DATE OUT: 13 / DEC / 2007

SUBJECT: FEE.PRODUCT CHEMISTRY REVIEW OF MP [ ]   EP [X]
DP BARCODE No.: D341263 **File Symbol No.:** 62719-LIR
PRODUCT NAME: GF-1847
COMPANY: Dow Agrosciences LLC
FOOD USE [X]   **INTEGRATED FORMULATION [X]**
PCC: 108702; **Decision No.** 373088

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INTRODUCTION:

The registrant has submitted product chemistry data in support of the registration application for the proposed end-use product. The registrant has submitted the product chemistry data corresponding to Subgroup A & B under MRID No. 471587-01 & 471587-02. The registrant has submitted CSF for basic formulation (dated 06-13-07) along with the product label. The TRB has been asked to evaluate product chemistry data submitted and determine acceptability of the proposed basic CSF.

SUMMARY OF FINDINGS

1. The proposed end use product contains Pyroxsulam MC [File Symbol No. 62719-LAT, 99%] as the active ingredient with product label claims of 4.31%. The source product of the Pyroxsulam TGAI/MUP used to formulate the proposed end use product is undergoing process of registration with the Agency.

2. The CSF of basic formulation (dated 06-13-07) is filled out correctly & completely. The nominal concentration of the active ingredient concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. All the food use inert ingredients used in the formulation are approved by the Agency for the proposed uses. The certified limits for the AI and inert ingredients are in compliance with standard certified limit table set forth in 40CFR§158.175(b)(2). The data submitted corresponding to guidelines 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the product chemistry data requirements of 40CFR§158.150 & 158.175 respectively [MRID No. 471587-01].

3. The data submitted corresponding to guideline 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), and 830.1670 (discussion on the formation of impurity) satisfy the data requirements of 40CFR §158.160, §158.165, & §158.167 respectively [MRID No. 471587-01].

4. The data submitted corresponding to guideline 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The active ingredient and the safner were determined by HPLC using Luna C8 (2) column. An acetonitrile/water gradient was used, and the detection was monitored with a UV detector at 280 nm. Quantification was carried out by peak area measurements using internal standard calculation [MRID No. 471587-01].

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5. The data submitted corresponding to guideline 830 series subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR158.190, except for one year storage stability (830.6317) and corrosion characteristics (830.6320) data [MRID No. 471587-02].

6. The registrant has stated that one year study for the guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics) on the proposed end use product are in progress. It is recommended that the observations must be made at 0, 3, 6, 9, and 12 month interval periods. The results must be submitted to the Agency on completion.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The product chemistry data submitted for the guidelines 830 Series Subgroup A are acceptable.

2. The acceptance of the proposed CSF for basic formulation (dated 06-13-07) is contingent upon the tolerance exemption approval for the safner to use in combination with the active ingredient pyroxsulam. At present the safner has tolerance exemption only when used in combination with the active ingredient pinoxaden in a 1:4 ratio of safner to active ingredient (40CFR§180.560). The IIAB is working on this issue.

3. The product chemistry data submitted corresponding to guidelines 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190 and are acceptable, except one year storage stability (830.6317), & corrosion characteristics (830.6320) studies.

4. The registrant is advised to submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) studies on the proposed product. It is recommended that the observations be made at 0, 6, 9, and 12 month periods for both the studies. It is recommended that a hard copy of the results must be submitted to the Agency along with an electronic copy.

5. The registration of the proposed product with File symbol No. 61729-LIR is subject to the approval of the registration application for the technical source of the active ingredient pyroxsulm (File symbol No. 62719-LAT) which is under going registration process with the Agency.

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	A	06-13-07
830.1600. Beginning Materials	A	471587-01
830.1650. Formulation Process	A	471587-01
830.1670. Discussion of Impurities	A	471587-01
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	A	06-13-07
830.1800. Enforcement Analytical Method (cited)	A	471587-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	A	Green to Brown	471587-02
830.6303. Physical State	A	Liquid	" " "
830.6304. Odor	A	Sweet	" " "
830.6314. Oxidation/Reduction Action	A	None	" " "
830.6315. Flammability	A	> 100°C	" " "
830.6316. Explodability	NA		
830.6317. Storage stability	G	1 year required	
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	G	1 year in required	
830.6321. Dielectric Breakdown Voltage	NA		
830.7000. pH	A	6.1 @ 20.0°C	471587-02
830.7100. Viscosity 23.3°C	A	Product is non-Newtonian	471587-02
830.7000. Density/Bulk Density (20 °C)	A	1.049 g/ml	471587-02

Explanations: A = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.