

US EPA ARCHIVE DOCUMENT

DP BARCODE No.: D358197 File Symbol No.: 228-LOT PRODUCT NAME: NUP-07333
Herbicide

DATE OUT: 17 / DEC / 2008

SUBJECT: FEE.PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D358197 File Symbol No.: 228-LOT
PRODUCT NAME: NUP-07333 Herbicide
COMPANY: NuFarm Americas Incorporation
FOOD USE [] INTEGRATED FORMULATION []
PCC: 116002; Decision No. 399829; ACTION: R301

FROM: Shyam Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

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12-17-08
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TO: Tobi Colvin-Snyder / James Tompkins, RM 25
Herbicide Branch / RD (7505P)

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 830 series group A & B under MRID Nos. 475356-01 and 475356-02. The registrant has submitted CSF for basic formulation (dated 08-24-08) and the proposed product label. TRB has been asked to evaluate product chemistry data submitted and determine its acceptability.

SUMMARY OF FINDINGS

1. The proposed end use product contains [REDACTED] as the active ingredient with product label claim of 14.0%.
2. The proposed CSF for basic formulation (dated 08-24-08) 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 inert ingredients present in the formulation have been approved by the Agency (IIAB, 12-17-08). The certified limits for the AI and the inert ingredients are in compliance with standard certified limit table set forth in 40CFR§158.350(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§158.320 & 158.350 respectively [MRID No. 475356-01].
3. The data submitted corresponding to guideline 830.1600 (description of materials used to produce the product), revised 830.1650 (description of formulation process), and 830.1670 (discussion on the formation of impurity) satisfy the data requirements of 40CFR §158.325, §158.335, & §158.340 respectively [MRID No. 475356-01].
4. The data submitted corresponding to guideline 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.355. The content of the active ingredient TEA salt of triclopyr was determined by HPLC/UV method. The method utilized an Alltech Rocket Platinum EPS 18 column, 53 mm x 7.0 mm x 3 µm with UV detector operating at 280 nm. The method employs internal standard calibration technique. This is an isocratic internal standard HPLC method. A standard of the ingredients proportional to the label claim was prepared using para-chlorophenol as an internal standard. A sample amount which is proportional to the standard amount was prepared and injected into HPLC instrument. The signal whose intensity is proportional to analyte concentration is detected by UV detector. The signal is displayed on the integrator as a peak corresponding to the retention time which is specific to the analyte and to the parameters set for this method [MRID No. 475356-01].

Product ingredient source information may be entitled to confidential treatment

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5. The data submitted corresponding to guideline 830 series subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR158.310(e), except for one year storage stability (830.6317) and corrosion characteristics (830.6320) data [MRID No. 475356-02].

6. No data were submitted on the guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics).

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 group A & group B are acceptable, except for the guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics).

2. The proposed CSF for basic formulation (dated 08-24-08) is acceptable.

3. The product chemistry data submitted corresponding to guidelines 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.310(e) and are acceptable, except for one year storage stability (830.6317) and corrosion characteristics (830.6320).

4. The registrant is advised to generate 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.

5. The registrant is recommended to send a copy of the enforcement analytical method to the EPA Analytical Laboratory at the following address:

USA EPA Analytical laboratory
701 Mapes Road,
Ft. Meade, MD 20755-5350
USA

Product Chemistry (Series 830 group A & group B)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	A	08-24-08
830.1600. Beginning Materials	A	475356-01
830.1650. Formulation Process (revised, 08-11-08)	A	" " "
830.1670. Discussion of Impurities	A	" " "
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	A	08-24-08
830.1800. Enforcement Analytical Method	A	475356-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	A	Brown to tan	475356-02
830.6303. Physical State	A	Solid granular	475356-02
830.6304. Odor	A	Amine like	475356-02
830.6314. Oxidation/Reduction Action	A	See Note 1	475356-02
830.6315. Flammability	A	> 200° F	475356-02
830.6316. Explodability	NA		
830.6317. Storage stability	G		
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	G		
830.6321. Dielectric Breakdown Voltage	NA		
830.7000. pH	A	6.70 @20°C	475356-02
830.7100. Viscosity	NA		
830.7000. Density	A	0.88 g/ml 0.926 g/ml	475356-02
	Pour		
	Tap		

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.

Note 1. 830.6314: Compatible with water, 10% monoammonium phosphate, Fe powder, & kerosene. Not compatible with 10% Potassium permanganate.