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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 18, 2000

MEMORANDUM

SUBJECT: Efficacy Label Review for BD1, EPA Reg. No. 4822-484
DP Barcode: D261295

FROM: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division 7510C

TO: Velma Noble, Team Leader - 31
Regulatory Management Branch I
Antimicrobials Division

Registrant: S.C. Johnson & Son Inc.

Background

On November 5, 1999, a meeting was held with Christine Benter, a registration specialist from S.C. Johnson & Son. Inc. (SCJ) to discuss labeling comments for SCJ's disinfectant product, BD1, EPA Reg. No. 4822-484. Velma Noble and Michele Wingfield represented the Agency during this meeting. The labeling claims discussed during the meeting consisted of the qualification of the term "non-porous", the residual claim of "up to 14 days" and the "kills germs" claim. SC Johnson has submitted new labeling based on the discussions with the Agency.

Recommendations

1. After a thorough review of the data submitted for registration of the product, it was determined that BD1 was tested under the more stringent conditions of a porous surface and therefore, the label claim should state that the product is for use on hard, inanimate, environmental surfaces.

2. In 1993, S.C. Johnson submitted to the Agency a protocol for evaluating the residual

antibacterial activity of their product BD1. The acceptance of the protocol was for the residual self-sanitizing activity of dried chemical residue on undisturbed hard inanimate surfaces where abrasion is not likely. A January 27, 1999 efficacy review accepted the data for residual self-sanitizing activity of BD1 against *Staphylococcus aureus*, *Escherichia coli*, and *Klebsiella pneumoniae*, and residual anti- mold and mildew against *Aspergillus niger* at an initial contact time of 1 minute and for residual effect for up to 14 days in the presence of 5% organic soil load. The data was generated on surfaces which were subject to multiple rinses (such as in a shower) however, the possibility of abrasion from multiple "touches" of the surface was not evaluated.

Based on the residual data submitted for this product, the following labeling changes must be made:

a. Revise the statement, "BD1 stops many bacteria (from coming back) (for up to 14 days)" to read, "BD1 stops Escherichia coli, Staphylococcus aureus, and Klebsiella pneumoniae from coming back for up to 14 days on undisturbed, and untouched, hard environmental surfaces such as shower stalls."

b. Revise the statement, ...most household germs... to read, ...many household germs.... This revision should be made everywhere this term, or similar statements regarding the term "most", appears on the label.

c. Revise the statement "Residual self-sanitizing for up to 14 days" to read, "Residual self-sanitizing against Escherichia coli, Staphylococcus aureus, and Klebsiella pneumoniae for up to 14 days on undisturbed, and untouched, hard environmental surfaces such as shower stalls."

d. Under the heading "Directions for Use" the directions for disinfection of hard surfaces must be separated from the directions for residual self-sanitizing activity. This section should also be set up with increasing levels of activity (i.e. to clean, to control mold and mildew, for residual self-sanitizing, to disinfect.) The residual self-sanitizing instructions must state that the product is for undisturbed, and untouched, hard environmental surfaces such as shower stalls (or similar sites which the registrant may propose.)

3. Since the applicant has provided data to demonstrate effectiveness of the product against bacteria, viruses, and fungi, the label may state a claim of "kills many germ" for their basic disinfectant activity claims but not for their residual activity claims.

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EFFICACY AND SCIENCE SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - I

In: 9/8/98 Out: January 27, 1999

Reviewed by: Ibrahim Barsoum Date: January 27, 1998

EPA Reg. No.: 4822-484

DP Barcode: D249784

EPA Petition No.: none

Date Division Received: 9/28/98

Type Product: Multipurpose Disinfectant, Sanitizer, Cleaner.

MRID No.: 446496-1, 446496-2, 446496-3

Product Manager: Velma Nobles, PM 31

PM Team Reviewer: Zenobia Jones

Product Name: BD1

Company Name: S.C. Johnson & Son INC.

Submission Purpose: efficacy data submitted to support label claims of residual antibacterial and antifungal effects of BD1.

Type Formulation: Liquid

Active Ingredients:

n-Alkyl dimethyl benzyl ammonium chloride	0.11%
n-Alkyl dimethyl ethylbenzyl ammonium chloride	0.11%
3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	0.11%

RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - II

EPA Reg. No.:	4822-484
DP Barcode:	D249784
EPA Petition No.:	none
Date Division Received:	9/28/98
Type Product:	Multipurpose Disinfectant, Sanitizer, Cleaner.
MRID No.:	446496-1, 446496-2, 446496-3
Product Manager:	Velma Nobles, PM 31
PM Team Reviewer:	Zenobia Jones
Product Name:	BD1
Company Name:	S.C. Johnson & Son INC.

200.0 **Introduction:**

200.1 **Uses:** General Disinfectant & Sanitizer

200.2 **Background Information:** The registrant is submitting efficacy data to support label claim for residual antibacterial and antifungal effect.

201.0 **Data Summary**: None

201.1 **Abstract of Test Reports: None**

201.2 **Brief Description of Test: (title)**

Residual antibacterial efficacy data of BD1 for 14 days against *Staphylococcus aureus* (ATCC 6538), *Escherichia Coli* (ATCC 11229), and *Klebsiella pneumoniae* (ATCC13883) and residual antifungal efficacy data against *Aspergillus Niger* (ATCC 6275) performed according to EPA approved methods STM 029 and STM 030 by Diane M. Falbo of S.C. Johnson & Son, Inc. at 1525 Howe St., Racine, WI 53403, dated September 22, 1998.

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.

202.0 **RECOMMENDATIONS**:

202.1 Efficacy:

The submitted efficacy data for residual self-sanitizing effect of BD1 against *Staphylococcus aureus*, *Escherichia coli*, and *Klebsiella pneumoniae* and residual antifungal effect against *Aspergillis niger* at an initial contact time of 1 minute and for a residual effect for up to 14 days at 28°C in the presence of 5% organic soil load, appear adequate to support the residual antibacterial and antifungal effectiveness of the product.

203.0 Labeling:

Remove the terminology "long lasting" everywhere it appears on the label. This is a non-quantifiable term and is inappropriate for labeling. The applicant should state the level of activity and the specific length of time the activity will remain (such as fungistatic for up to 14 days or residual self-sanitizing for up to 14 days.)

Remove the term "germs" everywhere it appears on the label. The broad term germs implies a wider range of microorganism types than those approved for this product. This product has only demonstrated antibacterial and antifungal properties.

RESUBMISSION

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH

EFFICACY REVIEW -I

ANTIMICROBIAL DIVISION

IN 06/27/97 OUT 07/08/97

Srinivas Gowda

Reviewed by Srinivas Gowda Date 07/08/97

EPA Reg. No. or File Symbol 4822-UIU

LAN Code 4822-UIU.797

EPA Petition or EUP No. None

Date Division Received 06-27-97

Type Product Hospital Disinfectant

MRID No (s) 441860-14

Product Manager PM 31 (Edwards)

PM Team Reviewer Barbara Pringle

Product Name BD1

Company Name S.C.Johnson & Son, Inc.

Submission Purpose Resubmission of Residual Self-Sanitizing Data
In response to Agency letter dated Jun 20 1997

Type Formulation Liquid Pump Spray

Active Ingredient (s): %

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
dimethyl benzyl ammonium chloride.....0.11

n-Alkyl (68% C12, 32% C14)
dimethyl ethylbenzyl ammonium chloride.....0.11

3-(trimethoxisilyl) propylmethyloctadecyl ammonium chloride.0.11

202.0 **Recommendations**

202.1 **Efficacy not Supported by the Data:**

"Residual Antibacterial Test for Bathroom Duck" by Diane M. Falbo, Technology specialist, S.C. Johnson Wax, Inc., 1525 Howe Street, Racine, Wisconsin 53403, dated December 21, 1996 (MRID No. 441860-14)

The submitted residual self-sanitizing test data are not acceptable for the following reasons:

1. Test and control surfaces were not recontaminated with the test inocula with organic soil at 24 hour intervals for up to seven days. See item 9.2.5 of the protocol under the heading "Procedures".

2. On day zero and once per day for up to seven days, tiles were rinsed for 5 minutes only instead of 30±5 minutes. See item 9.2.1 of the protocol under the heading "Procedures".

3. The 24 hour contact time employed in the test is too long and it does not simulate the real use situation.

NOTE TO PM: In the previous review for this product, the virucidal data for MRID # 441860-11 was accepted by mistake. Comments should read as follows:

"Efficacy Testing of Disinfectant Bathroom Duck - No Fragrance. Formula 7217H121 (BTC 2125M) Virucidal Claims 201M3" by Diane M. Falbo, S.C.Johnson Wax, Inc., 15425 Howe Street, Racine, WI 53403, dated December 1993 (MRID No. 441860-11)

The submitted virucidal data developed by the Modified AOAC Germicidal Spray Products Test Method are not acceptable because insufficient number of embrionated eggs survived virucidal testing for a valid test. Tests must be repeated using a good batch of viable embrionated eggs and a better neutralization procedure. For your information: You must stop the virucidal action immediately after 10 minute contact time by the addition of an appropriate neutralizer solution to the virus + disinfectant mixture prior to resuspension.

12.4 12.6

NEW APPLICATION

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH

EFFICACY REVIEW -I

ANTIMICROBIAL DIVISION

IN 05/21/97 OUT 06/16/97

Reviewed by Srinivas Gowda Date 06/16/97

EPA Reg. No. or File Symbol 4822-UIU

LAN Code 4822-UIU.697

EPA Petition or EUP No. None

Date Division Received 12-24-96

Type Product Hospital Disinfectant

MRID No (s) 441860-09 to 441860-16

Product Manager PM 31 (Edwards)

PM Team Reviewer Barbara Pringle

Product Name BD1

Company Name S.C.Johnson & Son, Inc.

Submission Purpose New Application with efficacy data and proposed label

Type Formulation Liquid Pump Spray

Active Ingredient (s): **%**

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride.....0.11

n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride.....0.11

3-(trimethoxisilyl) propylmethyloctadecyl ammonium chloride.0.11

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH

EFFICACY REVIEW -II

ANTIMICROBIAL DIVISION

EPA Reg. No. or File Symbol	4822-UIU
EPA Petition or EUP No.	None
Date Division Received	12-24-96
Type Product	Hospital Disinfectant
MRID No (s)	441860-09 to 441860-16
Product Manager	PM 31 (Edwards)
PM Team Reviewer	Barbara Pringle
Product Name	BD1
Company Name	S.C.Johnson & Son, Inc.

202.0 **Recommendations**

202.1 **Efficacy Supported by the Data:**

1. The submitted efficacy data (MRID Nos. 441860-09, 441860-15 to 441860-17) developed by the Modified AOAC Germicidal Spray Products Test Method appear adequate to support effectiveness of this product as a hospital disinfectant against Pseudomonas aeruginosa ATCC 15442, Salmonella choleraesuis ATCC 10708 and Staphylococcus aureus ATCC 6538; as a disinfectant against Escherichia coli 01H51:H7, ATCC 35150 and Vancomycin Resistant Enterococcus faecalis ATCC 51559, Streptococcus faecalis; as a fungicide against Trichophyton mentagrophytes and as a virucide against HIV-1 (AIDS virus), Herpes simplex types 1 and 2, and Influenza virus A2 (H2N2), when used as an undiluted pressurized spray on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 1 minutes at room temperature.

2. Also the submitted confirmatory efficacy data (441860-12 & 441860-13) to support the minor formulation change (fragranced) by the AOAC Germicidal Spray Products Test method are acceptable to support effectiveness of the product as a hospital disinfectant against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa when used as an undiluted pressurized spray on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 1 minutes at room temperature.

202.2 **Efficacy Not Supported by the Data:**

1. "Residual Antibacterial Test for Bathroom Duck" by Diane M. Falbo, Technology specialist, S.C. Johnson Wax, Inc., 1525 Howe Street, Racine, Wisconsin 53403, dated December 21, 1996 (MRID No. 441860-14)

The submitted residual self-sanitizing data are not acceptable because product failed to demonstrate residual self-sanitizing activity (≥ 99.9 % kill) against Staphylococcus aureus and Escherichia coli, and no organic soil was included to simulate the real use situation. You must submit proposed residual self-sanitizing protocol and proposed use directions/label claims for Agency's review prior to initiation of the test. The 24 hour contact time employed in the test is too long and it should be reduced (eg. 10 minutes) to simulate the real use situation

202.3 **Claims Not Related to Human Health**

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The claims for this product for mildew (Aspergillus niger) and odor control are not related to human health, and do not require submission of supporting efficacy data. Therefore, the data developed for Aspergillus niger were not reviewed.

203.0 Labeling:

Delete the phrases, "Long-lasting" and "for up to 7 days" wherever it appears on the label or submit data to support it.

Change "All-purpose Disinfectant" to read "Multi-purpose Disinfectant".

On page 1, specify the species of staphylococcus, Streptococcus and Salmonella. Also change "E. Coli" to read "Escherichia coli."

On page 1, change "porcelain" to read "glazed porcelain".

On page 2, revise the statement "For best results on tough soils, allow product to remain on surface longer" to read "For best results on cleaning tough soils, allow product to remain on surface longer".

On page 3, under the heading "To Disinfect" provide instructions to remove gross filth or heavy soil prior to application of the product.

Delete residual self-sanitizing claim for up to 7 days or submit residual self-sanitizing data developed in the presence of organic soil (5% blood serum) to support it.

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
A MANUFACTURING-USE [ ] OR AN END-USE PRODUCT [✓]
DP Barcode D235202 Reg. No. or File Symbol No. 4822-UIU

TO: (PM Team Reviewer)
PM Team No. 31 Marshall Swindell

FROM: (Chemist/Date) Anna Skapars 5-8-97
Product Chemistry Review Section
Registration Support Branch/RD (WH705W)

THRU: Harold Podall, Ph.D., Section Head
Registration Support Branch/RD (WH7505W)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Provided product chemistry data and compositional information for fragrance [redacted] has been reviewed and is acceptable.

Inert ingredient information not included.

Anna Skapars
5-8-97

H7505W:RO:RSB:PCRS:CS-1:Rmxxx:Reviewer:Typist Initials:xx/xx/94:703-308-xxxx:Code No.(Reg or Rereg No).

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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

JUN 13 1997

MEMORANDUM

SUBJECT: Raid BD493: Review of Acute Toxicity Data Submitted by the Registrant.

EPA Identification Numbers:

DP Barcode: D235923 Submission: S520836
MRID#'s: 44186004 through 44186008; 44218901.
P.C. Code: 069104

TO: Walter Francis
PM Team # 31
Antimicrobial Division (7505W)

FROM: Timothy F. McMahon, Ph.D. 6/11/97
Pharmacologist, RASSB
Antimicrobial Division (7505W)

THRU: Norm Cook 06.13.97
Chief, RASSB
Antimicrobial Division

Registrant: S.C. Johnson & Son, Inc.

Action Requested: Review of acute toxicity studies submitted for Raid BD493, a quaternary ammonium formulation, under a "me-too" application.

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Data Summary

1) Acute Oral Toxicity in Rats, MRID # 44186004

Citation: Glaza, Steven M. (1993): Acute Oral Toxicity of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rats. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103437. MRID # 44186004. Unpublished.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID # 44186004), young adult Crl:CD®BR strain rats (5/sex), were given a single oral dose of 5,000 mg/kg Raid BD493 and observed for clinical toxicity and mortality for up to 14 days post-dose.

Estimated Oral LD_{50} Males > 5,000 mg/kg
Estimated Oral LD_{50} Females > 5,000 mg/kg

Raid BD493 is assigned TOXICITY CATEGORY IV based on the LD50 in males and females.

This acute oral toxicity study is classified **acceptable** and satisfies the guideline requirement (§81-1) for an acute oral toxicity study.

2) Acute Dermal Toxicity in Rabbits, MRID # 44186005

CITATION: Glaza, Steven M. (1993): Acute Dermal Toxicity of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rabbits. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103438. MRID # 44186005. Unpublished.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID # 44186005), young adult Hra:(NZW)SPF strain rabbits (5/sex), were given a single dermal application of 2,000 mg/kg Raid BD493 and observed for clinical toxicity and mortality for up to 14 days post-dose.

Estimated Dermal LD_{50} Males > 2,000 mg/kg
Estimated Dermal LD_{50} Females > 2,000 mg/kg

Raid BD493 is assigned TOXICITY CATEGORY III based on the LD50 in males and females.

This acute dermal toxicity study is classified **acceptable** and satisfies the guideline requirement (§81-2) for an acute dermal toxicity study.

3) Acute Inhalation Toxicity in Rats, MRID # 44218901

CITATION: Hoffman, Gary M. (1993): An Acute (4-Hour) Inhalation Toxicity Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in the Rat via Nose-Only Exposure. Huntingdon Life Sciences, East Millstone, New Jersey. Study No. 92-5125 MRID # 44218901. Unpublished.

EXECUTIVE SUMMARY: In an acute (4-hour) inhalation toxicity test, male and female rats of the Sprague-Dawley strain (approximately 2 months old) were exposed nose-only to Raid BD493 at analytical concentrations of 4.8 and 5.6 mg/l as a liquid aerosol. Rats were observed for signs of clinical toxicity and mortality for up to 15 days post-exposure.

Estimated Inhalation LC_{50} Males > 5.6 mg/l
Estimated Inhalation LC_{50} Females > 5.6mg/l

Raid BD493 is assigned TOXICITY CATEGORY IV based on the LC50 in males and females.

This acute inhalation toxicity study is classified **acceptable** and satisfies the guideline requirement (§81-3) for an acute inhalation toxicity study.

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4) Primary Eye Irritation Study in Rabbits, MRID # 44186006

CITATION: Glaza, Steven M. (1993): Primary Eye Irritation Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rabbits. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103440. MRID # 44186004. Unpublished.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID # 44186006), adult HRA:(NZW)SPF strain rabbits (3/sex), received a single 0.1ml instillation of undiluted test material (Raid BD493) into the everted lower eyelid of the right eye. Eyes remained unflushed, and ocular irritation was recorded for up to 7 days post-treatment. The method of Draize was used for scoring. Eyes of all treated rabbits showed no ocular abnormalities by day 7 post-treatment. **In this study, Raid BD493 is considered a mild eye irritant and is placed in TOXICITY CATEGORY III** for primary eye irritation, based on corneal involvement which cleared in 7 days or less.

This primary eye irritation study is classified **acceptable** and satisfies the guideline requirement (§81-4) for a primary eye irritation study.

5) Primary Dermal Irritation in Rabbits, MRID # 44186007

CITATION: Glaza, Steven M. (1993): Primary Dermal Irritation Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Rabbits. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103440. MRID # 44186007. Unpublished.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID # 44186007), adult HRA:(NZW)SPF strain rabbits (3/sex), received a single 0.5ml dermal application of undiluted test material (Raid BD493) on the shaved back. Exposure time was 4 hours. Rabbits were observed for dermal irritation up to 7 days post-application. The method of Draize was used for scoring. Skin of all treated rabbits showed no dermal abnormalities by day 7 post-treatment. **In this study, Raid BD493 is considered a mild dermal irritant and is placed in TOXICITY CATEGORY IV** for primary dermal irritation, based on the presence of slight dermal irritation at 72 hours post-application.

This primary dermal irritation study is classified **acceptable** and satisfies the guideline requirement (§81-5) for a primary dermal irritation study.

6) Dermal Sensitization in Guinea Pigs, MRID # 44186008

CITATION: Glaza, Steven M. (1993): Dermal Sensitization Study of Raid BD493 /n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride/n-Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride/3-(trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride [7217H121] in Guinea Pigs - Closed Patch Technique. Hazleton Wisconsin, Inc. Laboratory Project I.D. HWI 21103442. MRID # 44186008. Unpublished.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID # 44186008), young adult albino guinea pigs of the Crl:(HA)BR strain were tested using the closed patch technique. Three induction phase applications of 0.4ml undiluted Raid BD493 were made to the shaved backs of 10 guinea pigs over a period of three weeks (1 application per week). Two weeks after the last induction dose, a challenge dose was applied in the same manner as the induction dose at a different site. Naive control guinea pigs were also treated at this time. Slight to moderate erythema reactions with pinpoint areas of subcutaneous hemorrhaging were observed in two of ten test animals after the third induction dose. After challenge application, no evidence of sensitization was observed in test animals or naive controls. Although positive control animals did not show evidence of sensitization (based on the degree of dermal reaction obtained during challenge), the test material itself was used undiluted, precluding the use of higher doses. Thus, the results of this study demonstrate that Raid BD493 is not a skin sensitizer, although more definitive positive control data would lend validity to the experimental procedure employed.

This dermal sensitization study is classified **acceptable** and satisfies the guideline requirement (§81-6) for a dermal sensitization study in guinea pigs.

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
A MANUFACTURING-USE [ ] OR AN END-USE PRODUCT [ ]
DP Barcode D235100 Reg. No. or File Symbol No. 4822-GIY

TO: (PM Team Reviewer)
PM Team No. 31 Marshall Swindell

FROM: (Chemist/Date) Anna Skopas 5-8-97
Product Chemistry Review Section
Registration Support Branch/RD (WH705W)

THRU: Harold Podall, Ph.D., Section Head
Registration Support Branch/RD (WH7505W)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Provided chemical identity of perfume [redacted] has been reviewed and is acceptable.

Inert ingredient information not included.

Anna Skopas
5-8-97

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
A MANUFACTURING-USE [ ] OR AN END-USE PRODUCT [✓]
DP Barcode D234689 Reg. No. or File Symbol No. 4822-UU4

TO: (PM Team Reviewer)
PM Team No. 32 Barbara Pringle

FROM: (Chemist/Date) Anna Skapars 3-24-97
Product Chemistry Review Section
Registration Support Branch/RD (WH705W)

THRU: Harold Podall, Ph.D., Section Head
Registration Support Branch/RD (WH7505W)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of a new product.

A. Submitted chemical identity of two fragrances are acceptable for use in this product,

B. Three Confidential Statements of Formula one basic and two alternate formulas are in compliance with PR Notice 91-2 they agree with the label and all three CSFs dated 8-23-96, are acceptable.

Note to PM:
There is no bean sheet for this submission.

Anna Skapars
3-24-97

WH705W:RD:RSB:PCRS:CS-1:Rmxxx:Reviewer:Typist Initials:xx/xx/94:703-308-xxxx:Code No.(Reg or Rereg No).