFM Ambient Sampler with Preseperator.

The mean particle size of the aerosol was 4.09 microns with a geometric standard deviation of 3.2. Particles greater than 10 or less than 1 micron were 22 and 29%, respectively.

Airflow, Chamber Temperature and Relative Humidity

The chamber was operated at a flow rate of 10 air changes per hour.

During the 4 hour study, the temperature ranged between 69 and 71° F. while relative humidity increased from an initial value of 58% to 91%.

C. OBSERVATIONS:

The rats were observed for mortality and pharmacotoxic signs frequently during the day of exposure and daily, thereafter, for 14 days. Body weights were obtained at initiation, day 7 and 14.

Male rats (4/5) gained weight when compared to the initial readings at 7 and 14 days. Female rats (5/5) showed a weight decrease at day 7 but weight gain was noted in all animals at day 14.

At the end of the exposure (265 minutes) all animals were inactive and had wet, matted fur. All animals showed hypoactivity 1 hour after exposure. At 2.5 hours, 3/5 males showed salivation. Except for the male that died on day 3, animals were unremarkable throughout the 14 day study.

The single male animal found dead on day 3 was hypoactive at 1, 2.5 and 4 hours after exposure. Salivation was noted at 4 hours, day 1, and day 2 together with prostration.

Pathology:

All animals were sacrificed by carbon dioxide asphyxiation at termination on day 14. Gross pathological examination was performed on any rats dying during the study and on all survivors at the end of the 14 day observation period.

The male animal that died on day 3 that had mottled lungs: the other animals were considered to be unremarkable.

D. CONCLUSIONS:

The LC_{50} (4 hours) was calculated to be greater than 5.06 mg/L.

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DATA EVALUATION REPORT

STUDY TYPE:	Primary Eye Irritation Study (81-4)
MRID NO.:	419668-04
TEST MATERIAL:	Bora-Care
SYNONYMS:	disodium octaborate decahydrate
COMPANY:	Nisus Corporation Cherokee Place 101 Concord Street North Knoxville, TN 37919
SPONSOR:	Perma-Chink Systems, Inc. 1605 Prosser Rd. Knoxville, TN 37914
AGENT for SPONSOR:	RegWest Co. P.O. Box 2220 Greeley, CO 80632-2220
TESTING FACILITY:	Tox Monitor Laboratories, Inc. 33 West Chicago Ave. Oak Park, IL 60302
REPORT NUMBER:	90-166-4
TITLE OF REPORT:	Primary Eye Irritation Study of TM 90-166
AUTHORS:	Michael Kukulinski, B.S., L.A.T.G.
REPORT ISSUED:	August 1, 1990
QUALITY ASSURANCE:	Quality assurance documentation was provided.
CONCLUSIONS:	Transient, mild primary eye irritant
CLASSIFICATION:	Core - guideline This study satisfies the guideline requirements 81-4 for a "Primary Eye Irritation Study."
TOXICITY CATEGORY:	-III- (No corneal opacity, irritation reversible within 7 days.

12

A. MATERIALS:

1. Test Compound:	Chemical:	disodium octaborate tetrahydrate
	Label:	Bora-Care
	Lot No.	1022
	Description:	clear liquid
	Purity:	40%
	Stability:	stable
2. Test Animal:	Species:	albino rabbit
	Strain:	New Zealand White
	Groups:	One (1) group of 6 animals
	Weight:	2.09 - 2.51 kg
	Age:	8 - 10 Weeks old
	Source:	Scientific Small Animals Laboratory, Arlington Hgts, Il

B. STUDY DESIGN:

Rabbits were conditioned for a least 4 days prior to the study initiation and received Purina Rabbit Chow and water ad libitum.

Animals were weighed at the initiation and at termination (72 hours).

Six (6) rabbits were selected and a dose of 0.1 ml of the test material was installed into the conjunctival sac of the right eye of each rabbit; the eyelids were held together for 1 second. The contralateral eye served as the untreated control.

The eyes were examined at 1, 24, 48 and 72 hours after treatment. A 2% sodium fluorescein and ultraviolet light were employed to reveal possible corneal injury.

Results

The mean conjunctival score was 6.3 at 1 hour and 1.0 at 24 hours. Animals were unremarkable at the 48 and 72 hour time periods (Table 1). The scale for scoring of ocular lesions was presented in Table 2.

Animals weights were considered to be unremarkable.

SUMMARY:

Transient mild irritation was noted in the primary eye irritation study in albino rabbits.

CONCLUSION:

The test compound was considered to be a mild primary eye irritant.

Table 1

Group Mean Eye Irritation Scores (Draize Values)

Rabbit Number	Tissue	Observation Time (hrs)			
		1	24	48	72
609	Cornea	0	0	0	0
	Iris	0	0	0	0
	Conjunct.(R-S-D)	4	0	0	0
	Total Score	4	0	0	0
610	Cornea	0	0	0	0
	Iris	0	0	0	0
	Conjunct.(R-S-D)	6	2	0	0
	Total Score	6	2	0	0
611	Cornea	0	0	0	0
	Iris	0	0	0	0
	Conjunct.	4	2	0	0
	Total Score	4	2	0	0
612	Cornea	0	0	0	0
	Iris	0	0	0	0
	Conjunct.(R-S-D)	8	0	0	0
	Total Score	8	0	0	0
613	Cornea	0	0	0	0
	Iris	0	0	0	0
	Conjunct.(R-S-D)	8	2	0	0
	Total Score	8	2	0	0
614	Cornea	0	0	0	0
	Iris	0	0	0	0
	Conjunct.(R-S-D)	8	0	0	0
	Total Score	8	0	0	0
Mean Score	Cornea	0	0	0	0
	Iris	0	0	0	0
	Conjunct.(R-S-D)	6.3	1	0	0
	Mean Score	6.3	1	0	0

R = redness
S = swelling
D = discharge
Score = (R+C+D)x2

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DATA EVALUATION REPORT

STUDY TYPE:	Primary Dermal Irritation Study (81-5)
MRID NO.:	419668-05
TEST MATERIAL:	Bora-Care
SYNONYMS:	disodium octaborate tetrahydrate
COMPANY:	Nisus Corporation Cherokee Place 101 Concord Street North Knoxville, TN 37919
SPONSOR:	Perma-Chink Systems, Inc. 1605 Prosser Rd. Knoxville, TN 37914
AGENT for SPONSOR	RegWest Co. P.O. Box 2220 Greeley, CO 80632-2220
TESTING FACILITY:	Tox Monitor Laboratories, Inc. 33 West Chicago Ave. Oak Park, IL 60302
REPORT NUMBER:	90-166-5
TITLE OF REPORT:	Primary Skin Irritation Study of TM 90-166-5
AUTHORS:	Michael Kukulinski, B.S., L.A.T.G.
REPORT ISSUED:	August 1, 1990
QUALITY ASSURANCE:	Quality assurance documentation was provided.
CONCLUSIONS:	The material was not considered to be a primary dermal irritant.
CLASSIFICATION:	Core - guideline This study satisfies requirements 81-5 for a "Primary Dermal Irritation Study".
TOXICITY CATEGORY:	-IV- as per 40 CFR 156.10, p. 79, 7/1/89.

A. MATERIALS

1. Test Compound:	Chemical:	disodium octaborate tetrahydrate
	Label:	Bora-Care
	Lot No.	1022
	Description:	clear liquid
	Purity:	40% active ingredient
	Stability:	stable
2. Test Animal:	Species:	albino rabbit
	Strain:	New Zealand White
	Groups:	One (1) group of 6 male animals
	Weight:	2.02 - 2.77 Kg
	Age:	information not available
	Source:	Scientific Small Animals Laboratory, Arlington Hgts, Il

B. STUDY DESIGN:

Rabbits were conditioned for a least 4 days prior to the study initiation and received Purina Rabbit Chow and water ad libitum.

Animals were weighed at the initiation and termination of the study.

The day before study initiation, electric clippers were used to remove the hair from the abdomen and sides of six rabbits. A 0.5 ml aliquot of the test material was applied, neat, to the site and covered with a 1 square inch gauze patch which was then covered by a 4 mil plastic wrap. At the end of the 4 hour contact period, the gauze and wrap were removed and excess material wiped from the site. The site was observed and scored. The study was terminated at the end of 3 days.

Dermal irritation readings were performed approximately 30 minutes after the patches were removed and 24, 48 and 72 hours after treatment. Grading and scoring of irritation were performed in accordance with the Draize scoring system (Table 1).

C. RESULTS:

A maximum erythema and edema score of 1 was noted respectively in 4/6 and 2/6 rabbits at the 4.5 hour observation period. Scores at other time periods were unremarkable.

No systemic toxicological effects were noted.

D. CONCLUSIONS:

The material was not considered to be a primary irritant.

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DATA EVALUATION REPORT

STUDY TYPE: Dermal Sensitization Study (81-6)

MRID NO.: 419668-06

TEST MATERIAL: Bora-Care

SYNONYMS: disodium octaborate tetrahydrate

COMPANY: Nisus Corporation
Cherokee Place
101 Concord Street North
Knoxville, TN 37919

SPONSOR: Perma-Chink Systems, Inc.
1605 Prosser Rd.
Knoxville, TN 37914

AGENT: RegWest Co.
P.O. Box 2220
Greeley, CO 80632-2220

TESTING FACILITY: Biological Safety Research, Inc.
519 West Hackley Ave.
Muskegon, MI 49444

REPORT NUMBER: BSR Study 023-001

TITLE OF REPORT: Skin Sensitization Test of Bora-Care Lot No. 1022 in Albino Guinea Pigs (Modified Buehler Test)

AUTHORS: Michael Kukulinski, B.S., L.A.T.G.

REPORT ISSUED: August 3, 1990

QUALITY ASSURANCE: Quality assurance documentation was provided.

CONCLUSIONS: The test substance was not considered to be a dermal sensitizing agent.

CLASSIFICATION: Core - guideline

This study satisfies the guideline requirements 81-6 for a "Dermal Sensitization Study"

A. MATERIALS:

1. Test Compound:	Chemical:	disodium octaborate tetrahydrate
	Label:	Bora-Care
	Lot No.	1022
	Description:	clear liquid
	Purity:	40% active ingredient
	Stability:	stable
2. Test Animals:	Species	guinea pig
	Strain:	Hartley
	Groups:	3 groups (10 males - treated; 6 males - positive controls; 2 males - negative control).
	Weight:	224 to 275 gms
	Age:	young
	Source:	Harlan Sprague Dawley Co. Indianapolis, IN

B. STUDY DESIGN:

Guinea pigs were conditioned for a least 4 days prior to the study initiation and received Wayne Guinea Pig Chow and water ad libitum.

Animals were weighed at initiation and at day 7, 14, 21 and termination of the study.

Compound Administration

The test material, Bora-Care, was administered, neat, to 10 guinea pigs according to a modification of the method of Buehler (Buehler, E.V. (1965). Delayed Contact Hypersensitivity in the Guinea Pig; Arch. Dermatol. 91:171-175).

An area of approximately 2x2 cm on the trunk of each animal was shaved with electric clippers on the day of dosing. The test material (0.2 ml) was placed in a Hilltop Chamber and applied to the shaved area of the skin. Elastoplast® was wrapped around the chamber and the entire trunk.

After the initial 24 hour dose or the succeeding 6 hour doses, the animal was unwrapped and the chamber removed. Animals were treated at least 3 times weekly with at least 1 day intervening between treatments for a total of 10 induction treatments.

Two (2) weeks after the final induction dose, each animal received a 6 hour topical challenge dose on a naive shaved area on the right trunk.

Using the same regimen as above, six (6) positive control animals received topically 0.2 ml of a 0.1% solution of 1-chloro 2,4 dinitrobenzene (DNCB).

Two (2) negative control animals were treated only with the challenge dose of the test substance which was applied for 24, rather than a 6 hour, contact period.

Animals in all groups were scored for skin responses at 24 and 48 hours after each application.

RESULTS:

Weight gain change was unremarkable throughout the study.

Scoring criteria for dermal reactions was presented in Table 1.

The initial dose of Bora-Care or DNCB produced no positive irritation scores in any of the guinea pigs. The ten dose average irritation score was 0 for Bora-Care and 0.12 for DNCB.

The challenge dose of the test material, Bora-Care, did not elicit a positive reaction in any of the 10 guinea pigs. The challenge dose of DNCB resulted in a positive reaction in 6/6 animals characterized by a average grade of 0.38 for erythema and/or edema. The 2 negative control animals treated with the test material did not elicit a positive reaction.

Based on comparisons of the initial test dose response to the challenge test dose and to the reactions elicited by the negative controls, Bora-Care, Lot No. 1022 would not be considered a dermal sensitizing agent.

CONCLUSIONS:

The test substance was not considered to be a dermal sensitizing agent.