

DATE OUT: 12/JAN/1999

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
BARCODE No.:250923 EPA RECEIVED DATE:14/MAY/1998 REG./File Symbol No.: 241-GOT
PRODUCT NAME: Chlorfenapyr Insecticide Cattle Ear Tag, 30% AI MRID.:445603-01
COMPANY NAME: American Cyanamid Company Action Code:100**

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

TO: 03 Susan Lewis/Ann Sibold
Insecticide Branch/RD (7505C)

INTRODUCTION:

With this submission, the applicant requests registration of subject product as per the regulations of FIFRA Section 3(c)(5). In support of this action, the applicant submitted product chemistry data, product's CSFs, a basic and alternate formulations dated 16/JUL/1997 & 14/OCT/1997, respectively, and label, EPA received on 14/MAY/1998.

FINDINGS:

1. This product is produced by an integrated formulation system, meaning that the technical source is not registered. According to the CRM's instructions on the tracking sheet, data on the technical source was reviewed by HED. The subject products, each contain 30% of the active ingredient, chlorfenapyr (a proposed common name): 4-Bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, Reg. No. 241-XXX.
2. The submitted product chemistry data is adequate and support the registration requirements for subject product.
3. A GC method of analysis, included in MRID #445603-01, is recommended for enforcement. The method utilizes octadecanophenone as an internal standard. GC parameters are cited in this memorandum.
4. The ingredient statement and the storage and disposal statement cited on product's label, EPA received 14/MAY/1998, satisfy the requirements of 40CFR§156.10 & the nominal concentration as per the regulations of PR Notice 91-2.
- 5a. The submitted product's CSFs, a basic and one alternate formulations dated 16/JUL/1997 & 14/OCT/1997, respectively, were filled out correctly and completely in compliance with the regulations of 40CFR§152.43. The nominal concentration of the active ingredient agrees 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).

- 5b. The upper and lower limits of the inert ingredients are wider than the standard limits of 40CFR§158.175(b)(2), however, adequate justifications were provided by the applicant as per the regulations of 40CFR§158.175(d)(2).
- 5c. All ingredients claimed on the CSFs are cleared for use in pesticide formulations recommended for food uses.

CONCLUSIONS:

After registration of the technical source, chlorfenapyr: 4-Bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, Reg. No. 241-XXX, we will have no objections to registration of this end-use product. Product's label and CSFs are acceptable as per Findings 4 & 5 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 08/MAY/1998 was included with this submission claiming confidentiality of some of the data requirements on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI information is to be found in Confidential Appendix A.
2. A GLP statement dated 08/MAY/1998 was included with this submission to the effect that some of the submitted studies were conducted in full compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #445603-01 The submitted study entitled "Product Identity, Description of Beginning Materials and Manufacturing Process, Theoretical Discussion of Impurities, Certification of Limits, Analytical Methods and Physical and Chemical Properties of Chlorfenapyr Insecticide Cattle Ear Tag", was authored by J. V. Grissom & J. A. Zupan, Performed by Ecto Development Corporation of Excelsoir Springs, MO & American Cyanamid Company, Completed 26/MAR/1998, 25 pages.

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 products, each contain 30% of the active ingredient, chlorfenapyr (a proposed common name): 4-Bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, Reg. No. 241-XXX.

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: MRID #444378-01.

A GC method of analysis, included in MRID #445603-01, is recommended for enforcement. The method utilizes octadecanophenone as an internal standard. The GC parameters are as follows:

Instrument..... HP5890mm DB-17
Column..... 0.530 mm DB-17
Oven Temperature..... 210°C Isothermal
Carrier..... Helium at 20 ml/min
Injector..... 270°C
Detector..... 270°C

Sample calculation was included with this submission.

GUIDELINE REFERENCE NO.(GRN)/TITLE	VALUE OR QUALITATIVE DESCRIPTION/METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Bright yellow.
-6303 Physical State	Solid.
-6304 Odor	None.
-6314 Oxidation/Reduction: Incompatibility	Will not act as an oxidizing or reducing agent.
-6315 Flammability/Flame Extension	NA
-6316 Explodability	not explosive.
-6317 Storage Stability	NA as per PR Notice 92-5
-6319 Miscibility	NA
-6320 Corrosion Characteristics	Non corrosive.
-6321 Dielectric Breakdown Voltage	NA
-7000 pH	NA
-7100 Viscosity	NA
-7300 Density/Relative Density Bulk Density	1.2247

Confidential Appendix A

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

Materials used are listed on The product's CSFs, a basic and alternate formulations dated 16/JUL/1997 & 14/OCT/1997, respectively.

830-1650 Description of Formulation Process:



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.

830-1700 Preliminary Analysis:

Not required since the full data requirements on the technical source was submitted and reviewed by HED.

830-1750 Certified Limits:

The applicant reported the same ingredients at percentages and low/upper limits as those reported on product's CSF.