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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 21 1998

MEMORANDUM

SUBJECT: Registration of Granola 97® (EPA File Symbol 4822-UOO) Containing 99% P-menthane 3,8-diol (65% cis and 34% trans isomers)a new active ingredient; Chemical No. 011550; Review of Product Chemistry Studies; MRID Nos. 444387-12, 444387-13, and 444893-01; Submission No. S538748; DP Barcode No. D243976

FROM: Freshteh Toghrol, Ph.D., Senior Scientist F. Toghrol
Biochemical pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

TO: John Tice, Regulatory Action Leader
Biochemical pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

ACTION REQUESTED

S.C. Johnson and Son, Inc. requests registration of Granola 97® (EPA File Symbol 4822-UOO). Granola 97® is a biochemical insect repellent, containing 99% (65% cis and 34% trans isomers)P-Menthane-3,8 diol as the active ingredient.

BPPD'S CONCLUSIONS AND RECOMMENDATIONS

1. The active ingredient will not be used to formulate food use products, therefore the tolerance establishment/exemption is not required.

2. The submitted product chemistry data satisfy the data requirements for Granola 97®/MP (EPA File Symbol 4822-UOO) regarding product identity (151-10), manufacturing process (GLN 151-11), discussion of formation of unintentional ingredients (GLN 151- 12).

4. Analysis of samples (GLN 151-13) and certification of

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limits (GLN 151-15) are acceptable. However, the CSF was not prepared from data submitted for five batches (703001, 703002, 908001, 908002, and 908003), which were used in this study(both isomers) are 100.4, 99.9, 99.9, 99.6, 99.6 (respectively).

5. The submitted CSF for Granola 97 is not acceptable. The registrant must submit a revised CSF using the five batch analysis for nominal concentration column 13(b), and upper limit and lower limit (column 14(a)and 14(b)respectively). *

6. The analytical method for certified limits (MRID No. 444387-12) is acceptable. The GC/FID analytical method was used to determine the concentration of the active ingredient P-Menthane-3,8 diol(65% cis and 34% trans isomers) in the product. The description of analytical method and chromatogram were submitted.

7. The active ingredient in Granola 97® is 99% (65% cis and 34% trans isomers)P-Menthane-3,8 diol, CAS No. 42822-86-6).

8. The data submitted for physical and chemical properties (GLN 151-17) for Granola 97® are acceptable.

cc: F. Toghrol, BPPD subject file, John Tice
F.Toghrol: F.T.:CS#1:(703)308-7014:7/21/98.

* revised CSF (reviewed with Freshteh on 12/22/99) is in compliance

DATA EVALUATION REPORT

GRANOLA 97

STUDY TYPES: Product Identity and Disclosure of Ingredients (Oppts 880.1100)
Description of Beginning Materials &
Manufacturing Process (Oppts 880.1200)
Discussion of Formation of Impurities (Oppts 880.1400)
Certification of Ingredient Limits (Oppts 830.1750)

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Station 1
2800 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37930
Task Order No. 22

Primary Reviewer: Robin Brothers, Ph.D.	Signature:	Robin Brothers
	Date:	5-11-98
Secondary Reviewers: Sylvia Milanez, Ph.D.,D.A.B.T.	Signature:	Sylvia Milanez
	Date:	5-11-98
Robert H. Ross, Group Leader	Signature:	RT Boyer
	Date:	5-11-98
Quality Assurance: Lee Ann Wilson, M.A.	Signature:	L. A. Wilson
	Date:	5-11-98

Disclaimer

This Data Evaluation Report may have been altered by the Biopesticides and Pollution Prevention Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Freshteh Toghrol, Ph.D. F. Toghrol Date 7/21/98
Biopesticides and Pollution Prevention Division (7511W)

DATA EVALUATION REPORT

STUDY TYPES: Product Identity and Disclosure of Ingredients, Description of Beginning Materials & Manufacturing Process, Discussion of Formation of Impurities, Certification of Ingredient Limits (OPPTS 830.1750 - 880.1400).

CASE NO: 061954

PC CODE: 011550

DP BARCODE: D243976

SUBMISSION: S538748

MRID NO: 44438713

TEST MATERIAL: Granola 97 (Active ingredient p-menthane-3,8-diol, 99%, nominal)

SYNONYMS: p-Menthane-3,8-diol or Cyclohexanemethanol, 2-hydroxy-alpha,. alpha, 4-trimethyl

STUDY NUMBER: S.C. Johnson Project ID 346

SPONSOR: S.C. Johnson and Son, Inc., 1525 Howe St., Racine, WI 53403

TESTING FACILITY: Not reported in this volume.

TITLE OF REPORT: Product Chemistry Data for Granola 97 Formula Number 14735R108

AUTHOR: Heidi J. Uick

REPORT ISSUED: November 20, 1997

EXECUTIVE SUMMARY: The product identity, ingredients, certified ingredient limits, manufacturing process, and discussion of formation of impurities for Granola 97 are given in MRID 44438713. The active ingredient of Granola 97 is p-menthane-3,8-diol. Granola 97 (p-menthane-3,8-diol) is produced in an integrated process beginning with the raw materials of [redacted]

Manufacturing process information not included.

Classification of the study - The product identification, manufacturing process and formation of impurities were acceptable. The certification of ingredient limits was unacceptable by itself because the method to certify limits was not given. The study is acceptable when considered with the method to certify limits given in MRID 44438712.

COMPLIANCE: Signed and dated Data Confidentiality Statements and GLP statements were provided. GLP Statements stated that the study did not meet the requirements of 40 CFR Part

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160 because it is not currently required to do so. No Quality Assurance Statements were provided.

A. PRODUCT IDENTITY AND DISCLOSURE OF INGREDIENTS (OPPTS 880.1100)

Granola 97 is an insect repellant manufacturing product that consists of p-menthane-3,8-diol as the active ingredient (99.0% nominal w/w). The product is a mixture of +/-cis and +/-trans isomers of p-menthane-3,8-diol. Inert ingredients that may be present in quantities greater than 0.1% include [redacted]

B. MANUFACTURING PROCESS (OPPTS 880.1200)

[redacted]

Manufacturing process information not included.

C. DISCUSSION OF FORMATION OF IMPURITIES (OPPTS 880.1400)

[redacted]

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Manufacturing process information not included.

D. CERTIFICATION OF INGREDIENT LIMITS (OPPTS 830.1750)

TABLE 1 Formula of Granola 97

Ingredient	Stated Percent by weight	Certified limit (%)	
		Upper	Lower
p-menthane-3,8-diol CASRN: 42822-86-6	99	100	96
[redacted]			

F. DISCUSSION

The product identity and disclosure of ingredients were adequately described, and the manufacturing process was sufficiently explained. No method to certify the ingredient limits was given. This, however was performed in MRID 44438712. It is unclear if the producer or the product sponsor performed the analysis for certification of limits.

G. STUDY DEFICIENCIES

The CAS numbers for the starting materials and the intermediate products were not provided, except for [redacted] The purity of the internal intermediate products were not given for all intermediates. The CAS number listed on page 4 of the confidential attachment for the [redacted] impurity is incorrect. The study does not include the method to certify the ingredient limits which was given in MRID 44438712.

Classification: Unacceptable by itself because the method to certify limits was not given. The study is acceptable when considered with the preliminary analysis and the method to certify limits in MRID 44438712.

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DATA EVALUATION REPORT

Granola 97

STUDY TYPES: Physical And Chemical Characteristics (Oppts 830.6302-830.7950)
Preliminary Analysis of Samples (Oppts 830.1700)
Enforcement Analytical Method (Oppts 830.1800)

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Station 1
2800 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37930
Task Order No. 22

Primary Reviewer: Robin Brothers, Ph.D..	Signature:	Robin Brothers
	Date:	5-11-98
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	Date:	5-11-98
Robert H. Ross, M.S., Group Leader	Signature:	Robert H. Ross
	Date:	5-11-98
Quality Assurance: Lee Ann Wilson, M.A.	Signature:	L. A. Wilson
	Date:	5-11-98

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EPA Reviewer: Freshteh Toghrol, Ph.D. F. Toghrol, Date 7/21/98
Biopesticides and Pollution Prevention Division (7511W)

DATA EVALUATION REPORT

STUDY TYPE: Physical and Chemical Characteristics (OPPTS 8300.6302 - 830.7950)
Preliminary Analysis of Samples (OPPTS 830.1700)
Enforcement Analytical Method (OPPTS 830.1800)

P.C. CODE: 011550

DP BARCODE: D243976

CASE: 061954

SUBMISSION: S538748

MRID NO.: 44438712 and 44489301

TEST MATERIAL: Granola 97 (Active ingredient: p-menthane-3,8-diol, 99% nominal)

SYNONYMS: p-menthane-3,8-diol

SPONSOR: S.C. Johnson & Son, Inc., 1525 Howe St., Racine, WI 53403

TESTING FACILITY: MRID 44438712: S.C. Johnson & Son, Inc., 1525 Howe St., Racine, WI
MRID 44489301: Covance Laboratories, Inc., 3301 Kinsman Boulevard Madison, WI 53704

TITLE OF REPORTS Physical and Chemical Characteristics of Granola 97 Formula Number 14735R108 (MRID 44438712)

Vapor Pressure Determination of Granola 97 (MRID 44489301)

AUTHOR: MRID 44438712 Kenneth J. Welch
MRID 44489301 Mark Morrissey

STUDY COMPLETED ON: November 24, 1997 (MRID 44438712)
January 28, 1998 (MRID 44489301)

EXECUTIVE SUMMARY: The physical and chemical characteristics of Granola 97 were reported in MRID 44438712 with the exception of vapor pressure which was reported in MRID 44489301. Granola 97 is a technical grade product which contains p-menthane-3,8-diol as the active ingredient. MRID 44438712 also contains the results of the preliminary analysis of samples and provides the method for enforcement of certified limits. In the preliminary analysis of samples reported in this study the range of total p-menthane-3,8-diol (w/w%) was [redacted]

Classification of the Study: Acceptable Manufacturing process information not included.

COMPLIANCE: MRID 44438712: Good Laboratory Practices were not followed. A deviation occurred when an entry to a raw data sheet was made in pencil. The deviation was not found to affect the

quality of the data. Audits and reports from the Quality Assurance Unit were conducted. A statement of non-confidentiality was provided.

MRID 44489301: Good Laboratory Practices were followed. Audits and reports from the Quality Assurance Unit were conducted. A statement of non-confidentiality was provided.

A. PRELIMINARY ANALYSIS OF SAMPLES OF GRANOLA 97 (OPPTS 830.1700)

Samples from five batches of Granola 97 were analyzed for active ingredients and possible impurities. The results are given below.

Component	Batch (weight %)				
	703001	703002	908001	908002	908003
p-menthane-3,8-diol (all isomers)	[redacted]				

NQ= Analyte detected but not quantified. Limit of quantification was about 0.1% (w/w).
ND= Analyte not detected. Limit of detection was about 0.01% (w/w).
Analysis performed at S.C. Johnson & Son, Inc., 1525 Howe St. , Racine WI 53403.

B. ENFORCEMENT ANALYTICAL METHOD

[redacted]

C. PHYSICAL AND CHEMICAL CHARACTERISTICS (OPPTS 830.6302-830.7950)

830.6302 Color: opaque-white

830.6303 Physical State: solid, specific observation temperature not noted.

Manufacturing process information not included.

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830.6304 Odor: Faint mint

830.7200 Melting Point: 34.5°C

830.7220 Boiling Point: not required, solid at room temperature.

830.7300 Density :0.989 g/mL determined at 24°C

830.7840 Solubility: 0.29 g/L at 25°C

830.7950 Vapor Pressure: 0.181 Pa, determined by method of gas saturation (Covance)

830.7370 Dissociation Constants in Water: not reported but as given in discussion of pH test, product is not dispersible with water.

830.7550 Octanol/Water Partition Coefficient: not required- the Agency has concluded that this compound and its intended use pattern do not present an environmental fate concern.

830.7000 pH: not applicable, product is not dispersible with water.

830.6313 Stability: product exhibited stability to sunlight, heat (54°C), metal (iron, aluminum), and metal ions (iron (II) acetate, aluminum acetate)

830.6314 Oxidizing or Reducing Action: not discussed.

830.6315 Flammability: flash point 139.8°C.

830.6317 Storage Stability: not applicable, the product is a technical grade active ingredient.

830.7100 Viscosity: 56.1 cP at 60°C

830.6319 Miscibility: not applicable- product not intended for dilution with petroleum solvents.

830.6320 Corrosion Characteristics: not applicable- product is a technical grade active ingredient.

D. DISCUSSION

MRID 44438712 describes the physical and chemical characteristics of Granola 97, contains the results of the preliminary analysis of samples (99% active ingredient) and provides the method for enforcement of certified limits. The enforcement analytical method was included to complete the requirements for certification of ingredient limits found in MRID 44438713 which lacked these sections. A thorough discussion of the analytical procedures was provided.

E. STUDY DEFICIENCIES

MRID 44438712 by itself lacks the discussion of vapor pressure but this was provided in MRID 44489301 to yield an acceptable report.

Classification of Study: Acceptable