

DATE OUT: 12/JUL/2005

FEE: PRODUCT CHEMISTRY REVIEW OF: AN END-USE PRODUCT [X]

DP BARCODE #: D318724 EPA RECEIVED DATE: 05/JUL/2005 FILE SYMBOL/REG : 2596-RL

PRODUCT NAME: Hartz Reference 123 MRID NO.: 465816-01 COMPANY: The Hartz Mountain Corporation

NON-FOOD USE [X] ACTION CODE: R26

PPC NUMBER OF THE TGAIs IN THE PRODUCT: 044312 DECISION #: 358347

FROM: Sami Malak, Chemist
Technical Review Branch/RD (7505C)

TO: 01 Daniel Kenny/Rita Kumar
Insecticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 27/JUN/2005, the applicant requested the applicant requested registration of subject product. In support of this action, the applicant included product chemistry data, a basic and one alternate CSFs both dated 06/JUN/20054 and a draft label EPA received on 05/JUL/2005, Formulator's Exemption, a Certificate With Respect to Citation of Data, and Data Matrix.

1. The subject product, Hartz Reference 123, was produced by a non-integrated formulation system, meaning that the active ingredient in the product is registered. The product contains 14.85% Dinotefuran, [REDACTED] in the basic and [REDACTED] in the alternate formulation..
2. The subject product, an insecticide, is intended for rapid flea drop in cats.
3. Adequate analytical method is available for enforcement. The method for the pure active ingredient was previously submitted and reviewed in connection with the [REDACTED]
[REDACTED]

A method was included with this submission entitled "Determination of Dinotefuran by HPLC." The method is reviewed in this memorandum.

- 4a. The applicant should be advised to submit the results of product's storage stability and corrosion characteristics as per the regulations of GRN 830.6317 & 830.6320, respectively.
- 4b. Except for the data gaps in Finding 4(a) above, the submitted product chemistry data is adequate and support registration of subject product.
5. The label claim nominal concentrations of 14.85% dinotefuran is consistent with that in the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.

(1)

- 6 The proposed basic and one alternate CSFs both dated 06/JUN/2005 were filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed in the CSFs are cleared for use in pesticide formulations intended for non-food uses.

CONCLUSIONS:

After resolving Finding 4(a) above, the TRB will have no objections for registration of subject product. Product's label and the submitted basic and one alternate CSFs both dated 06/JUN/2005 are acceptable as per Findings 5 & 6 above.

NOTE TO RM:

The applicant should be advised to make minor corrections to the submitted CSFs: (a) Check alternate instead of basic in page 2 of the alternate CSF; (b) indicate the registration number in box 4 of both CSFs; (c) no need to indicate the upper/lower limits corresponding to the percentage by weight of 15%; and (d) highlight the nominal concentration of 14.85% in bold or by placing it between parenthesis, also delete the indicators (A) & (T) corresponding to the nominal and percentage by weight.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 21/JUN/2005 was included with this submission claiming confidentiality of some the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data was moved to Confidential Appendix A.
2. A GLP statement dated 16/JUN/2005 was included with this submission to the effect that some of the submitted studies are not within the scope of the GLP requirements of 40CFR§160.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The subject product contains one registered technical grade of an active ingredient plus cleared inert ingredients intended for non-food uses (refer to the proposed CSFs dated 06/JUN/2005).

830-1600 Description of Materials Used to Produce the Product:

Refer to Confidential appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential appendix A.

830-1750 Certified Limits:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method for the pure active ingredient was previously submitted and reviewed in connection with the [REDACTED]

A method was included with this submission entitled "Determination of Dinotefuran by HPLC." In this method dinotefuran is determined by reverse phase HPLC in raw materials and one spot using caffeine as an internal standard.

Method validation data regarding recovery, accuracy, precision, and linearity are adequate. Sample chromatograms and calculation were included with this submission.

The method was used to determine the percentages pure active ingredient in the product.

Table 1: Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800 (40 CFR 158.155 to 158.180)

Table 1: Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	465816-01
.1600 Description of materials used to produce the product	Y	465816-01
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	465816-01
.1670 Discussion of formation of impurities	Y	465816-01
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	465816-01
.1800 Enforcement analytical method	Y	465816-01

Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

Table 2: Physical and Chemical Properties, 40CFR158.190

The applicant complied with PR Notice 98-1 on self-certification of product chemistry data. An

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abstract summary of the physical/chemical properties was included in EPA Form 8570-36. Further, a self-certification statement, EPA Form 8570-37, dated 21/JUN/2005 was also included. A summary of the properties are shown in the table below:

GRN	Requirement	M&ID Status ¹		Result ² or Deficiency
830.6302	Color	465816-01	A	Colorless to light yellow.
830.6303	Physical State	465816-01	A	Liquid.
830.6304	Odor	465816-01	A	Characteristics of ethyl lactate.
830.6314	Oxidation/Reduction	465816-01	A	No significant reaction with water, monoammonium phosphate, a slight discoloration with zinc powder, and immediate reaction with potassium permanganate solution with a color change and effervescent foaming.
830.6315	Flammability	465816-01	A	142°F.
830.6316	Explodability	465816-01	A	The formulation does not contain explosive materials.
830.6317	Storage Stability		I	
830.6319	Miscibility	465816-01	A	Miscible with water.
830.6320	Corrosion Characteristics		I	
830.7000	pH	465816-01	A	5.8 @ 25 °C
830.7100	Viscosity	465816-01	A	50 cPs @ 25 °C
830.7300	Density/Relative Density/Bulk Density	465816-01	A	9 lbs/gal @ 25 °C
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable; I = In progress. ² For example, "brown" for 830.6302; "155° C" for 830.7200.				

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Product Name: Bay DPH 313724 Dosed 7/5/05 MC1046811

Page 5 is not included in this copy.

Pages through are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☒ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) .
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.