US EPA ARCHIVE DOCUMENT

DATE OUT: **20/November/ 2007**

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.: D343725 **EPA File Symbol No.:** 62719-LIE
PRODUCT NAME: GF-1848
COMPANY: Dow AgroSciences LLC
FOOD USE [X] INTEGRATED FORMULATION [ ]
PCC: 108702, 129108, 128968 **Decision No.** 380789
ACTION CODE: RO 2.4

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Technical Review Branch / RD (7505P)

for SBM 11-20-07

TO: James Stone / Joanne Miller, RM 23
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INTRODUCTION:

The Registrant has submitted a basic CSF for a new product and has proposed a product specific label (both dated June 13, 2007) to support the registration of the proposed end-use formulation under EPA File Symbol 62719-LIE. The product chemistry data for the proposed product have been submitted under MRID Nos. 47166901 and 47166902. Label text indicates that the proposed formulation has food uses. TRB has been requested to evaluate the product chemistry data for the registration of the proposed herbicide product.

SUMMARY OF FINDINGS:

1. The three active ingredients of the proposed basic formulation are: Pyroxsulam (1.20%), Florasulam (0.20%), and Fluroxypyr-meptyl (11.57%).

2. The source materials of two of the three active ingredients used in the proposed formulation are not registered with the Agency.

3. The nominal concentrations of the three active ingredients in the proposed formulation for Pyroxsulam, Florasulam , and Fluroxypyr-meptyl are 1.20%, 0.20%, and 11.57%. Standard procedures have been used to estimate certified limits of the nominal concentrations of the active and inert ingredients in this formulation and therefore are in compliance with 40 CFR§ 158.175 (b) (2).

4. The CSF of the basic formulation (dated June 13, 2007) is filled out completely but not correctly. This is because (a). one inert ingredient (mixture) used in the formulation has not been cleared for pesticide use by the Agency. (b) another inert ingredient that has been used in this formulation should not be used with the active ingredients designated for this product because tolerances with aforesaid active ingredients have not been established as of this time (see confidential appendix). However, the nominal concentrations of the active ingredients match with the label claim. These are in compliance with PR Notice 91-2.

5. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition, 830.1600 (materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.155, 158.160, 158.165, 158.167, and 158.175 respectively for the subject formulation [MRID 47166901].

6. The method proposed corresponding to guideline 830-1800 (enforcement analytical method) satisfies the data requirements of 40 CFR§158.190 for the proposed formulation [MRID 47166901]. A liquid chromatographic method was used to quantify all three active ingredients. A Phenomenex Luna C8 column (150mm x 4.6mm, 5 µm particle size) and an ultraviolet detector were used. The validation of the method used involving linearity, accuracy and precision has been described.

7a. The guideline 830 series Group A requirements are satisfied.

7b. Except for storage stability / corrosion studies Guidelines 830.6317 / 830.6320, the remaining product chemistry Group B data are fulfilled [MRID 47166902].

CONCLUSIONS:

1. TRB has reviewed the CSF of the proposed basic formulation (dated June 13, 2007) and has found it to be unacceptable. The reasons are as follows: (a). The sources of two active ingredients are not registered (b). one inert has not been cleared for food use (c). another inert should have not been used with the active ingredients of this formulation.

2. The guideline 830 series Group A requirements are satisfied.

3. Except for storage stability / corrosion studies, Guidelines 830.6317 / 830.6320, the remaining Group B product chemistry data are fulfilled.

4. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.

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PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated 06/13/2007)	A	47166901
830.1600. Beginning Materials	A	47166901
830.1650. Formulation process	A	47166901
830.1670. Discussion of Impurities	A	47166901
830.1700. Preliminary Analysis	N/A	
830.1750. Certified Limits (Basic CSF dated 06/13/2007)	A	47166901
830.1800. Enforcement Analytical Method	A	47166901

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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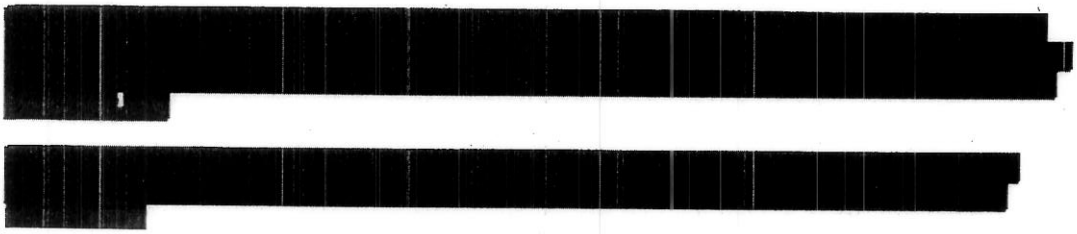
CONFIDENTIAL APPENDIX

1. The two unregistered sources of the active ingredients that have been used in this formulation are: Pyroxsulam MC (EPA File Symbol 62719-LAT, 99%) and Florasulam (EPA File Symbol 62719-LLO, 99.2%).