

DATE OUT: 09/APR/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D273260 REG./File Symbol No.: 48139-RR
PRODUCT NAME: Invicta Clothing Insect Repellent Kit

FROM: Shyam Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

S Mathur
4-9-01

TO: Arnold Layne, PM 03
Insecticide Branch/RD(7505C)

INTRODUCTION:

The registrant has submitted product chemistry data to support the registration of the subject end-use product. The product chemistry data were submitted under MRID No. 453400-01. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 432-1137. The data corresponding to 830 Series Subgroup B has been cited under MRID No. 441487-01. The product chemistry data corresponding to guideline reference 830.1800 (Enforcement analytical method) and Corrosion characteristics have been cited to the registered product with Reg. No. 4816-646.

SUMMARY OF FINDINGS

1. The proposed product contains [REDACTED] as the active ingredient with product label claim of 0.50%.
2. The CSF for the basic formulation (dated 02-06-01) is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. The data submitted corresponding to the guideline reference 830.1550 (Product Identity) and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.
3. The data submitted corresponding to the guideline reference 830.1650 (Description of formulation process) and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR158.165 and 158.167 respectively.
4. The data cited (Reg. No. 4816-646) corresponding to the guideline reference 830.1800 (Enforcement of analytical method) satisfy the data requirements of 40CFR§158.180.

PRODUCT INGREDIENT SOURCE INFORMATION HAS BEEN REMOVED

5. The data cited (MRID No. 441487-01) corresponding to the guideline reference Physical state(830.6303), density(830.7300), pH(830.7000), Oxidation/Reduction(830.6314), Flammability(830.6315), Explodability(830.6316), Storage stability (830.6317), Viscosity (830.7100), Miscibility(830.6319), & Dielectric breakdown voltage (830.6321) satisfy the data requirements of 40CFR§158.190.

6. The registrant has cited the product with Reg. No. 4816-646 to support the data for Corrosion characteristics(830.6320).

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the subject end-use product and has concluded that:

1. The product chemistry data submitted and cited for proposed product satisfy the data requirements of 40CFR§158.150 to 158.190 and are acceptable.

2. The CSF for basic formulation(dated 02-06-01)is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. The data submitted corresponding to the guideline reference 830.1550(Product Identity)and 830.1750(Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively. The CSF for basic formulation is acceptable.

3. The proposed product was determined to be substantially similar to the registered product with Reg. No. 432-1137 from the product chemistry stand point of view.

PRODUCT CHEMISTRY REVIEW OF MP ☐ EP ☒
 DP BARCODE No.: D273260 REG./File Symbol No.: 48139-RR
 PRODUCT NAME: Invicta Clothing Insect Repellent Kit
 DATE: 04-09-01

1. Reviewer: S.B.Mathur 2. Company: Hilton Head Laboratories
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.: 432-1137

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant

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 _____
 • 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 ☐
- 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]	(0.50)	(0.55)	(0.45)

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 [X] • no []

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 []

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

<u>14. Chemical IDs/Manufacture/ Analytical Information</u> New Guideline:830.--	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
1550. Chemical Identity(CSF)	Y	02-06-01
1600. Beginning Materials	Y	453400-01
1650. Formulation Process	Y	
1670. Discussion of Impurities	Y	" "
1700. Preliminary Analysis	NA	
1750. Certified Limits(CSF)	Y	02-06-01
1800. Enforcemnt. of Anal.Method	Y(cited) Note 1	Reg. No. 4816-646

<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>
6303. Physical Stat	Y	Liquid	441487-01
7300. Density/Bulk Den.	Y	0.9504 g/ml	" "
7000. pH	Y	6-8 (Note 2)	" "
6314. Oxid/Red Action	Y	None	" "
6315. Flamm.-Flash Pt.	Y	>200°F	" "
6315. Flame Exten.	NA		
6316. Explodability	Y	None	" "
6317. Storage Stability.	PR 92-5		" "
7100. Viscosity	Y	34780 cPs	" "
6319. Miscibility	NA		" "
6320. Corrosion Charac	Y(cited)	non- corrosive	Reg. No. 4816-646
6321. Dielec.Bkd.Vltg	NA		441487-01

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

Note 1.830.1800. Enforcement analytical method: (Reg. No. 432-1112)

The active ingredient Permethrin was determined by using the GC Method; Method No. FAC-12(Fairfield American Corporation).

Note 2. 830.7000. pH: the pH adjusted with citric acid and/or triethanolamine.