

US EPA ARCHIVE DOCUMENT



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

JAN 20 2004

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of Claire-1 (EPA File Symbol No. 4822-LEI) Containing 10% p-Menthane-diol (Chemical No. 011550) As Its Active Ingredient. Review of Product Chemistry, Toxicity, and Efficacy Studies. DP Barcode 285177; Case No. Submission No. S616170. DP Barcode D285177. Case 072228. Submission S616170; MRID Nos: 456506-01 to -10.

FROM: Manying Xue, Chemist
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

THROUGH: Russell S. Jones, Ph.D., Senior Biologist
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

TO: Todd Peterson, Ph.D., Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

ACTION REQUESTED

S. C. Johnson & Son, Inc. requests registration of Claire-1 (EPA File Symbol No. 4822-LEI) containing 10% p-menthane-3, 8-diol as its active ingredient. The product is intended for use as a dermally-applied, spray-on, insect repellent. The active ingredient is obtained from an EPA-registered TGAI (EPA Reg. No. 4822-499). In support of the registration, the registrant has submitted product chemistry, toxicity, and efficacy studies; Confidential Statements of Formula (CSFs, dated 04/05/2002) for one basic formulation and 11 alternate formulations (see Background below for details), and a proposed label.

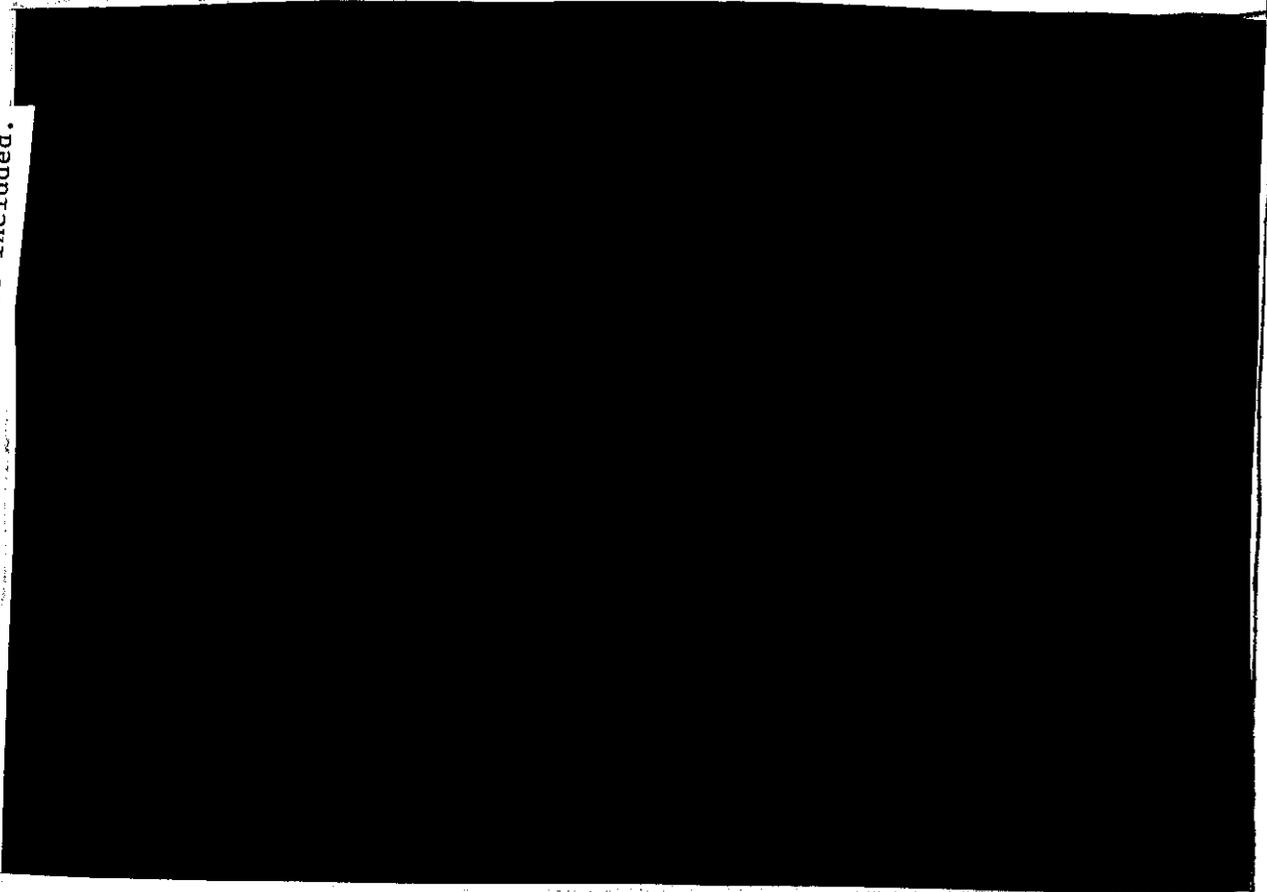
THE FOLLOWING PAGES CONTAIN CONFIDENTIAL BUSINESS INFORMATION

BACKGROUND

A letter from J. Fugate (S. C. Johnson) to S. K. Reilly and J. Downing (EPA/BPPD; dated 04/05/2002) contained an attachment from J. E. Swanson (toxicologist, S. C. Johnson) to J. Fugate (dated 04/02/2002). This attachment provided a rationale for using toxicology data submitted for the original Claire-1 formulation (NB# 15125P98-1, SOF# 25612; no EPA Reg. No.) containing 10% p-menthane-3, 8-diol as its active ingredient, to support toxicology data requirements for the 12 related Claire-1 formulations (under EPA File Symbol No. 4822-LEI).

The twelve formulas (one basic and 11 alternates) are grouped into four groups of three formulas each:

Inert ingredient information not included.

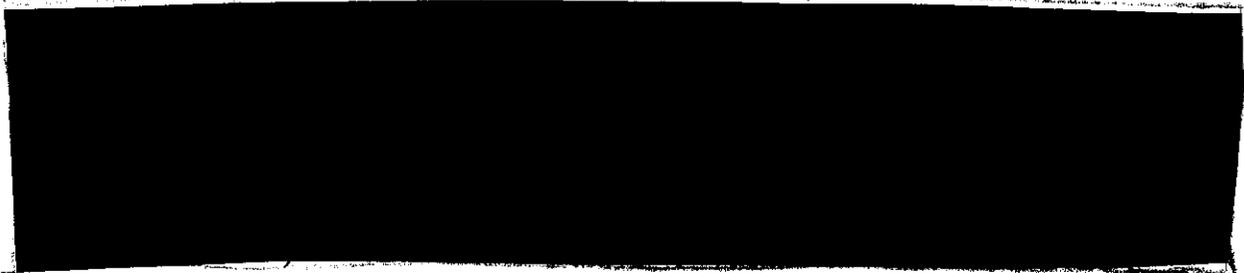


BPPD concludes that the minor changes in the formulation will not substantially change the physical/chemical properties of the end-use products.

The registrant concludes that the aforementioned formula changes will not appreciably change the toxicological profile of the products, and requests that toxicity studies submitted for the Claire-1 formulation 15125P98-1 be used to support the registration of EPA File Symbol No. 4822-LEI (one basic and 11 alternate formulations). BPPD concurs with this conclusion.

CONCLUSIONS AND RECOMMENDATIONS:

- 1a. The submitted product chemistry data are acceptable, pending minor changes to all CSFs. No other additional data are required.
- 1b. The following minor revisions must be made to the appropriate CSFs:



- 1c. In a letter from J. Fugate (S. C. Johnson) to S. K. Reilly & J. Downing (EPA/BPPD), the Agency was informed that two inerts intended for use in the alternate formulations were not cleared for food use and that the registrant submitted applications for food use clearance in the Inerts Branch of RD. No food use clearance under 40 CFR 180.1001 is required for any of the 12 products covered under EPA File Symbol No. 4822-LEI, because the products are intended for use as dermally-applied insect repellents, and will not be used on food.
- 2. All submitted acute toxicity studies are acceptable; no additional data are required. All other Tier I toxicity studies/data submitted in support of EPA Reg. No. 4822-499 are bridged to support the registration of the 12 formulations under 4822-LEI.
- 3. No non-target organism studies are required for dermally-applied insect repellents.
- 4. The submitted product performance (efficacy) studies are acceptable to support label claims.

Inert ingredient information not included.

STUDY SUMMARIES

Product Chemistry

Claire-1 (EPA Reg. No. 4822-LEI) is an end-use product (EP) and an insect repellent. There are one basic formulation (Formula 29717B) and 11 alternate formulations. All formulations contain 10.00% p-menthane-3,8-diol as its active ingredient. The source of the active ingredient is an EPA-registered TGAI (EPA Reg. No. 4822-499). The basic formulation contains



(see Background above for details), the formulations are substantially similar. The end-use products are formulated via a simple mixing of ingredients. No impurities occur in the manufacturing process which is by a non-integrated system and involves no chemical reaction. Preliminary analysis was not conducted and is not required. The upper and lower certified limits of the active and inert ingredients of all formulations are acceptable. The analytical method is adequately described, although not required for this end-use product. The physical/chemical properties are reported for Claire-1, Formula 15125P98-1, which is substantially similar to the 12 end-use products. The physical chemical properties of Claire-1 (Formula No. 15125P98-1) are listed below. Due to the substantial similarity of the 12 products to one another, it is expected that the physical/chemical properties will also be substantially similar.

OPPTS Guideline	Parameters	Physical/Chemical Properties
830.6302	Color	Clear colorless
830.6303	Physical State	Liquid
830.6304	Odor	Faint floral
830.7300	Density	0.78 g/mL
830.6314	Oxidation/Reduction	Product does not contain oxidizing or reducing agents.
830.6315	Flammability ^a	63°F
830.6316	Explosibility	Not applicable (NA); product does not contain explosive components.
830.6317	Storage Stability	Will be evaluated in a separate study. ^b
830.6320	Corrosion Characteristics	Will be evaluated in a separate study. ^b
830.7000	pH	NA; product is non-aqueous.
830.7100	Viscosity	1.7 cP at 25°C and 1.2 cP at 50°C
830.7300	Density	0.78 g/mL at 23°C
830.6321	Dielectric Breakdown Voltage	NA; product is not for use in and around electrical outlets.
830.6319	Miscibility	NA

Inert ingredient information not included.

^b not required for an end-use product using an EPA-registered TGA1.

Classification: Acceptable; no additional data are required.

Toxicity

The toxicity data submitted for Claire-1 (Formula No. 15125P98-1) are summarized in the following table:

Guideline/Study Type	Data	Toxicity Category	MRID No.
OPPTS 870.1100 Acute oral toxicity	LD ₅₀ >5000 mg/kg (rat)	IV	456506-03
OPPTS 870.1300 Acute dermal toxicity	LD ₅₀ >5000 mg/kg (rat)	IV	456506-04
OPPTS 870.1300 Acute inhalation toxicity	LC ₅₀ >2.38 mg/L (rat)	IV	456506-06
OPPTS 870.2400 Primary eye irritation	Mild corneal effects, iritis, and conjunctivitis clearing by 24 hrs (rabbit); slight eye irritant	III	456506-05
OPPTS 870.2500 Primary dermal irritation	Slight to moderate erythema and/or very slight to slight edema throughout study (rabbit); moderate dermal irritant	III	456506-07
OPPTS 870.2600 Hypersensitivity	Slight patchy to confluent or moderate patchy erythema with edema, blanching, and/or desquamation was noted on almost all test animals after induction; no positive reaction was noted on any test or naive control animals after challenge and rechallenge (guinea pig)	not a dermal sensitizer	456506-08

Product Performance (Efficacy)

The submitted product performance studies (MRID 456506-09) for the determination of repellency of Claire-1 (10% p-menthane 3,8 diol) against biting gnats (commonly called no-see-ums, *Culicoides* spp.), biting flies (black flies, *Simulium* spp.), and mosquitoes (*Culicidae*) in the field are adequate to satisfy the requirements described in OPPTS 810.3300. The average protection time exceeded 2 hours in the combined sand gnat studies and exceeded 4 hours in the combined blackfly studies. The average protection time exceeded 2 hours in the combined mosquito studies. The data support label claims stating that the product repels the aforementioned insects for up to 2 hours.

The submitted product performance study (MRID 456506-10) for the determination of repellency of Claire-1 (10% p-menthane 3,8 diol) against ticks (*Ixodes scapularis* and *Amblyomma americanum* Adults) are adequate to satisfy the requirements described in OPPTS 810.3300. Claire-1 repelled 100% of *Ixodes* ticks and 90% of *Amblyomma* ticks for 2 hours. The data support label claims stating that the product repels the aforementioned insects for up to 2 hours.

cc: R. S. Jones, M. Xue, BPPD Chron file.
R. S. Jones, FT, CM2. 1/20/2004

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

STUDY TYPE: Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRIDs 45650601 and 45650602

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 147

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

DATA EVALUATION RECORD

EPA Secondary Reviewers: Manying Xue, Ph.D., Chemist

STUDY TYPE: Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRID NOS: 45650601 and 45650602

DP BARCODE NO: D285177

CASE NO: 072228

SUBMISSION NO: S616170

TEST MATERIAL: Claire-1 (EPA Reg No. 4822-LEI; 10.00% p-menthane-3,8-diol, a.i.)

PROJECT NO: Not reported (MRID 45650601)
429A2 (MRID 45650602)

SPONSOR: S.C. Johnson & Son, Inc., Racine, WI

TESTING FACILITY: S.C. Johnson & Son, Inc., Racine, WI

TITLE OF REPORT: Product Chemistry Data for Claire-1, Formula Number 15125P98-1 (MRID 45650601);
Physical and Chemical Characteristics of Claire-1, Formula Number 15125P-98 (MRID 45650602)

AUTHORS: Phillip A. Kongshaug (MRID 45650601);
Gary A. Smith (MRID 45650602)

STUDY COMPLETED: January 30, 2002 (MRID 45650601);
August 3, 2000 (MRID 45650602)

GOOD LABORATORY PRACTICE: Not GLP Compliant (MRID 45650601);
GLP Compliant (MRID 45650602)

SUMMARY:

Claire-1 (EPA Reg. No. 4822-LEI) is an end-use product (EP) and an insect repellent. There are one basic formulation (Formula 29717B) and 11 alternate formulations. All formulations contain 10.00% p-menthane-3,8-diol (EPA Reg. No. 4822-499) as the active ingredient.

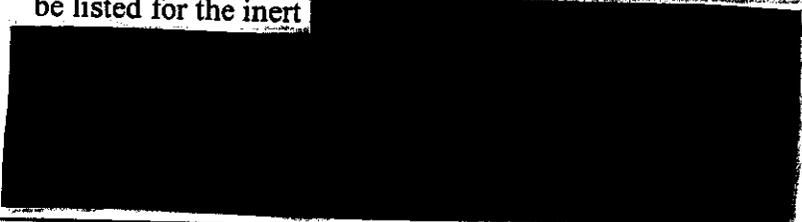


The formulation process was not described for the currently submitted formulation, but for a previously submitted similar formulation. No impurities will occur in the manufacturing process which is by a non-integrated system and involves no chemical reaction. Preliminary analysis was not conducted and is not required. The upper and lower certified limits of the active and inert ingredients of all formulations are within the recommended range in the guideline proposed in OPPTS 830.1750. The enforcement analytical method is adequately described. The physical/chemical properties except the flash point for basic and alternate formulations are not reported, instead, they are reported for Claire-1, Formula 15125P98-1, which does not correspond to any of the CSFs submitted for registration.

Inert ingredient information not included.

CLASSIFICATION:

ACCEPTABLE, pending minor revisions to the CSFs. The following minor revisions must be made to the appropriate CSFs: (i) if available, a CAS No. must be listed for the inert



CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Test Material: Claire-1 containing 10.00% p-menthane-3,8-diol, a.i.

- I. **PRODUCT IDENTITY AND COMPOSITION:** Claire-1 (EPA Reg. No. 4822-LEI) is an end-use product (EP) and an insect repellent. CSFs were included for one basic formulation (Formula 29717B) and 11 alternate formulations (Formulas 29730A, 29731A, 30365A, 30366A, 30367A, 29770A, 29774A, 29775A, 30369A, 30370A, and 30372A). All formulations contain 10.00% p-menthane-3,8-diol (CAS No. 42822-86-6, PC code 011550; active source material is p-Menthane-3,8-Diol Technical (EPA Reg. No. 4822-499), 99.0% active as the active ingredient.

The basic formulation (Formula 29717B) contains the inerts

Inert ingredient information not included.

Page 10 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

[REDACTED]

Deficiencies: Descriptions of the containers and descriptions of manufacturing conditions are not presented in the study. In addition, the registrant needs to provide the formulation process for the basic formulation, formula 29717B [REDACTED]

- III. **DISCUSSION OF FORMATION OF IMPURITIES:** No chemical reactions occurs during the manufacturing process and formation of new impurities is not expected to occur.
- IV. **PRELIMINARY ANALYSIS:** Preliminary analysis was not conducted and is not required for a batch process using a registered active ingredient and in which no chemical reactions occur.
- V. **CERTIFIED LIMITS:** Claire-1 contains 10.00% by weight (limits of 9.50-10.49%, by weight) p-menthane-3,8-diol (Table 2). The lower and upper certified limits for [REDACTED]

[REDACTED] The upper and lower certified limits of the active and inert ingredients of the basic formulation (Formula 29717B) and the 11 alternate formulations are within the recommended range proposed in OPPTS 830.1750.

Inert ingredient information not included.

Table 2. Nominal concentrations and the upper and lower limits for the ingredients			
	Nominal	Lower Limit	Upper Limit
% by weight			
Active ingredient			
p-Menthane-3,8-diol Technical p-Menthane-3,8-diol	10.100% (10.00% pure a.i.)	(10.49% pure a.i.)	(9.50% pure a.i.)
Inert ingredient			
Total	100%	-	-

Inert ingredient information not included.

VI. ENFORCEMENT ANALYTICAL METHOD: The active ingredient p-menthane-3,8-diol is determined by gas chromatograph equipped with a flame ionization detector and capillary column (30 m, 0.32 mm id, 0.25 micron film thickness, DB-1 fused silica capillary) with dipropyl phthalate as an internal standard. The retention time for p-menthane-3,8-diol is 4-8 minutes and for dipropyl phthalate is 7-12 minutes. Details of apparatus and reagents, procedure, calculations, system suitability criteria, validation, and references are included in the study (MRID 45650601).

VII. PHYSICAL AND CHEMICAL CHARACTERISTICS:

1. **Methods:** See the table below.
2. **Results:** The physical/chemical properties for Claire-1, Formula 15125P98-1 are listed in the following table. This formula does not corresponds to any of the CSFs submitted for registration. A letter dated 4/5/2002 stated that "the data package for Claire-1 was generated using a formula containing both [REDACTED] Flammability data for the current basic and 11 alternate formulations were included in the submission, but the registrant needs to provide the rest of the physical and chemical characteristics for the new formula, or at least for the basic formulation (Formula 29717B).

OPPTS Guideline	Parameters	Physical/Chemical Properties	Methods
830.6302	Color	Clear colorless	SCJ Analytical Method A-7
830.6303	Physical State	Liquid	SCJ Analytical Method A-7
830.6304	Odor	Faint floral	SCJ Analytical Method A-7
830.6313	Stability	Not required for EP	
830.6314	Oxidation/Reduction	Product does not contain oxidizing or reducing agents.	
830.6315	Flammability ^a	63°F	ASTM Method D-56
830.6316	Explosibility	Product does not contain explosive components.	
830.6317	Storage Stability	Will be evaluated in a separate study.	
830.6320	Corrosion Characteristics	Will be evaluated in a separate study.	
830.7000	pH	Product is non-aqueous.	
830.7100	Viscosity	1.7 cP at 25°C and 1.2 cP at 50°C	SCJ Physical Sciences Method PSTM 201; using Brookfield Synchro-Lectric Viscometer
830.7200	Melting Point	Not required for EP	
830.7220	Boiling Point	Not required for EP	
830.7300	Density	0.78 g/mL at 23°C	SCJ Analytical Research Method ARTM-GA-1; using specific gravity bottles
830.7370	Dissociation Constant	Not required for EP	
830.7520	Particle Size	Not required for EP	
830.7550	Partition Coefficient (n-octanol/water)	Not required for EP	
830.7860	Water Solubility	Not required for EP	
830.7950	Vapor Pressure	Not required for EP	
830.6321	Dielectric Breakdown Voltage	Product is not for use in and around electrical outlets.	
830.6319	Miscibility	Product is not intended for dilution with petroleum solvents.	

^b not available to the reviewer.

Inert ingredient information not included.

VIII. DISCUSSION: The registrant adequately addressed the product identity and composition, description of beginning materials, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method of Claire-1 (EPA Reg No. 4822-LEI) in MRIDs 45650601 and 45650602, the CSFs, and the product label. Physical and chemical characteristics were addressed for a similar product but not for the product being currently registered with the exception of flammability. There are one basic formulation (Formula 29717B) and 11 alternate formulations which all contain 10.00% p-menthane-3,8-diol as the active ingredient.

Inert ingredient information not included.

[REDACTED] The registrant needs to resolve the discrepancies and make corrections.

[REDACTED] However, the suppliers are provided on the CSFs dated 4/5/2002.

The formulation process was presented for the old formulations containing [REDACTED] but not for the new formulations without [REDACTED]. The new procedure should be described.

The physical/chemical properties for Claire-1, Formula 15125P98-1 which does not correspond to any of the CSFs submitted for registration are reported. The composition of this formula is unknown but it is likely the old formulation containing [REDACTED]. With the exception of flammability data which were provided, physical and chemical properties should be given for all new formulations.

The packet classification is **UNACCEPTABLE**. The registrant needs to correct and be consistent with the CAS Nos. for [REDACTED] on the CSFs and MRID 45650601. MSDSs of [REDACTED] need to be provided. The formulation process and the physical/chemical properties with the exception of the flammability data for the product currently being registered are needed.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: ACUTE ORAL TOXICITY - RAT (870.1100)
MRID 45650603**

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 147

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

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DATA EVALUATION RECORD

EPA Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Acute Oral Toxicity - Rats (OPPTS 870.1100)

MRID NO: 45650603

DP BARCODE NO: D285177

CASE NO: 072228

SUBMISSION NO: S616170

TEST MATERIAL: Claire-1 (EPA Reg No. 4822-LEI; 10.00% p-menthane-3,8-diol, a.i.)

PROJECT NO: 3068.260

SPONSOR: S.C. Johnson & Son, Inc., Racine, WI

TESTING FACILITY: Springborn Laboratories, Inc., Spencerville, OH

TITLE OF REPORT: An Acute Oral Toxicity Study in Rats with Claire-1

AUTHOR: Kimberly L. Bonnette, M.S., LATG

STUDY COMPLETED: October 26, 2000

GOOD LABORATORY PRACTICE: GLP Compliant

CONCLUSION: The oral LD₅₀ for males, females, and combined was greater than 5000 mg/kg.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test Material:** Claire-1, Formula 15125P98-1, Batch No. 429D2; clear colorless liquid
2. **Test Animals:** Five male and five female Sprague-Dawley rats were received from Harlan Sprague Dawley, Inc., assigned, and weighed 330-354 g (males) and 215-226 g (females) on the day of dosing. The young adult animals, approximately 11-12 weeks old, were housed individually in suspended stainless steel cages. PMI certified Rodent Chow No. 5002 and municipal tap water were available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 19-21°C; relative humidity, 66-70%; photoperiod, 12 hour light/dark cycle; and 10-15 air changes per hour.
3. **Methods:** Rats were ear-tagged: males (Nos. A5812 to A5816) and females (Nos. A5779 to A5782 and A5808). The rats were quarantined for a minimum of 5 days and fasted overnight prior to dosing. The test material (5000 mg/kg body weight) was dosed as received by gavage (Table 1). Body weights were recorded prior to fasting and dosing, and on days 7. 16

The test animals were observed for clinical abnormalities two times post-dosing and daily thereafter for 14 days. All decedent or euthanized animals were necropsied.

II. RESULTS:

1. **Mortality**: Mortality is given in Table 1. One male (No. A5812) died post dosing on the day of dosing. All other rats survived the study.

TABLE 1. Doses, mortality/animals treated			
Dose (mg/kg)	Males	Females	Combined
5000	1/5	0/5	1/10

Data taken from Table 1, p. 16-21, MRID 45650603.

2. **Body Weights**: All surviving males and three females gained weight during the study. Two females (Nos. A5779 and A5781) lost weight during the second week.
3. **Clinical Observations**: The decedent had rales, labored/congested breathing, wobbly gait, hunched posture, dark eyes, and salivation prior to death. In addition, the surviving animals had fecal/urine stain, soft stools, dark material around the facial area, decreased food consumption, decreased defecation, prostration, clear ocular discharge, and/or dilated pupils starting after dosing with recovery by day 5.
4. **Gross Necropsy**: The decedent had abnormal content in the stomach and small intestines, a blackish purple liver, dark red lungs with light red fluid and white foam, and light red fluid in the thoracic cavity. No significant changes were noted for the survivors.

III. DISCUSSION:

The packet classification is **ACCEPTABLE** for the acute oral toxicity study with rats under OPPTS guideline 870.1100. The oral LD₅₀ for males, females, and combined was greater than 5000 mg/kg. This places Claire-1 in TOXICITY CATEGORY IV.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: ACUTE DERMAL TOXICITY - RABBIT (870.1200)
MRID 45650604**

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 147

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

DATA EVALUATION RECORD

Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Acute Dermal Toxicity - Rabbits (OPPTS 870.1200)

MRID NO: 45650604

DP BARCODE NO: D285177

CASE NO: 072228

SUBMISSION NO: S616170

TEST MATERIAL: Claire-1 (EPA Reg No. 4822-LEI; 10.00% p-menthane-3,8-diol, a.i.)

PROJECT NO: 3068.261

SPONSOR: S.C. Johnson & Son, Inc., Racine, WI

TESTING FACILITY: Springborn Laboratories, Inc., Spencerville, OH

TITLE OF REPORT: An Acute Dermal Toxicity Study in Rabbits with Claire-1

AUTHOR: Kimberly L. Bonnette, M.S., LATG

STUDY COMPLETED: October 2, 2000

GOOD LABORATORY PRACTICE: GLP Compliant

CONCLUSION: The dermal LD₅₀ for males, females, and combined was greater than 5000 mg/kg.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test Material:** Claire-1, Formula 15125P98-1, Batch No. 429D2; clear colorless liquid
2. **Test Animals:** Five male and five female New Zealand White rabbits were received from Myrtle's Rabbitry, Thompson Station, TN, assigned, and weighed 2.7-3.1 kg (males) and 2.6-3.1 kg (females) on the day of dosing. The young adult animals, approximately 12-13 weeks old, were housed individually in suspended stainless steel cages. PMI Certified Rabbit Chow No. 5322 and municipal tap water were available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 17-20°C; relative humidity, 62-68%; photoperiod, 12 hour light/dark cycle; and 10-15 air changes per hour.
3. **Methods:** Rabbits were ear-tagged: Male – Nos. R2472, R2482, R2525, R2526, and R2527; Female – Nos. R2508, R2541, R2542, R2544, and R2547 and were quarantined for a minimum of 5 days. The test material (5000 mg/kg body weight) was spread evenly over approximately

10% of the body surface area on the clipped dorsal trunk. The application site was covered with gauze dressing backed with a plastic wrap and secured with adhesive tape around the trunk. After dosing, collars were placed on the animals until the end of the study. The coverings were removed after 24 hours and the excess test material was removed with gauze moistened with deionized water. The test animals were observed for dermal irritation following patch removal and observed for clinical signs twice on the day of treatment and daily thereafter for 14 days. The rabbits were weighed prior to treatment and on days 7 and 14. The rabbits were euthanized on day 14 and necropsied.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.
2. **Clinical Observations:** Decreased food consumption, decreased defecation, feces small in size, and/or clear nasal discharge were noted from all animals with recovery by day 3 or 4. In the second week, dark material around the mouth was noted on two females (Nos. R2547 and R2508). Dermal irritation including edema, blanching, eschar, and/or desquamation were noted at the treatment site on all animals throughout the observation period.
3. **Body Weights:** All animals lost weight during the first week and one female (No. R2508) kept losing weight during the second week. The other animals gained weight by the end of the study.
4. **Gross Necropsy:** No significant changes were noted.

III. DISCUSSION:

The packet classification is **ACCEPTABLE** for the acute dermal toxicity study with rabbits under OPPTS guideline 870.1200. The dermal LD₅₀ for males, females, and combined was greater than 5000 mg/kg. This places Claire-1 in TOXICITY CATEGORY IV.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870.2400)
MRID 45650605**

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 147

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.),
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Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

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This review may have been altered subsequent to the contractor's signatures above.

DATA EVALUATION RECORD

Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Acute Eye Irritation - Rabbits (OPPTS 870.2400)

MRID NO: 45650605

DP BARCODE NO: D285177

CASE NO: 072228

SUBMISSION NO: S616170

TEST MATERIAL: Claire-1 (EPA Reg No. 4822-LEI; 10.00% p-menthane-3,8-diol, a.i.)

PROJECT NO: 3068.263

SPONSOR: S.C. Johnson & Son, Inc., Racine, WI

TESTING FACILITY: Springborn Laboratories, Inc., Spencerville, OH

TITLE OF REPORT: A Primary Eye Irritation Study in Rabbits with Claire-1

AUTHOR: Kimberly L. Bonnette, M.S., LATG

STUDY COMPLETED: October 2, 2000

GOOD LABORATORY PRACTICE: GLP Compliant

CONCLUSION: Corneal opacity was noted on 1/3 rabbits with rinsed eyes 24 hours after test material instillation with resolution by 72 hours. Iritis was noted on 3/3 rabbits with non-rinsed eyes and 3/3 rabbits with rinsed eyes one hour after test material instillation with resolution by 72 hours. Positive conjunctival irritation (score 2) was noted on 3/3 rabbits with non-rinsed eyes and 2/3 rabbits with rinsed eyes one hour after test material instillation with resolution by 24 hours. The maximum average scores were 17.00 and 12.33 for non-rinsed eyes and rinsed eyes, respectively, at one hour after test material instillation. Claire-1 was mildly irritating.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. **Test Material:** Claire-1, Formula 15125P98-1, Batch No. 429D2; clear colorless liquid

2. **Test Animals:** Three male and three female New Zealand White rabbits were received from Myrtle's Rabbitry, Thompson Station, TN, assigned, and weighed 2.6-2.7 kg (males) and 2.6-2.8 kg (females) on the day of treatment. The young adult animals, approximately 12 weeks old, were housed individually in suspended stainless steel cages. PMI Certified Rabbit Chow No. 5322 and municipal tap water were available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 18-19°C; relative humidity, 47-69%; photoperiod, 12 hour light/dark cycle; and air changes per hour, 10-15.
3. **Methods:** Rabbits were ear-tagged: Nos. R2517, R2531, and R2534 (males) and R2550, R2551, and R2552 (females) and were quarantined for a minimum of 5 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of the right eye, and the eye held closed for approximately one second. The contralateral eye served as control. Approximately 30 seconds after instillation of the test material, the eyes of one male and two females were rinsed with sterile water for approximately 30 seconds. The eyes were examined and scored 1, 24, 48, and 72 hours and up to 7 days after test material instillation.

II. RESULTS:

1. **Mortality:** No animals died during the study.
2. **Ocular Lesions:** Corneal opacity was noted on 1/3 rabbits with rinsed eyes 24 hours after test material instillation with resolution by 72 hours (Table 1). Iritis was noted on 3/3 rabbits with non-rinsed eyes and 3/3 rabbits with rinsed eyes one hour after test material instillation with resolution by 72 hours. Positive conjunctival irritation (score 2) was noted on 3/3 rabbits with non-rinsed eyes and 2/3 rabbits with rinsed eyes one hour after test material instillation with resolution by 24 hours (Table 2). The maximum average scores were 17.00 and 12.33 for non-rinsed eyes and rinsed eyes, respectively, at one hour after test material instillation (Table 3).

TABLE 1. Individual Male (M) and Female (F) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)

Animal No.	1 hour	24 hours	48 hours	72 hours	7 days

23

	A	B	A	B	A	B	A	B	A	B
Rabbits with non-rinsed Eyes										
R2517	0	0	0	0	0	0	0	0	0	0
R2550	0	0	0	0	0	0	0	0	0	0
R2531	0	0	0	0	0	0	0	0	0	0
Rabbits with Rinsed Eyes										
R2551	0	0	1	1	1	1	0	0	0	0
R2534	0	0	0	0	0	0	0	0	-	-
R2552	0	0	0	0	0	0	0	0	0	0

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris					
Score Conditions	1 hour	24 hours	48 hours	72 hours	7 days
Rabbits with Non-rinsed Eyes					
Conjunctiva					
Erythema	2	1 to 2	1	1	0
Chemosis	2	1	1	1	0
Discharge	2	0 to 1	0	0	0
Iris	1	0 to 1	0 to 1	0	0
Rabbits with Rinsed Eyes					
Conjunctiva					
Erythema	1 to 2	1	1	0 to 1	0
Chemosis	1	1	1	0 to 1	0
Discharge	1	0	0	0	0
Iris	1	1	0 to 1	0	0

Irritation score is based on Draize Method

Scale for Scoring Ocular Lesions

(O) Cornea Opacity: degree of density (area most dense taken for reading)
No ulceration or opacity

0

Scattered or diffuse areas of opacity (other than slight dulling of normal luster), details of iris clearly visible	1*
Easily discernible translucent areas, details of iris slightly obscured	2*
Nacreous areas; no details of iris visible; size of pupil barely discernible	3*
Opaque cornea, iris not discernible through the opacity	4*

(A) Area of corneal involved:

No ulceration or opacity	0
One quarter (or less) but not zero	1
Greater than one quarter, but less than half	2
Greater than half, but less than three quarters	3
Greater than three quarters, up to whole area	4
Cornea Score = O x A x 5	Total Maximum = 80

(I) Iris:

Normal	0
Marked deepened rugae, congestion, swelling, moderate circumcorneal hyperemia or injection, any of these or combination thereof, iris still reacting to light (sluggish reaction is positive)	1*
No reaction to light, hemorrhage, gross destruction (any or all of these).	2*
Iris Score = I x 5	Total Maximum = 10

(R) Conjunctival redness: (refers to the most severe reading of palpebral and bulbar conjunctivae, as compared to the control eye)

Blood vessels normal	0
Some blood vessels definitely hyperemic (injected) above normal (slight erythema)	1
Diffuse, crimson color; individual vessels not easily discernible (moderate erythema)	2*
Diffuse beefy red (marked erythema)	3*

(S) Conjunctival swelling: lids and/or nictating membranes

No swelling	0
Any swelling above normal (includes nictitating membrane, slight swollen)	1
Obvious swelling with partial eversion of lids	2*
Swelling with lids about half closed	3*
Swelling with lids more than half closed	4*

(D) Conjunctival Discharge:

No discharge	0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1
Discharge with moistening of the lids and hairs just adjacent to lids	2
Discharge with moistening of the lids and hairs a considerable area around the eye	3
Conjunctival Score = (R + S + D) x 2	Total Maximum = 20

*Positive Effect

TABLE 3. Summary of Total* and Primary Eye Irritation Scores with Time					
Animal #	1 h	24 h	48 h	72 h	7 d
Rabbits with Non-rinsed Eyes					
R2517	17	11	9	4	0

R2550	17	9	4	4	0
R2531	17	6	4	4	0
^b Total	17.00	8.67	5.67	4.00	0.00
Rabbits with Rinsed Eyes					
R2551	13	14	14	4	0
R2534	13	9	9	0	-
R2552	11	9	4	2	0
^b Total	12.33	10.67	9.00	2.00	0.00

^aFormula: Total Irritation Score = I + II + III, where,

I = Corneal Score = [Density (A) x Area (B)] x 5

II = Iris Score = Severity x 5

III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2

^bPrimary Irritation = Sum of Total Irritation Scores ÷ 3

III. DISCUSSION:

The packet classification is **ACCEPTABLE** for the acute eye irritation study with rabbits under OPPTS guideline 870.2400. Corneal opacity was noted on 1/3 rabbits with rinsed eyes 24 hours after test material instillation with resolution by 72 hours. Iritis was noted on 3/3 rabbits with non-rinsed eyes and 3/3 rabbits with rinsed eyes one hour after test material instillation with resolution by 72 hours. Positive conjunctival irritation (score 2) was noted on 3/3 rabbits with non-rinsed eyes and 2/3 rabbits with rinsed eyes one hour after test material instillation with resolution by 24 hours. The maximum average scores were 17.00 and 12.33 for non-rinsed eyes and rinsed eyes, respectively, at one hour after test material instillation. Claire-1 was mildly irritating and is in TOXICITY CATEGORY III.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (870.1300)
MRID 45650606**

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 147

Primary Reviewer:
Susan Chang, M.S.

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Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.),
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Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Acute Inhalation Toxicity - Rats (OPPTS 870.1300)

MRID NO: 45650606

DP BARCODE NO: D285177

CASE NO: 072228

SUBMISSION NO: S616170

TEST MATERIAL: Claire-1 (EPA Reg No. 4822-LEI; 10.00% p-menthane-3,8-diol, a.i.)

PROJECT NO: 3068.262

SPONSOR: S.C. Johnson & Son, Inc., Racine, WI

TESTING FACILITY: Springborn Laboratories, Inc., Spencerville, OH

TITLE OF REPORT: An Acute Nose-Only Inhalation Toxicity Study in Rats with Claire-1

AUTHOR: Kimberly L. Bonnette, M.S., LATG

STUDY COMPLETED: October 30, 2000

GOOD LABORATORY PRACTICE: GLP Compliant

CONCLUSION: The inhalation LC₅₀ for males, females, and combined was > 2.38 mg/L.

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test Material:** Claire-1, Formula 15125P98-1, Batch No. 429D2; clear colorless liquid
2. **Test Animals:** Five male and ten female Sprague-Dawley rats were received from Harlan Sprague Dawley, Inc., assigned, and weighed 343-384 g (males) and 205-239 g (females) on the day of exposure. The young adult animals, approximately 11 weeks old, were housed individually in suspended stainless steel cages. PMI certified Rodent Chow No. 5002 and municipal tap water were available *ad libitum*. The environmental conditions of the animal

room were as follows: temperature, 18-21°C; relative humidity, 43-69%; photoperiod, 12 hour light/dark cycle; and 10-15 air changes per hour.

3. **Methods:** Rats were ear-tagged: Male – Nos. A6109, A6116, A6118, A6122, and A6123; Female – Nos. A6130, A6138, A6145, A6146, and A6152. The rats were quarantined for a minimum of 5 days prior to exposure. Animals were assigned to the test groups noted in Table 1. The rats were exposed in a Unifab nose-only dynamic flow inhalation chamber for four hours and 14 minutes. They were observed during exposure, two times post exposure on day 0, and daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All rats were sacrificed and necropsied on day 14.

Nominal Conc. (mg/L)	Anal. Conc. (mg/L)	MMAD (µm)	GSD (µm)	Particles <4.0 µm (%)	Temp (°C)	Humidity (%)	Mortality		
							Male	Female	Combined
3.89	2.38	2.0	2.4	80	68.6-71.2	12.5-22.0	0/5	0/5	0/10

Data taken from Tables 1 and 2, pp. 20 and 21-23, MRID 45650606.

Generation of the test atmosphere and description of the chamber: The exposure atmosphere was generated using a 1/4 inch JSS atomizer (Spraying Systems) with conditioned high pressure external air. The test aerosol was blown through the Unifab 100L nose-only inhalation chamber. The average total airflow was not reported, but time to equilibrium was approximately 7 min.

Test atmosphere concentration: Gravimetric samples were collected three times using glass fiber filters from the breathing zone of the animals during exposure. Filters were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration. Gas chromatography was used to quantitate p-menthane-3,8-diol. The average results are in Table 1 above.

Particle size determination: Particle size distribution of each exposure concentration was determined three times using the IPT 7 L/min cascade impactor. The test material concentration collected by each stage was determined gravimetrically. The aerodynamic mass median diameter (MMAD) and geometric standard deviation (GSD) were determined graphically utilizing three cycle logarithmic probability paper. Results are in Table 1 above.

II. RESULTS:

1. **Mortality:** All rats survived the study.
2. **Clinical Observations:** Breathing abnormalities and dark material around the facial area were noted from all animals on day 0 with recovery by day 4.

3. **Body Weights:** Four males and four females lost weight during the first week, but gained weight during the second week with the exception of one male (A6122) that did not regain his original weight and one female (A6138) that regained her original weight.
4. **Gross Necropsy:** No significant changes were noted for the survivors.

III. DISCUSSION:

The packet classification is **ACCEPTABLE** for the acute inhalation toxicity study with rats under OPPTS guideline 870.1300. The inhalation LC₅₀ for males, females, and combined was > 2.38 mg/L. This places Claire-1 in TOXICITY CATEGORY IV.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (870.2500)
MRID 45650607**

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 147

Primary Reviewer:
Susan Chang, M.S.

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H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

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Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

DATA EVALUATION RECORD

Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Primary Dermal Irritation - Rabbits (OPPTS 870.2500)

MRID NO: 45650607

DP BARCODE NO: D285177

CASE NO: 072228

SUBMISSION NO: S616170

TEST MATERIAL: Claire-1 (EPA Reg No. 4822-LEI; 10.00% p-menthane-3,8-diol, a.i.)

PROJECT NO: 3068.264

SPONSOR: S.C. Johnson & Son, Inc., Racine, WI

TESTING FACILITY: Springborn Laboratories, Inc., Spencerville, OH

TITLE OF REPORT: A Primary Skin Irritation Study in Rabbits with Claire-1

AUTHOR: Kimberly L. Bonnette, M.S., LATG

STUDY COMPLETED: October 26, 2000

GOOD LABORATORY PRACTICE: GLP Compliant

CONCLUSION: Very slight to moderate erythema with or without very slight to slight edema was noted on all rabbits throughout the study. The primary irritation index was 3.5. Claire-1 was moderately irritating

CLASSIFICATION: ACCEPTABLE -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. **Test Material:** Claire-1, Formula 15125P98-1, Batch No. 429D2; clear colorless liquid
2. **Test Animals:** Two male and one female New Zealand White rabbits were received from Myrtle's Rabbitry, Thompson Station, TN, assigned, and weighed 2.6-2.8 kg (males) and 2.9 kg (females) on the day of treatment. The young adult animals, approximately 12 weeks old, were housed individually in suspended stainless steel cages. PMI Certified Rabbit Chow No. 5322 and municipal tap water were available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 17-22°C; relative humidity, 47-75%; photoperiod, 12 hour light/dark cycle; and 10-15 air changes per hour.
3. **Methods:** Rabbits were ear-tagged: Nos. R2532 and R2535 (males) and R2553 (female). The rabbits were quarantined for a minimum of 5 days. The fur on the dorsal trunk of each

rabbit was clipped on the day prior to treatment. The rabbits were given a 0.5 mL dose of test material applied under a 1 inch x 1 inch gauze pad that was secured with nonirritating tape. The pad and the entire trunk were covered with an elastic wrap (a semi-occlusive binding) and secured with adhesive tape. Collars were placed on the rabbits. The covering and the collar were removed 4 hours later and the site wiped with gauze moistened with deionized water to remove any residual test material. The animals were observed twice daily for gross toxicity and behavior changes during the study. Dermal examination was recorded at 1, 24, 48, and 72 hours and up to 14 days after removal of the patch.

II. RESULTS:

- Mortality:** All rabbits survived the study.
- Dermal responses:** Very slight to well defined erythema was noted on all rabbits one hour after patch removal. By 24 hours, the erythema was well defined and persisted or intensified to moderate by 72 hours. Very slight to well defined erythema persisted through the end of the study. Very slight to slight edema was noted on all rabbits throughout the study with clearance by day 14 on two rabbits. Desquamation and/or superficial lightening were noted on all rabbits. The primary irritation index was 3.5.

Irritation Scores:

TABLE 1. Summary of individual rabbit's dermal irritation scores with time							
Animal No.	Hours				Days		
	1	24	48	72	7	10	14
R2553	1/1 *	2/1	3/2	3/2	2/2	2/2	2/0
R2535	1/1	2/1	2/2	2/2	1/0	2/1	2/0
R2532	2/1	2/1	2/2	2/2	2/1	2/2	2/1

Data taken from Table 1, p. 17 and 18, MRID 45650607.

*Erythema/Edema

Description of rating method:

Evaluation of Skin Reaction:

Erythema formation:	<u>Score</u>
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness)	4

Edema Formation:

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised approximately 1 mm)	4

III. DISCUSSION:

The packet classification is **ACCEPTABLE** for the acute dermal irritation study with rabbits under OPPTS guideline 870.2500. Very slight to moderate erythema with or without very slight to slight edema was noted on all rabbits throughout the study. The primary irritation index was 3.5. Claire-1 was moderately irritating and is in TOXICITY CATEGORY III.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: SKIN SENSITIZATION - GUINEA PIG (870.2600)
MRID 45650608**

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 147

Primary Reviewer:
Susan Chang, M.S.

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Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

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This review may have been altered subsequent to the contractor's signatures above.

DATA EVALUATION RECORD

Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Skin Sensitization - Guinea Pigs (OPPTS 870.2600)
MRID NO: 45650608
DP BARCODE NO: D285177
CASE NO: 072228
SUBMISSION NO: S616170
TEST MATERIAL: Claire-1 (EPA Reg No. 4822-LEI; 10.00% p-menthane-3,8-diol, a.i.)
PROJECT NO: 3068.265
SPONSOR: S.C. Johnson & Son, Inc., Racine, WI
TESTING FACILITY: Springborn Laboratories, Inc., Spencerville, OH
TITLE OF REPORT: A Dermal Sensitization Study in Guinea Pigs with Claire-1, Modified Buehler Design
AUTHOR: Kimberly L. Bonnette, M.S., LATG
STUDY COMPLETED: October 30, 2000
GOOD LABORATORY PRACTICE: GLP Compliant
CONCLUSION: After three weekly inductions, no positive reaction was noted on any test or naive control animals after challenge and rechallenge. Claire-1 was not a dermal sensitizer.
CLASSIFICATION: ACCEPTABLE

I. STUDY DESIGN:

1. **Test Material:** Claire-1, Formula 15125P98-1, Batch No. 429D2; clear colorless liquid
2. **Test Animals:** Twenty-four male and 24 female Hartley guinea pigs received from Hilltop Lab Animals, Inc., Scottsdale, PA were assigned to groups and weighed 373-443 g (males) and 339-398 g (females) prior to first induction. The young adult animals, approximately 7-8 weeks old, were housed individually in suspended stainless steel cages. PMI Certified Rabbit Chow No. 50262 and municipal tap water were available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 17-21°C; relative humidity, 44-79%; photoperiod, 12 hour light/dark cycle; and 10-15 air changes per hour.
3. **Methods:** Guinea pigs were ear-tagged and grouped: Test – Nos. G6024 to G6033 (males) and G6087 to G6096 (females); Naive Control – Nos. G6034 to G6038 and G6039 to G6043 (males) and G6097 to G6101 and G6102 to G6106 (females). The guinea pigs were quarantined for a

minimum of 5 days. The animals were induced and challenged according to the method of Buehler. The hair on the left side of 20 test guinea pigs and 10 naive control animals was clipped prior to each treatment. For induction, 0.3 mL of 35% w/w test material in acetone was applied to the animal using a Hill Top Chamber and secured with adhesive tape (occlusive patch). The chamber was removed after six hours. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.3 mL of 25% w/w test material in acetone under occlusion to naive sites. At challenge, a naive control group (10 animals) was treated with 0.3 mL of test material in acetone. On day 34, a rechallenge was performed with 0.3 mL of 25% w/w test material in acetone on the test animals and 10 additional naive control animals. Reactions were scored at approximately 24 and 48 hours following induction, challenge, and rechallenge application.

II. RESULTS:

- 1. Mortality:** No deaths were observed in any group. One female (No. G6094) was euthanized due to mechanical injury for humaneness.
- 2. Body Weights:** All guinea pigs gained weight during the study.
- 3. Skin Effects:** Slight patchy to confluent or moderate patchy erythema with edema, blanching, and/or desquamation was noted on almost all test animals after induction. No positive reaction was noted on any test or naive control animals after challenge or rechallenge (Tables 1 and 2). The study included DNCB and HCA positive control studies which were conducted within six months of the current study. The results were appropriate.

Time	24 hours				48 hours			
	0	0.5	1	2	0	0.5	1	2
Erythema Score	0	0.5	1	2	0	0.5	1	2
Treated	19	0	0	0	19	0	0	0
Naive Control	8	2	0	0	10	0	0	0

Time	24 hours				48 hours			
	0	0.5	1	2	0	0.5	1	2
Erythema Score	0	0.5	1	2	0	0.5	1	2
Treated	16	3	0	0	19	0	0	0
Naive Control	6	4	0	0	9	1	0	0

*Number of animals affected

Evaluation score is based on Buehler Grading Scale.

Scale for Scoring Skin Reaction

Buehler sensitization scoring scale

Erythema
No reaction

Score
0

37

Slight patchy erythema	0.5
Slight, but confluent or moderate patchy erythema	1
Moderate, confluent erythema	2
Severe erythema with or without edema	3

III. DISCUSSION:

The packet classification is **ACCEPTABLE** for the acute skin sensitization study with pigs under OPPTS guideline 870.2600. Slight patchy to confluent or moderate patchy erythema with edema, blanching, and/or desquamation was noted on almost all test animals after induction. No positive reaction was noted on any test or naive control animals after challenge and rechallenge. The study included DNCB and HCA positive control studies that were conducted within six months of the current study. The results were appropriate. Claire-1 was not a dermal sensitizer.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: Product Performance, OPPTS 810.3300
MRID 45650609**

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
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Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Work Assignment No. 147

Primary Reviewer:
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Signature: _____
Date: _____

Secondary Reviewers:
Anthony O. Armstrong, M.S.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

DATA EVALUATION RECORD

Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID NO: 45650609

DP BARCODE: D285177

CASE NO: 072228

SUBMISSION NO: S616170

TEST MATERIAL: Claire-1 (10% p-menthane-3,8-diol)

STUDY NO: 429E1

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

TESTING FACILITY: Entomology Research Center, Racine, WI

TITLE OF REPORT: Determining Repellency of Claire-1 (10% p-menthane-3,8-diol) Against Biting Gnats (commonly called no-see-ums) (*Culicoides* spp.), Biting Flies (Black Flies) *Simulium* spp.) and Mosquitoes (*Culicidae*) in the Field

AUTHOR: D.T. Ropiak

STUDY COMPLETED: December, 2001 (report date)

CONFIDENTIALITY CLAIMS: None

**STUDY
SUMMARY:**

Field tests using human subjects were conducted to determine the efficacy of Claire-1 insect repellent (10% p-menthane-3,8-diol) against sand gnats (two tests), black flies (two tests), and mosquitoes (three tests). Claire-1 was applied at a rate of 1 g/645 cm² to the forearms and lower legs of the test subjects, with one limb of each individual left untreated as a control. During continuous exposure for approximately four hours, the time of each insect landing or bite was recorded. Protection times were calculated, and in one sand gnat test, the time for repellency to fall below 95% was determined. In the combined sand gnat tests, the average protection time was 146 minutes, and the time until repellency was < 95% was 200 minutes. In the combined black fly tests, only one subject received a second bite, and the average protection time was 243 minutes. In the combined mosquito tests, the average protection time was 143 minutes.

CLASSIFICATION:

Acceptable

**GOOD LABORATORY
PRACTICE**

The study was not conducted in compliance with 40 CFR Part 160. No quality assurance audit was performed, weather data were not collected with equipment maintained according to 40 CFR 160.63, and some signatures on raw data were late.

TEST MATERIAL

Claire-1 (10% p-menthane-3,8-diol)

TEST METHOD

Field tests using human subjects were conducted to determine the efficacy of Claire-1 (10% p-menthane-3,8-diol) against sand gnats (*Culicoides mississippiensis*), black flies (*Simulium venustum*, *S. truncatum*, *S. rostratum*, *S. decorum*, *Prosimulium mixtum*), and mosquitoes (*Aedes taeniorhynchus*, *A. sollicitans*, *Culex nigripalpus*, *C. salinarius*, *Psoraphora ferox*, *P. ciliata*, *Anopheles crucians*, *Mansonia dyari*). The sand gnat tests were conducted near Yankeetown, FL in a dense mangrove salt marsh, and Crystal River, FL, in a semi-urban setting. The black fly tests were conducted in Algonquin Provincial Park, Ontario, and Copper Harbor, MI, on a riverbank. The mosquito tests were conducted near Naples, FL, in a densely forested mangrove swamp, and Anahuac, TX in a swampy grassland area. Prior to the test, the forearms and legs of the test subjects were washed with Ivory soap and water, followed by an alcohol/water rinse. Using two fingers, Claire-1 was then evenly applied at a target rate of 1 g/645 cm² to the forearms and lower legs. One of the four limbs of each individual was left untreated to serve as a control. During the test, the treated limbs were continuously exposed for approximately four hours and the time of each landing or bite was recorded. When a treated limb received two bites within 30 minutes, it was withdrawn from the test, with the exception of the sand gnat test at Crystal River, where the test continued until repellency fell below 95%. While it was not stated in the study text, the data sheets indicate that control limbs were exposed for 1 minute at least once/hour, and the number of landings was recorded.

RESULTS SUMMARY

The results are summarized in Table 1. In the combined sand gnat tests, the average protection time (based on a second bite within 30 minutes of the first) was 146 minutes. The time until repellency fell below 95% was 200 minutes in the single test using that parameter. In the combined black fly tests, only one subject received a second bite, and the average protection time was 243 minutes. In the combined mosquito tests, the average protection time was 143 minutes.

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that the mean protection time for Claire-1 (10% p-menthane-3,8-diol) against sand gnats, blackflies, and mosquitoes lasted longer than 2 hours.

REVIEWER'S CONCLUSIONS

The submitted product performance studies for the determination of repellency of Claire-1 (10% p-menthane 3,8 diol) against biting gnats (commonly called no-see-ums, *Culicoides* spp.), biting flies (black flies, *Simulium* spp.), and mosquitoes (*Culicidae*) in the field are adequate to satisfy the requirements described in OPPTS 810.3300. The average protection time exceeded 2 hours in the combined sand gnat studies and exceeded 4 hours in the combined blackfly studies. The average

protection time exceeded 2 hours in the combined mosquito studies. The product label for the proposed use directions are adequate.

Table 1. Protection time provided by Claire-1 (10% p-methane-3,8-diol) against mosquitoes.

Test Insect/ Location	Number of reps	Time until first bite (min)	Time until second bite (min)	Time until <95% repellency (min)*
Sand gnats Yankeetown, FL	15	84	92	Not tested
Sand gnats Crystal River, FL	15	192	200	200
Mean protection time (min)		138	146	--
Blackflies Ontario, Canada	12	No bites in 240 minutes	No bites in 240 minutes	Not tested
Blackflies Copper Harbor, MI	12	247	247	Not tested
Mean protection time (min)		243	243	--
Mosquitoes I Naples, FL	15	75	100	Not tested
Mosquitoes II Naples, FL	15	148	194	Not tested
Mosquitoes Anahuac, TX	15	135	135	Not tested
Mean protection time (min)		119	143	--

*To calculate 95% repellency, the number of bites on each treated limb was added together and divided by a running average control bite number. This number was then subtracted from 1 and multiplied by 100 to get percent repellency. A detailed explanation is given on p. 28 of 56 in MRID 4560609.

DATA EVALUATION RECORD

**P-MENTHANE-3,8-DIOL
(CLAIRE-1)**

**STUDY TYPE: Product Performance, OPPTS 810.3300
MRID 45650610**

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Work Assignment No. 147

Primary Reviewer:

Eric B. Lewis, M.S.

Signature: _____

Date: _____

Secondary Reviewers:

Anthony O. Armstrong, M.S.

Signature: _____

Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____

Date: _____

Quality Assurance:

Lee Ann Wilson, M.A.

Signature: _____

Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

DATA EVALUATION RECORD

Secondary Reviewer: Manying Xue, Chemist

STUDY TYPE: Product Performance, OPPTS 810.3300
DP BARCODE: D285177
CASE NO: 072228
SUBMISSION NO: S616170
MRID NO: 45650610
TEST MATERIAL: Claire-1 (10% p-methane-3,8-diol)
STUDY NO: 429E2
SPONSOR: S.C. Johnson & Son, Inc.
TESTING FACILITY: Entomology Research Center, Racine, WI
TITLE OF REPORT: Determining Repellency of Claire-1 (10% p-menthane 3,8 diol) Against Ticks (*Ixodes scapularis* and *Amblyomma americanum* Adults) in the Laboratory.
AUTHOR: D.T. Ropiak
STUDY COMPLETED: September, 2001
CONFIDENTIALITY CLAIMS: None
STUDY SUMMARY: Laboratory tests were conducted with human subjects to determine the efficacy of Claire-1 insect repellent (10% p-menthane-3,8-diol) to repel the movement of two species of adult ticks on the skin. One forearm was treated with the test material at a rate of 1.0 g/645 cm² and three ticks were placed on the hand. During one five-minute exposure per hour for four consecutive hours, the number of ticks that crossed from the hand onto the forearm was counted. For *Amblyomma* ticks, the test material provided 99% repellency the first hour, 90% the second hour, 68% the third hour, and 66% the fourth hour. For *Ixodes* ticks, the test material provided 100% repellency for all four hours.
CLASSIFICATION: Acceptable
GOOD LABORATORY PRACTICE: The study was conducted in compliance with 40 CFR Part 160 with the exception that some signatures for arm measurements were late.

TEST MATERIAL

Claire-1 (10% p-methane-3,8-diol)

TEST METHOD

Laboratory tests were conducted with human subjects to determine the efficacy of Claire-1 (10% p-methane-3,8-diol) to repel the movement of adult ticks (*Ixodes scapularis* and *Amblyomma americanum*) on skin. The forearms of the test subjects were washed with Ivory soap and water and rinsed with a 70% ethanol/30% water solution. Using two fingers, the test material was applied at a target rate of 1.0 g/645 cm² to one forearm from wrist to elbow. The untreated opposite forearm served as the control. A line was drawn 3 cm above the wrist, and one hour after treatment, three ticks were placed on the back of each hand. The hands were then turned over to promote movement toward the treated surface. Ticks that crossed the line drawn on the forearm were picked up and replaced on the hand, so it was possible for one tick to make multiple crossings. The number of crossings was counted for 5 minutes, after which the ticks were killed. The test consisted of one five-minute exposure per hour for four consecutive hours, using new ticks each time.

RESULTS

A summary of the results is given in Table 1. For *Amblyomma*, the test material provided 99% repellency for the first hour, declining to 90% for the second hour, 68% for the third hour, and 66% for the fourth hour. In the test using *Ixodes*, the ticks appeared lethargic and only one tick each crossed on the treated and control forearms. It was assumed that a problem had developed during shipping of the ticks to the laboratory, and the test was redone two weeks later with new ticks. In the second test, the ticks were 100% repelled at all test times for three of the four subjects. In the fourth subject, repellency increased from 50% to 100% during the test, which is the opposite of what would be expected. It was observed that all the crossings for that treated arm followed a common path. It was speculated that the test material had been mis-applied to that arm, and over time, gradually soaked into the mis-applied area, to provide increased repellency over time. When that one rep was deleted, the repellency against *Ixodes* was 100% for all test times. If the rep was included, the average repellency was 90% for the first hour, 94% for the second hour, 99% for the third hour, and 100% for the fourth hour.

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that the study substantiates the claim that the test material repels ticks from human subjects.

REVIEWER'S CONCLUSIONS

The submitted product performance study for the determination of repellency of Claire-1 (10% p-menthane 3,8 diol) against ticks (*Ixodes scapularis* and *Amblyomma americanum* Adults) are adequate to satisfy the requirements described in OPPTS 810.3300. Claire-1 repelled 100% of *Ixodes* ticks and 90% of *Amblyomma* ticks for 2 hours. The product label for the proposed use directions are adequate.

Table 1. % Repellency of Claire-1 against ticks

Treatment	Subject	Number crossing to forearm				% Repelled ^a			
		1 hr	2 hr	3 hr	4 hr	1 hr	2 hr	3 hr	4 hr
<i>Amblyomma americanum</i>									
Claire-1	DAC	0	0	4	0	100	100	0	100
Control	DAC	10	13	2	11	--	--	--	--
Claire-1	WGM	1	0	2	1	94	ND	78	80
Control	WGM	18	0	9	5	--	--	--	--
Claire-1	DAS	0	1	0	3	100	86	100	83
Control	DAS	2	7	3	18	--	--	--	--
Claire-1	SRB	0	0	2	7	100	100	75	0
Control	SRB	7	9	8	5	--	--	--	--
Claire-1	DTR	0	1	1	2	100	75	89	67
Control	DTR	1	4	9	6	--	--	--	--
Avg						99	90	68	66
<i>Ixodes scapularis</i>									
Claire-1	REV	0	0	0	0	100	100	100	100
Control	REV	1	1	5	6	--	--	--	--
Claire-1	KAC	2	2	1	0	50 ^b	71 ^b	95 ^b	100 ^b
Control	KAC	4	7	21	2	--	--	--	--
Claire-1	SRB	0	0	0	0	100	100	100	100
Control	SRB	20	4	16	12	--	--	--	--
Claire-1	WGM	0	0	0	0	100	100	100	100
Control	WGM	6	5	6	12	--	--	--	--
Claire-1	CAT	0	0	0	0	100	100	100	100
Control	CAT	4	8	6	2	--	--	--	--
Avg (4 reps only)						100	100	100	100

^a Calculated as 1-(number of crossings on treated arm/number of crossings on control arm) x 100

^b Not included in average repellency calculation. See Test Method section for explanation.

PC 011550

P-MENTHANE-3,8-DIOL

Page _____ is not included in this copy.

Pages 48 through 71 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Claire-1

ACTIVE INGREDIENT:

[p-Menthane-3,8-diol]* 10.0%
OTHER INGREDIENTS** 90.0%

- *cis/trans isomer ratio: min. 60% (+/-) cis and max. 40% (+/-) trans*
- *** Contains petroleum distillates*

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements and complete directions for use.

Net Contents: XXX

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: May be harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Do not use on children under the age of three. Apply with caution to young children. Do not allow children to apply this product to themselves. Do not apply to excessively sunburned or damaged skin. May cause skin reaction in rare cases. Avoid breathing spray in enclosed areas.

(Note to reviewer: Boxed format or bullets may be used in First Aid section if label space permits.)

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

IF SWALLOWED: Immediately call a poison control center or doctor for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person. IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. SKIN: If you or your child react to this product, wash treated skin and call your doctor.

NOTE TO PHYSICIAN

Contains petroleum distillates – vomiting may cause aspiration pneumonitis.

PHYSICAL & CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all directions before using this product.

General Instructions: Hold container 6 to 8 inches from skin or clothing and spray with a slow sweeping motion. Do not use as a space spray. Use sufficient repellent to cover exposed skin evenly and completely. Wash hands thoroughly with soap and water after applying. For continued protection from listed insects, reapply every 2 hours or after swimming, perspiration, vigorous activity or toweling. Application To Face: Do not spray directly on or near face. Instead, spray in palm of hand and spread on face and neck. Do not apply to face or hands of young children. For maximum protection, spread evenly with hand to moisten all exposed skin. Works On Clothing Too: Spray shirts, pants, socks and hats. Do not apply on or around Spandex. Wash treated clothing before reuse. After returning indoors, wash treated skin with soap and water.

STORAGE: Store away from heat or flame in an area inaccessible to children.

DISPOSAL: Before disposing, empty container by using the product according to the label. Do not reuse this container. Place in trash or offer for recycling if available.

If partially filled: Call your local solid waste agency or 1-800-558-5252 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions? Comments? Call 800-558-5252 or write Helen Johnson. © (2002) S.C. Johnson & Son, Inc. Racine, WI 53404-2236 U.S.A. All rights reserved.

EPA Reg. No. XXX

EPA Est. No. XXX

(Optional Marketing Language – Note: parenthesis indicate optional text)

- NEW!
- Insect Repellent
- (Relaxing) (Outdoor) protection
- Not sticky or greasy
- (Non-greasy) (formula)
- Keep on hand to keep bugs OFF!
- With (a delicate blend of) (botanical plant extracts) (botanical plant derivatives)
- (Contains) (With) Aloe (Vera)
- (Feels great on.) (Keeps bugs OFF!)
- Leaves your skin feeling smooth and natural
- S.C. Johnson A Family Company
- Dermatologist Tested
- Mild
- Botanical
- (Summer fun) (Take-along) (To-go) (On-the-Go) pack
- A must have for all parents
- Contains plant (extracts) (oils) (derivatives)
- (Contains) (With) a plant-based repellent
- OFF! Protection has never felt better!
- Plant-based (repellent) (protection)
- Duplicates the repellency of eucalyptus
- Also available (product name for 4822-515)
- Mosquito-free playtime
- Unscented (Spritz) (Spray)
- No chemical scent
- (Clean) (fresh) (light) (pleasant) (great) scent
- (Clean) (fresh) (light) (pleasant) (great) fragrance
- Repels (mosquitoes) (black flies, gnats, no-see-ums and ticks) (up to 2 hours)
- Contains no (added) dyes
- Gentle (formula)
- A luxurious insect repellent
- Skin-conditioning (formula) (for beauty without bites)
- (Provides) (Plant-based) (long lasting) protection from (annoying) mosquitoes (black flies, gnats, no-see-ums and ticks) (for up to 2 hours)
- Botanically-inspired (insect) repellent
- (Contains a) botanically-derived insect repellent
- Enjoy the outdoors (with Claire-1)
- Contains (the) (insect) repellent found in eucalyptus
- (New (plant-based) ingredient repels mosquitoes, (black flies, gnats, no-see-ums, and ticks))
- Claire-1's unique formula uses a plant-based ingredient (to repel mosquitoes, black flies, gnats, no-see-ums and ticks).
- It contains the insect repellent found in eucalyptus plants.
- This new ingredient repels mosquitoes, black flies, gnats, no-see-ums and ticks (.) (!)
- Claire-1 is effective dependable protection that feels great on – not sticky or greasy – and it has a light, clean, fresh fragrance).
- (...) And because it's from the makers of OFF!, it's specially formulated to effectively repel mosquitoes, black flies, gnats (no-see-ums) and ticks (including ticks that cause Lyme disease) for up to 2 hours.
- ((Place) (Carry) (Have) Claire-1 (:)) ((Place) (Carry) (Have) a bottle (:)) (everywhere) (in) (your) (purse) (glove compartment) (glove box) (golf bag) (tennis bag) (tackle box) (tent) (book bag) (backpack) (fanny pack) (beach bag) (boat) (summer cabin) (first-aid kit).
- For use at (:) (home) (or) (on the go) (on a picnic) (picnicing) (camping) (at sporting events) (boating) (fishing) (hiking) (while) (gardening) (playing) (outside))
- Contains: **(insert complete list of active and inert ingredient descriptors)**