

DATE OUT: 13/MAY/2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
DP BARCODE No. D280841 RECEIVED DATE: 07/JAN/2002 REG./File Symbol No.: 11556-RGG
PRODUCT NAME: Advantix 20 For Dogs
COMPANY NAME: Bayer Corporation MRID No. 455630-01 Action Code: 166

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

TO: 03 Arnold Layne/William Sproat
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INTRODUCTION:

The applicant requested a FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration of subject product claiming its similarity to Advantix 10 For Dogs, Reg. No. 11556-RGE. In support of this action, the applicant included a proposed basic formulation, CSF dated 13/DEC/2001, product's label EPA received 07/JAN/2002, and data matrix. In addition, product chemistry data was included with Advantix 10 For Dogs Reg. No. 11556-RGE.

FINDINGS:

- 1a. The subject product is produced by a non-integrated formulation system, meaning that the two active ingredients in the product are registered. The product contains 8.8% Imidacloprid, Reg. No. 3125-414; plus 44% permethrin, Reg. No. 432-1069 or 4816-559.
- 1b. The subject product, an insecticide, is intended for the prevention and treatment of flea and tick infestations on dogs.
2. The subject product is identical in labeling and composition to Advantix 10 For Dogs, Reg. No. 11556-RGE.
3. The submitted/reference product chemistry data is adequate and support a FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration of subject product.
4. Adequate analytical methods are available for enforcement. The methods were previously submitted and reviewed in connection with the registration of the technical sources, Imidacloprid, Reg. No. 3125-414 & permethrin, Reg. No. 432-1069 or 4816-559.

A method included with this submission, MRID #455630-01 pages 58-66, is entitled "Analysis of G804S16 Insecticide (8.8% Imidacloprid 44% Permethrin) by HPLC." The method, reviewed in this memorandum, was identified as Ecto Report #G804R23-1, Ecto Study #G804S23, dated 15/NOV/2001.
5. The label claim nominal concentrations of 8.8% Imidacloprid plus 44% permethrin is consistent with that on 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§156.10.
6. The submitted product's basic formulation, CSF dated 13/DEC/2001, was 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 on the CSF are cleared for use in pesticide formulations.

CONCLUSIONS:

1. From the product chemistry view point, the subject product is Identical to Advantix 10 For Dogs , Reg. No. 11556-RGE
2. Pending registration of Advantix 10 For Dogs , Reg. No. 11556-RGE, we will have no objections for a FIFRA sec. 3(c)(3)(B)(i)(I) "me-too" registration of subject product. Product's label and CSF are acceptable as per Findings 5 & 6 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 26/NOV/2001 was included with this submission claiming confidentiality of some of 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 is to be found in Confidential Appendix A.
2. A GLP statement dated 27/NOV/2001 was included with this submission to the effect that some of the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #455630-01: The submitted studies entitled: "Report for the Chemistry Evaluation of "G804S16 Insecticide" Containing 44% Permethrin and 8.8% Imidacloprid" Data Requirements of Guideline Reference Numbers #61, 62 & 63." The studies were authored by J. E. Rose; Performed by Ecto Development Corporation of Excelsior Springs, Missouri (66 + 30 pages).

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

830-1550 Product Identity and Composition

This product contain two registered technical grade of active ingredients plus cleared inert ingredients (refer to product's CSF dated 13/DEC/2001).

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 methods are available for enforcement. The methods were previously submitted and reviewed in connection with the registration of the technical sources, Imidacloprid, Reg. No. 3125-414 & permethrin, Reg. No. 432-1069 or 4816-559.

A method included with this submission, MRID #455630-01 pages 58-66, is entitled "Analysis of G804S16 Insecticide (8.8% Imidacloprid 44% Permethrin) by HPLC." The method, dated 15/NOV/2001, was identified as Ecto Report #G804R23-1, Ecto Study #G804S23.

In this method, a sample of G804S16 Insecticide, containing 8.8% Imidacloprid 44% Permethrin, is dissolved in acetonitrile and quantitated by HPLC. The chromatographic parameters are described in this submissions. Further, method validation regarding recovery, accuracy, precision, linearity, specificity, and reproducibility are adequate. Sample calculation and chromatograms are included.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190):

GUIDELINE REFERENCE NO.(GRN 830.)/TITLE	VALUE OR QUALITATIVE DESCRIPTION
.6302 Color	Clear amber.
.6303 Physical State	Liquid.
.6304 Odor	No apparent odor.
.6314 Oxidation/Reduction: Incompatibility	Will not act as an oxidizing or reducing agent.
.6315 Flammability/Flame Extension	> 212°F
.6316 Explodability	NA. The product does not contain any explosive ingredients.
.6317 Storage Stability	NA as per PR Notice 92-5.
.6319 Miscibility	NA. The product is not an emulsifiable concentrate.
.6320 Corrosion Characteristics	Non considered to be corrosive.
.6321 Dielectric Breakdown Voltage	Not recommended for use around electrical equipment.
.7000 pH	NA. The product is not intended to be diluted or dispersed in water.
.7100 Viscosity	6.9 centistokes @25°C
.7300 Density/Relative Density Bulk Density	1.145 @ 20°C

~~Confidential Appendix A~~ CF 9/22/04

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

Two registered technical grade of active ingredients, imidacloprid, Reg. No. 3125-414 plus 44% permethrin, Reg. No. 432-1069 or 4816-559; plus cleared inert ingredients (refer to product's CSF dated 13/DEC/2001).

830-1650 Description of Formulation Process:

This product was formulated as a batch process under ambient warehouse conditions and atmospheric pressure. In the process, the appropriate amounts of the ingredients are mixed until evenly thoroughly homogenous. The product is then packaged in after release by quality control in a predetermined suitable containers (refer to product's CSF dated 13/DEC/2001).

830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities $\geq 0.1\%$ by weight were known to be formed during formulation and storage of the product. There was no chemical reaction in the process.

830-1700 Preliminary Analysis:

Not required for subject non-integrated product.

830-1750 Certified Limits:

The applicant reported the same limits as those listed in product's CSF, a basic formulation dated 08/JAN/2002.