

DATE OUT: 28 / MAY / 2003

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]**
DP BARCODE No.: D288147 File Symbol No.: 62719-LNG
PRODUCT NAME: GF-947 Granule SF
FOOD USE [X] PCC: 119031

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5/28/03
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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 proposed product is for selective weed control in water-seeded rice. The 830 Series Subgroup A and subgroup B product chemistry data have been submitted under MRID No. 458307-04 and MRID No. 458307-11 respectively. The Physical-Chemical properties (830 Series Subgroup B) have been submitted under Self certification program in compliance with PR Notice 98-1. The registrant has submitted CSF for basic formulation (dated 11-19-02) and the product label. The TRB has been asked to evaluate product chemistry data.

SUMMARY OF FINDINGS

1. The proposed end-use-product contains Penoxsulam technical (Reg. No. 62719-UOO, 98.0%) as the active ingredient with product label claim of 0.24%.
2. The CSF for basic formulation (dated 11-19 -02) is filled out correctly and completely. It is in compliance with PR Notice 91-2. The nominal concentration of the active ingredient concurs with the label claim nominal concentration. The data submitted corresponding to the guideline reference 830.1550 (Product Identity & composition) and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively. [MRID No. 458307-04]
3. The data submitted corresponding to the guideline reference 830.1600 (Description of materials use to produce the product), 830.1650 (Description of formulation process) and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR158.160, 158.165 and 158.167 respectively. [MRID No. 458307-04]
4. The data submitted corresponding to the guideline reference 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The active ingredient was assayed by HPLC / UV (285 nm) method. [MRID No. 458307-04]
5. The data submitted corresponding to guideline reference color (830.6302), odor (830.6304), Physical state (830.6303), density (830.7300), pH (830.7000), Oxidation/Reduction (830.6314), Flammability (830.6315), Explodability (830.6316), Viscosity (830.7100), Miscibility (830.6319), Dielectric breakdown voltage (830.6321) satisfy the data requirements of 40CFR§158.190. [MRID No. 458307-11].
6. No data have been submitted corresponding to corresponding to guide line reference 830.6317 (one year storage stability), this is considered as data gap.
7. With regards to guideline reference 830.6320 (corrosion characteristics), the registrant stated that the results will be submitted in a separate report. No separate report was found with this submission.

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CONCLUSIONS:

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

1. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup A and Subgroup B (Physical/Chemical properties) satisfy the data requirements of 40CFR§158.150 to 158.190 and are acceptable, except for one year storage stability and corrosion characteristics studies.

2. The CSF for basic and formulation (dated 11-19 - 02) is acceptable.

Note: the nominal concentration of AI based on 98% of the PAI is 0.2352% which was rounded up to 0.24% so that it concurs with product label claim nominal concentration.

3. The registrant must submit the results of one year storage stability (830.6317) . The results of corrosion characteristics (830.6320) studies should be send to the Agency.

4. The registration of the proposed end-use -product is subject to the approval and registration of the technical Penoxsulam source active ingredient (File symbol No.: 62719-UOO, 98%), which is under process of registration with the Agency.

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 PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity	Y	11-19-02-CSF
830.1600. Beginning Materials	Y	458307-04
830.1650. Formulation Process	Y	" " "
830.1670. Discussion of Impurities	Y	" " "
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits(CSF)	Y	11-19-02-CSF
830.1800. Enforcement Analytical Method	Y	458307-04

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Gray	458307-11
830.6303. Physical State	Y	Granular solid	" " "
830.6304. Odor	Y	None	" " "
830.6314. Oxidation/Reduction Action	Y	None	" " "
830.6315. Flammability	NA		" " "
830.6316. Explodability	Y	non-explosive	" " "
830.6317. Storage stability	G		
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	G		
830.6321. Dielec. Bkd. Vltg.	NA		
830.7000. pH	Y	8.80	" " "
830.7100. Viscosity	NA		" " "
830.7000. Density/Bulk Density	Y	0.67 g/ml @ 24.2°C	" " "

Explanations: Y = 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.

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830.1800. Enforcement analytical method: (MRID No. 458307-04)

The HPLC/UV method was used to determine the active ingredient in the proposed product.

Equipment: HP 1 100LC system, consisting of pump, degasser, autosampler and UV detector.

Column: Zorbax Rx-C8, 4.6 x 250 mm x 5 μ m

Column temperature: RT

Mobile phase: 60/40/0.1 (v/v/v) Acetonitrile/water/phosphoric acid

Flow rate: 1.0 ml/minute

Injection volume: 20 μ l

Detector: UV at 285 nm

Approximate retention time: XDE-638: 4.8 minute

This method was validated over a range of 0.06 % to 0.48% penoxsulam by weight. The method was validated for linearity, accuracy, precision, solution stability, interferences, ruggedness and limitations. The quantitation was done by external standard calculation using peak area.