Manufacturing process information may be entitled to confidential treatment

DATE OUT: 06/AUG/2008

FEE: PRODUCT CHEMISTRY REVIEW OF: AN End-Use Product [X]
DP BARCODE: D340541 **RECEIVED DATE:** 12/JUN//2007 **FILE SYMBOL:** 264-RNAA
PRODUCT NAME: SC 465 Herbicide **FOOD USES [X]**
COMPANY NAME: Bayer CropScience LP **MRID.:** 471140-01 **ACTION CODE:** R01.0
PPC#'s OF THE TGAIs IN THIS PRODUCT: 015804, 123000 **DECISION No.:** 379125

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

TO: 23 Joanne Miller/Hope Johnson
Herbicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 09/MAY/2007, the applicant requested registration of subject product. In support of this application, the applicant included product chemistry data, a proposed basic CSF dated 22/JAN/2007and one alternate formulation dated 23/JAN/2007, a proposed label EPA received on 12/JAN/2007, Certificate With respect to Citation of Data, and data Matrix.

FINDINGS:

1. The subject product was produced by an integrated formulation system, meaning that one of two active ingredients in the product, thiencarbazone-methyl technical, is currently under trilateral review by the EPA, PMRA, and the UK. This end-use product, however, is not included in the trilateral review because of a minor change in its use pattern. The product contains 7.6% thiencarbazone-methyl technical, Reg. No. 264-RNAN (97.58% on the label, 97.6% on the CSFs); plus 19.0% isoxaflutole, Reg. No. 264-566 (98% on the label, 98.5% on the CSFs). In addition, the product contains [redacted] cyprosulfamide as a safener.

2. The subject product, a herbicide, is intended for weed control in field corn in certain states cited on the label.

3a. The applicant should be advised to submit the results of product's storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320), when complete.

3b. Except for the data gaps in Finding 3(a) above, the submitted product chemistry data is adequate and support registration of subject product.

4a. Adequate analytical methods are available for enforcement. The method for isoxaflutole was previously submitted and reviewed in connection with its registration, Reg. No. 264-566.

4b. A HPLC method #AM001803FF2 was included with this submission, MRID #471140-01. The method entitled "Determination of thiencarbazone-methyl (BYH 18636) cyprosulfamide (AE 0001789) and isoxaflutole (AE B197278) in formulations by liquid chromatography (HPLC)." The method is reviewed in this memorandum.

4c. The method in 4(b) above will need to be validated by the EPA's laboratory. The applicant should be advised to submit a copy of the method and samples to EPA's laboratory for validation at the following address: EPA's Analytical Chemistry Laboratory, 701 Mapes Road, Fort Meade, Maryland 20755-5350.

5a. The label claim nominal concentrations of 7.6% thiencarbazone-methyl technical plus 19.0% isoxaflutole are consistent with the same in the basic CSFs dated 22 & 23/JAN/2007, 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.

5b. . The applicant should be advised to list, in product's label, a statement pertaining to "The Physical or Chemical Hazards."

5c. The label ingredient statement that reads "Inert Ingredients" must be corrected to read "Other Ingredients."

6a. The proposed basic and one alternate CSFs dated 22 & 23/JAN/2007, respectively, 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).

6b. The applicant should be advised to submit the chemical name, CAS registry number, and percent of each component in an inert ingredient not approved for use in pesticide formulations intended for food uses (refer to Confidential Appendix A).

6c The safener cyprosulfamide is currently under review by the Inert Ingredient Branch and, at this time, is not approved to be used in pesticide formulations.

6d. Except for the non-cleared ingredients in Findings 6b & 6c above, the remaining ingredients claimed in the basic and alternate CSFs have been approved for use in pesticide formulations intended for food uses.

7. The proposed label ingredient statement and the nominal concentration for thiencarbazone-methyl in both CSFs for this end-use product may need to be revised if the results of five batch analysis for technical thiencarbazone-methyl reflecting commercial scale production showed a nominal concentration for thien-

crabazone-methyl different from 97.6% (refer to this requirement in Reg. No. 264-RNAN).

CONCLUSIONS:

After registration of the technical source, thiencarbazione-methyl technical, Reg. No. 264-RNAN, and approval of the safener, cyprosulfamide, by the Inert Ingredient Branch for use in pesticide formulations plus resolving findings 3(a), 4(b), 5(b), 5(c) & 6(b) above, the TRB will have no objections for registration of subject product. The proposed label EPA received on 12/JUN/2007and the basic and one alternate CSFs dated 22 & 23/JAN/2007 are unacceptable.

Note to RM:

Please note Findings 6(c) and 7 above.

EVIEW OF PRODUCT CHEMISTRY DATA (MRID #460585-01:

1. A statement of data confidentiality dated 05/JUN/2007 was included with this submission claiming confidentiality of any of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of this data was moved to Confidential Appendix A.

2. A GLP statement dated 08/MAR/2007 was included with this submission to the effect that some of the studies were conducted in compliance with standard laboratory and industrial practices.

830-1800 Enforcement Analytical Method:

Adequate analytical methods are available for enforcement. The method for isoxaflutole was previously submiteed and reviewed in connection with its registration, Reg. No. 264-566. A HPLC method was included with this submission, MRID #471140-01. The method entitled "Determination of thiencarbazone-methyl (BYH 18636) cyprosulfamide (AE 0001789) and isoxaflutole (AE B197278) in formulations by liquid chromatography (HPLC)."

In this method, the test substance is dissolved in acetonitrile. The samples are then placed in an ultrasonic bath for 5 minutes, diluted to the desired volume with acetonitrile and sonicated for 10 minutes. The samples are then allowed to cool to ambient temperature. Aliquots of 5 µl are then injected to the HPLC. The compounds are separated from the formulation on a reversed phase HPLC column and detected by UV with the use of external standards.

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

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

830-1550 Product Identity and Composition

The product contains thiencarbazone-methyl technical currently undergoing trilateral review by the EPA, PMRA, and the UK plus registered isoxaflutole. In addition, the product contains the safener cyprosulfamide plus intentionally added inert ingredients. cleared for food uses (refer to the proposed basic and one alternate CSFs dated 22 & 23/JAN/2007, respectively).

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.

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

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	471140-01
.1600 Description of materials used to produce the product	Y	471140-01
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	471140-01
.1670 Discussion of formation of impurities	Y	471407-01
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	471140-01
1800 Enforcement analytical method	Y	471140-01

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.

Physical and Chemical Properties of Diuron Technical; 40CFR158.190

Except for product's storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320), the submitted physical/chemical properties are adequate and support registration of subject product.

Confidential Appendix A

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

One technical grade of an active ingredient currently under trilateral review by the EPA, PMRA, and the UK plus a second registered technical grade of an active ingredient. In addition, the product contains the safener cyprosulfamide plus intentionally added inert ingredients. refer to the proposed basic and one alternate CSFs dated 22 & 23/JAN/2007, respectively).

830-1650 Description of Formulation Process:

[redacted]

830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities ≥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:

Will be required if registration of thiencarbazone-methyl is not imminent.

830-1750 Certified Limits:

The applicant reported the same certified limits as those in the proposed basic and one alternate CSFs dated 22 & 23/JAN/2007, respectively.

Non-Cleared Inert Ingredient for Food Uses:

[redacted]

cc::S. Malak and Central File (Reg. No. 264-RNAA).
7505C:RD:TRB:CM-2:Rm.268:s.m.:06/AUG/2008:703-308-9365:<264-RNAA>.

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