

DATE OUT: 28 / MAY / 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [X] EP []
DP BARCODE No.: D288066 File Symbol No.: 62719-LNE
PRODUCT NAME: GF-881 Manufacturing Use Concentrate
FOOD USE [X] INTEGRATED FORMULATION []
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 manufacturing-use product (MUP). The 830 Series Subgroup A and subgroup B product chemistry data have been submitted under MRID No. 458307-02 and MRID No. 458307-09 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 manufacturing-use-product contains Penoxsulam technical (Reg. No. 62719-UOO, 98.0%) as the active ingredient with product label claim of 50.0%.
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. 458307-02]
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 40CFR§158.160, 158.165 and 158.167 respectively. [MRID No. 458307-02]
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. 458307-02]
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. 458307-09].
6. No data have been submitted corresponding to corresponding to guideline 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.
3. The registrant must submit the results of one year storage stability (830.6317) . The results of corrosion characteristics (830.6320) studies should be sent to the Agency.
4. The registration of the proposed manufacturing -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	458307-02
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	458307-02

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Pale brown	458307-09
830.6303. Physical State	Y	Opaque liquid	" " "
830.6304. Odor	Y	Musty	" " "
830.6314. Oxidation/Reduction Action	Y	None	" " "
830.6315. Flammability	Y	> 100°C	" " "
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	4.24	" " "
830.7100. Viscosity	Y	non-newtonian fluid (Note 1)	" " "
830.7000. Density/Bulk Density	Y	1.287 g/ml @ 20°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.

Note 1. 830.7100. Viscosity: Non-Newtonian fluid at 20°C and 40°C; viscosity decreases with increasing shear rate.

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830.1800. Enforcement analytical method: (MRID No. 458307-02)

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 um

Column temperature: RT

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

Flow rate: 1.0 ml/minute

Injection volume: 10 ul

Detector: UV at 285 nm

Internal standard: ethyl benzoate

Approximate retention time: XDE-638: 4.8 minute

Ethyl benzoate: 6.5 minute

This method was validated over a range of 18.7% to 65.2% penoxsulam by weight. The method was validated for linearity, accuracy, precision, solution stability, interferences, ruggedness and limitations.

The sample was dispersed in water, then internal standard solution containing ethylbenzoate was added.

The solution was diluted in mobile phase prior to LC analysis.

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