

DATE OUT: 23/AUGUST/2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D267236 REG./File Symbol No.: 028293-GEI
PRODUCT NAME: Unicorn .25% Permethrin Granules

FROM: Ann Mary Nefcy, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

Ann Mary Nefcy
08/23/00

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

INTRODUCTION

The registrant has submitted a registration application for the end-use product, Unicorn .25% Permethrin Granules.

SUMMARY OF FINDINGS:

1. The subject product contains the following active ingredient:

[REDACTED]

2. The CSF for the basic formulation(dated 06/13/00)is not filled out correctly and completely. The data submitted corresponding to the guideline reference 830.1750 (Certified limits) does not satisfies the data requirements of 40CFR§158.175 respectively. The data was not submitted to substantiate the Product Chemistry Requirements, upon which the CSF was based (refer to comments below).

3. The data submitted corresponding to the guideline reference 830.1550(Product Identity), 830.1600 (Descriptions of materials used to produce the product), 830.1650(Description of formulation process)and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR158.155, 158.160, 158.165 and 158.167 respectively.

4. The data submitted corresponding to the guideline reference 830.1800(Enforcement of analytical method) do not satisfy the data requirements of 40CFR§158.180. These data were not submitted.

5. The data submitted 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), Miscibility (830.6319), Viscosity (830.7100), and Corrosion (830.6320) do not satisfy the data requirements of 40CFR§158.190. These data were not submitted.

6. The following Product Chemistry Data Requirements (Group A and B) require a signed statement indicating compliance with Good Laboratory Practices for conducting end-use product studies (40CFR Part 160):

830.1750 Certified Limits
830.1800 Enforcement Analytical Methods
830.6317 Storage Stability

CONCLUSIONS:

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

1. The CSF for the basic formulation(dated 06/13/00)is not filled out correctly and completely. The data submitted corresponding to the guideline reference 830.1750 (Certified limits) does not satisfies the data requirements of 40CFR§158.175. The data was not submitted to substantiate the Product Chemistry Requirements, upon which the CSF was based (refer to comments below). Therefore, the data are unacceptable.
2. The data submitted corresponding to the guideline reference 830.1550(Product Identity), 830.1600 (Descriptions of materials used to produce the product), 830.1650(Description of formulation process)and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR158.155, 158.160, 158.165 and 158.167 respectively. These data are acceptable.
3. The data submitted corresponding to the guideline reference 830.1800(Enforcement of analytical method) do not satisfy the data requirements of 40CFR§158.180. These data were not submitted, and are, therefore, unacceptable.

4. The data submitted 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), Miscibility (830.6319), Viscosity (830.7100), and Corrosion (830.6320) do not satisfy the data requirements of 40CFR§158.190. These data were not submitted, and are, therefore, unacceptable.

5. The following Product Chemistry Data Requirements (Group A and B) require a signed statement indicating compliance with Good Laboratory Practices for conducting end-use product studies (40CFR Part 160):

830.1750 Certified Limits
830.1800 Enforcement Analytical Methods
830.6317 Storage Stability

The registrant must submit the required signed statement.

PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]

DP BARCODE No.: D267236 REG./File Symbol No.: 28293-GEI

PRODUCT NAME: Unicorn .25% Permethrin Granules

DATE: 08/23/2000

1. Reviewer: A.M.Nefcy
2. Company: UNICORN LABORATORIES
3. Type of Submission: Registration [X] Reregistration []
 New [X] Resubmission [] Amendment []
 Alternate Formulation [] Experimental Use Permit []
 Other (Specify) _____

CONFIDENTIAL STATEMENT OF FORMULA

4. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system.....[X]
 - Are all technical grade active ingredients used registered? • yes [X] • no [], If no, specify _____
 - Integrated formulation system.....[]
5. 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):
 - 5(a) Formulation intended for food use under 40CFR§180.1001:
 - yes [x] • no [] • Some are cleared, others are not []
 - Cleared under list: • c[X] • d[] • e [X]
 - Are there any limitations for use as an inert under 40CFR§180.1001?
 - yes [] • no [X], If yes, specify _____
 - 5(b) Formulation intended for non-food use:
 - yes [X] • no [] • Some are cleared, others are not []
6. 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 [] • no [X]

CSF was submitted with no substantiating data.

7. 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
Permethrin		(0.25)	(0.275)	(0.225)
CAS #52645-53-1				

8. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
- yes [X] • no []
9. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
- yes [X] • no []

PRODUCT LABEL

10. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [x] • no []
11. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
- yes [] • no [X] • not applicable []
- Cannot confirm, since these data were not submitted.
12. 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)	U	06/13/00
1600. Beginning Materials	Y	06/13/00
1650. Formulation Process	Y	451555-01
1670. Discussion of Impurities	Y	451555-01
1750. Certified Limits	U	06/13/00
1800. Enforcement Analytical Method	N	

<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 State	N	Data not submitted	
6314. Oxid/Red Action	N	Data not submitted	
6315. Flammability	N	Data not submitted	
6316. Explodability	N	Data not submitted	
6317. Storage Stability	N	Data not submitted	
6319. Miscibility	N	Data not submitted	
6320. Corrosion Charac.	N	Data not submitted	
6321. Dielectric	N	Data not submitted	
7000. pH	N	Data not submitted	
7100. Viscosity	N	Data not submitted	
7300. Density/Bulk Den.	N	Data not submitted	

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.