

US EPA ARCHIVE DOCUMENT

DATE OUT: 06/JUN/2007

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

DP BARCODE :D329400 RECEIVED DATE:30/MAY/2006 FILE SYMBOL 62719-LAG

PRODUCT NAME: GF-184 FOOD USES [X] ACTION CODE: R01.0

COMPANY NAME: Dow AgroSciences LLC MRIDs: 468066-01 & -02

PC NUMBER OF THE TGAI IN THE PRODUCT:128968, 129108 DECISION #: 366693

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

STBm 6/6/07

TO: 23 Joanne Miller/Dianne Morgan
Herbicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 29/MAR/2006 the applicant requested registration of subject product. In support of this application, the applicant included product chemistry data, a basic CSF dated 06/FEB/2006, and a proposed label EPA received on 30/MAY/2006.

FINDINGS:

1. The subject product was produced by an integrated formulation system, meaning that one of two active ingredients in the product is not registered. The product contains 0.25% florasulam, Reg. No. 62719-LAR (reviewed by PMRA); plus 14.53% fluroxypyr-methylheptyl ester, Reg. No. 62719-285.
2. The subject product, a herbicide, is intended for postemergent control of annual broadleaf weeds in wheat, barley, oats, rye and triticale.
3. Adequate analytical methods are available for enforcement. The method for fluroxypyr-methylheptyl ester was previously submitted and reviewed in connection with its registration, Reg. No. 62719-285. A HPLC method for florasulam was included with this submission, MRID #468066-01, entitled "Florasulam Standard Method." The method is reviewed in this memorandum.
4. The submitted product chemistry data is adequate and support registration of subject product.
5. The label nominal concentrations 0.25% florasulam (reviewed by PMRA); plus 14.53% fluroxypyr-methylheptyl ester, are consistent with the same in the basic CSF dated 06/FEB/2006, 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.
6. The proposed basic CSF dated 06/FEB/2006, was filled out correctly and

disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.

6. The proposed basic CSF dated 24/JAN/2006 (showing registration numbers for MCPA), 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 in the CSF are cleared for use in pesticide formulations intended for food uses (refer to the one page CR#07-0209 dated 05/JUN/2007).

CONCLUSIONS:

Pending registration of the technical source in the product, florasulam, and resolving Findings 4(a), the TRB will have no objections for registration of subject product. The submitted basic CSF dated 24/JAN/2006 (showing registration numbers for MCPA) and label EPA received on 31/MAR/2006 are acceptable as per Findings 5 & 6 above.

VIEW OF PRODUCT CHEMISTRY DATA

1. A statement of data confidentiality dated 27/JAN/2006 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 14/DEC/2005 was included with this submission to the effect that some of the submitted studies were conducted in compliance with the GLP standards of 40CFR§160.

830-1800 Enforcement Analytical Method:

Adequate analytical method for florasulam is available for enforcement. A HPLC method was included with this submission, MRID #468067-01, entitled "Florasulam Standard Method."

In this method, a certain weight of the test substance is mixed with 5 ml of propiophenone internal standard plus 30 ml water and 65 ml acetonitrile. Aliquots of 10 µl of this mixture are injected into the HPLC. Characterization of the active ingredient is achieved by comparing the retention time obtained in the sample solution with that obtained from the standard solution. No method was included for MCPA.

Sample chromatograms and calculations were 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 subject product contains one registered technical grade of an active ingredient, Reg. No. 62719-285, and a second reviewed by PMRA, Reg. No. 62719-LAR; plus intentionally added inert ingredients intended for food uses (refer to the proposed basic CSF dated 06/FEB/2006).

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	468066-01
.1600 Description of materials used to produce the product	Y	468066-01
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	468066-01
.1670 Discussion of formation of impurities	Y	468066-01
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	468066-01
.1800 Enforcement analytical method	Y	468066-01
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

The submitted physical/chemical properties included with this submission, MRID #468966-02, are adequate and support registration of subject product.

Confidential Appendix A

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

One registered technical grade of an active ingredient and a second undergoing registration recently reviewed by PMRA (Reg. No. 62719-LAR); plus intentionally added inert ingredients intended for food uses (refer to product's basic CSF dated 06/FEB/2006).

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. There was no chemical reaction in the process.

830-1700 Preliminary Analysis:

Will be required if registration of one of two technical sources (Reg. No. 62719-LAR) is not imminent..

830-1750 Certified Limits:

The applicant reported the same certified limits as those in product's basic CSF dated 06/FEB/2006.

Manufacturing process information may be entitled to confidential treatment