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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE OUT: October 5, 2005

SUBJECT: Product Chemistry Review of Hartz Reference 121  
Barcode #:322068 Decision #:357507 Reg No:2596-RLU  
PC Code(s):044312, 129032, 109701 Food Use:NO

FROM: Linda L. Kutney, Chemist *Linda L. Kutney*  
Product Chemistry Team *10/5/05*  
Technical Review Branch/RD (7505C)

TO: Daniel Kenny, Rita Kumar RM-01  
Insecticide Rodenticide Branch/ RD (7505C) *SBW 10/5/05*

INTRODUCTION:

The Hartz Mountain Corporation has submitted product chemistry data to support registration of their new product, Hartz Reference 121, to be dermally applied insecticide for dogs and puppies. Data were faxed and hand-delivered to the reviewer, but not yet assigned an MRID.

Hartz intends that the most recently submitted alternate CSF, dated 9/29/05, supersede all previously submitted alternate CSFs.

This review is a follow-up to the TRB review of 9/29/05.

SUMMARY OF FINDINGS:

1. The product consists of equal amounts of liquid in Chamber A and Chamber B.
2. The nominal concentration of ais given on the proposed label are:  
  
45.00 % Permethrin (Chamber A)  
AND  
14.85 % Dinotefuran (Chamber B)  
1.50 % Sumilarv (Chamber B)
3. The nominal concentration for all of the proposed CSFs agrees with the label claim (PRN 91-2 is satisfied).
4. All conditions required for alternate formulations listed in 40CFR 152.43 are satisfied.

TRB CONCLUSIONS:

1. The physical or chemical hazards statement on the label must state, 'Combustible. Do not use or store near heat or open flame,' in accordance with 40 CFR 156.78.
2. We note that the nominal concentration of sumilarv is 1.50%, not 1.48%, as listed on the label, but this slight difference is acceptable.
3. The alternate proposed CSF, dated 9/29/05, is now acceptable.
4. Subgroup A product chemistry data requirements for the following Guidelines will be satisfactory, providing the Registrant sends the Agency acceptably formatted (PRN-86-5 acceptable) copies of the following:  
  
Discussion of Impurities - (GDLN 830.1670)  
  
Submission of Analytical Enforcement Methods for all 3 ais (GDLN 830.1800)
5. The RM is requested to send a copy of the formally submitted GDLN 830.1670 and 830.1800 to this reviewer to confirm their acceptability and to include assigned MRID numbers into the Agency database for future use, prior to Registration.
6. Subgroup B product chemistry data requirements are still pending for:

Storage Stability (GDLN 830.6317) - In Progress

Corrosion Characteristics (GDLN 830.6320) - In Progress

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

Subgroup A, Guideline 830.--:	<u>Data</u> OK?	<u>MRID</u>
1550. Chemical Identity (CSF)	Yes	CSF
1600. Beginning Materials	Yes	46552701
1650. Formulation Process	Yes	46552701
1670. Discussion of Impurities	Yes, pending adequate formal submission to the Agency	To be assigned
1750. Certified Limits (CSF)	Yes	CSF
1800 Enforcement Analytical Method	Yes, pending adequate formal submission to the Agency  HPLC TM# 440-0 Luna C18 (2), 5 micron, 4.6 mm x 150 mm Column or equivalent UV detector at 254 nm 2.5 ml/min flow rate 10 microliter injection volume Di-N-Amyl Phthalate (DAP) internal standard was used	To be assigned

<u>Subgroup B,</u> <u>Guideline 830.--:</u>	<u>Data</u> OK?	<u>Description</u>	<u>MRID</u>
6302 Color	Yes	Chamber A- Permethrin- colorless to light yellow	46552701
6303 Physical State	Yes	Clear Liquids	46552701
6304 Odor	Yes	Ethyl Lactate	46552701

		Smell	
6314 Oxidation/Reduction	Yes	Both components did not react with water or monoammonium phosphate but did slightly discolor in zinc.  Chamber B- Dinotefuran- pyriproxifen compartment of the formulation showed immediate reaction with potassium permanganate-with color change and effervescent foaming.	46552701
6315 Flammability/Flame Extension	Yes	Chamber A- Permethrin 139 F  Chamber B- Dinotefuran- pyriproxifen 143 F Dinotefuran:pyripr oxifen 2.5:1 152F	46552701
6316 Explodability	Yes	Not reported to contain explosive components.	46552701
6317 Storage Stability	NO	Study in progress.	46552701
6319 Miscibility	Yes	NA. Not mixed with petroleum solvents.	46552701
6320 Corrosion Characteristics	NO	Study in progress.	46552701
6321 Dielectric Breakdown Voltage	Yes	Not used around electrical equipment.	46552701

7000 pH	Yes	Chamber A: The Permethrin component does not contain water, so the pH does not exist. Chamber B: Dinotefuran:pyripr oxifen is about 5.8 at 25C.	46552701
7100 Viscosity	Yes	Chamber A: Permethrin 16 cP Brookfield spindle 2 at 10 rpm Chamber B: Dinotefuran/pyripr oxifen 40 cP Brookfield spindle 2 at 10 rpm	46552701
7300. Density/Bulk Density	Yes	Chamber A: Permethrin 9.23 lb/gal Chamber B: Dinotefuran:pyripr oxifen 8.99 lb/gal	46552701

Explanations: NA = Not Applicable