

US EPA ARCHIVE DOCUMENT

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE: 25/JUL/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D275563
REG./File Symbol: 9404-IT
PRODUCT NAME: Permethrin 0.25% Insecticide Granules
COMPANY: Sunniland Corp.

FROM: Linda L. Kutney, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

Linda L. Kutney
7/25/01

TO: Arnold Layne, Linda Gerber PM 3
Insecticide Branch/RD(7505C)

INTRODUCTION

The Sunniland Corp. has sent (in a letter dated 6/4/01) a me-too registration request for their insecticide, Permethrin 0.25% Insecticide Granules, based on its reported similarity to Micro Flo Company's (now Aventis Corporation's) Permethrin 0.25% Granules, Reg. No. 51036-322.

The proposed CSF for Sunniland's Permethrin 0.25% Insecticide Granules contains [REDACTED] pure permethrin a.i. which is a source of the nominal 0.25% permethrin in the proposed end-use product. Product chemistry data supplied in support of this request have been assigned MRID number 452546-01. The intended use of Permethrin 0.25% Insecticide Granules is a non-food use on residential lawns, ornamentals, recreational turf and golf courses.

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FINDINGS

- The Agency was informed, in a 6/4/01 FAX of a letter from consultants H. R. McLane, Inc., that [REDACTED] has agreed to support this registration request for Permethrin 0.25% Insecticide Granules, partly because [REDACTED] is the a.i. source.
- The densities, pH's, and flash points/flame extensions of Permethrin 0.25% Insecticide Granules are essentially identical to Permethrin 0.25% Granules, Reg. No. 51036-322."
- The Physical or Chemical Hazard statements on the proposed label for Permethrin 0.25% Insecticide Granules are appropriate with respect to its flammability and satisfy the requirements specified in 40 CFR 156.10 (h)(2)(iii).
- The analytical method requirement (40 CFR 158.180) has been previously satisfied.

CONCLUSIONS:

TRB has reviewed this submission and concluded that Sunniland Corporation's Permethrin 0.25% Insecticide Granules can not be declared substantially similar to Avenis's Product, Permethrin 0.25% Granules, Reg. No. 51036-322, until the deficiencies *italicized* below are adequately addressed and submitted to the Agency for additional consideration.:

- *The proposed storage and disposal instructions must be revised to correctly spell out, "Store product in original container in a locked cool, dry storage area out of reach of children and pets " in accordance with PR 83-3.*
- The nominal concentration of the permethrin product a.i. agrees with the label concentration, in accordance with the requirements of PR 91-2. *The proposed 6/4/01 CSF identifies the a.i. as [REDACTED] in column 10. The chemical name of the a.i., permethrin, must be as is listed on the label in the CSF, column 10, along with the purity of the permethrin.*
- *Column 11 of the proposed 5/18/01 CSF should give the full supplier name and address for all components in the label.*
- *Guideline submissions for 830.1550 (Product Identity) and 830.1750 (Certified limits) do not satisfy 40CFR§158.155 and 158.175, respectively, because the study states the [REDACTED] the CSF states the ai is [REDACTED]. Sunniland must provide a clear, consistent description of product identity and certified limits within their study and proposed CSF.*

- *Guideline 830.1600 (Beginning Materials) and Guideline 830.1620 (Formulation Process) must be provided. Data given in the study must be consistent with the proposed CSF.*
- *Guideline requirements withing 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics) are expected to satisfy the requirements for the Permethrin 0.25% Insecticide Granules, when similarity between the Summiland product and the Aventis product is established.*

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COMPANY: Sunniland Corp.

1. Reviewer: Linda L. Kutney
2. Company: Sunniland Corp.
3. Type of Submission: Registration Reregistration New Resubmission
Amendment "ME-TOO" Alternate Formulation Experimental Use
Permit Other (Specify)
4. If "Me-TOO" Registration, this product is is not similar or substantially similar
to EPA's Reg. No.:
If not, comment in Confidential Appendix A on the differences between the registered and
new source, where applicable

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system.....
 - Are all technical grade active ingredients used registered? ● yes ● no , If no,
specify The technical is under process of registration
 - Integrated formulation system.....
6. Clearance of intentionally added ingredients in the formulation for the intended use
(indicate in the Confidential Appendix those that are not cleared; the PC Codes should be
provided by the chemist on the CSF for those that are cleared):
 - 6(a) Formulation intended for food use under 40CFR§180.1001:
 - yes ● no ● Some are cleared, others are not
 - Cleared under list: ● c ● d ● e Are there any limitations for use as an
inert under 40CFR§180. 1001?
 - yes ● no , If yes, specify
 - 6(b) Formulation intended for non-food use:
 - yes ● no ● Some are cleared, others are not

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- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).

• yes [] • no [] • Some are cleared, others are not []
If yes, the entire formulation is cleared under 21CFR§

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 830.7300(density), 830.7000(pH), and 830.6315(Flammability), respectively:

• yes [X] • no []

8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
[REDACTED] Permethrin, [REDACTED]	0.25	0.28	0.225

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:

• yes [X] • no []

10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:

• yes [X] • no []

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [] • no [X]

The proposed 6/4/01 CSF says only [REDACTED] in column 10 for the ai, it must also give the chemical name, permethrin, along with its purity.

12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:

• yes [] • no [] • not applicable [X]

13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:

• yes [X] • no []

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PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

14. Chemical IDs/Manufacture/ Analytical Information New Guideline:830.--	Data Required Fulfilled	MRID No.
1550. Chemical Identity(CSF)	No Study states [REDACTED] CSF states at is [REDACTED]	452546-01 6/4/01 CSF
1600. Beginning Materials 1620. Formulation Process	Not provided, study lists different inerts than 6/4/01 CSF	452546-01 6/4/01 CSF
1750. Certified Limits (CSF)	No Study states [REDACTED] CSF states at is [REDACTED] & contains different inerts than 6/4/01 CSF	452546-01 6/4/01 CSF
1800. Enforcement of Analytical Method (required for integrated products & those of tox. concern)	Yes, already available for permethrin	
1900. Submittal of Samples (required for integrated products, those of tox. concern, and for nonintegrated products with interference, etc, method problems)	N/A	

<u>15. Physical/Chemical Properties</u> New Guideline No. 830.---	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
6302. Color (if required by PR 92-5)	Yes	tan	452546-01
6303. Physical State	Yes	granules	452546-01
6304. Odor (if required by PR 92-5)	Yes	earthy	452546-01

6314. Oxidation Reduction Reaction	N/A		452546-01
6315. Flammability/Flame Extension	N/A	> 500 F	452546-01
6316. Explodability	Yes	Contains no explosive ingredienets	452546-01
6317. Storage Stability	Yes	Reported as stable product, acceptable due to me-too product stability	452546-01
6319. Miscibility	N/A	granule	452546-01
6320. Corrosion Characteristics	Yes	Reported as stable product, acceptable due to me-too product stability	452546-01
6321. Dielectric Breakdown Voltage	N/A	granule	452546-01
7000. pH	N/A	granule	452546-01
7100. Viscosity	N/A	granule	452546-01
7300. Density/Bulk Den.	Yes	29-32 lb/ft3	452546-01

NA = Not Applicable;