DATE OUT: 15 / NOV / 2005

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.: D312228 **File Symbol No.:** 62719-LEL
PRODUCT NAME: GF-982
COMPANY: Dow Agrosciences LLC
FOOD USE [X] **INTEGRATED FORMULATION [X]**
PCC: 005209, 128968; **Decision No.** 352343

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INTRODUCTION:

The registrant has submitted product chemistry data in support of the registration application for the proposed end-use product GF-982. The submitted product chemistry data were assigned MRID Nos. 464389-01and 464342-02. The registrant initially has submitted a CSF for basic formulation (dated 09/21/04) and the product label. After the preliminary screening was done, the registrant was advised to correct few errors in the CSF and submit the corrected CSF. The registrant provided on 11-09-05 a revised & corrected basic CSF (dated 11-09-05). The revised CSF will replace the basic CSF dated 09-11-04. The TRB has been asked to evaluate product chemistry data submitted.

SUMMARY OF FINDINGS

1. The end use product contains Triisopropanolamine (TIPA) salt of aminopyralid and Fluroxypry methylheptyl ester (Reg. No. 62719-285, 98%) as the active ingredients with the product label claims of 1.92% and 20.22% respectively.

2. The Triisopropanolamine (TIPA) salt of the active ingredient was made by an integrated process during the reaction of TIPA with aminopyralid technical (Reg. No. 62719-518, 95.3%).

3. The CSF for basic formulation (dated 11-09-05) is filled out correctly & completely. The nominal concentrations of the active ingredients concur with the product label claim nominal concentrations. The CSF is in compliance with PR Notice 91-2. The certified limits for the active ingredients and for the food use inert ingredients are based on the standard certified limits 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§158.155 & 158.175 respectively [MRID No. 464389-01].

4. 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. 464389-01].

5. The data submitted corresponding to guideline 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180.The validated HPLC/UV (270 nm) analytical method was used for the determination of active ingredient contents of the end use product. The quantification was carried out by peak height measurements using internal standard calculations. The method validation was achieved by generating specificity, accuracy, linearity, and precision data under the specified analysis conditions [MRID No. 464389-01].

6. The data submitted corresponding to guideline 830 series subgroup B (physical-chemical properties) corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation-reduction), 830.6315 (flammability), 830.6319 (miscibility), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) satisfy the data requirements of 40CFR §158.190, except for storage stability and corrosion characteristics studies. [MRID No. 464342-02].

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 corresponding to guidelines 830 Series Subgroup A and Subgroup B are acceptable, except for one year storage stability (830.6317) and corrosion characteristics (830.6320)studies.

2. The CSF for basic formulation (dated 11-09-05) is acceptable. All the food use inert ingredients present in the formulation are cleared by the Agency and are exempted form tolerance requirements for food use, except for one. For the name please refer to Confidential Appendix.

3. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) studies for the proposed product. It is recommended that the observation must be made at 0, 3, 6, 9, and 12 months period and the results must be submitted to the Agency on completion along with an electronic copy as well.

4. The registrant is recommended to revise the Ingredient statement on the product label, the term “Inert ingredients” should be changed to “Other Ingredients”.

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PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	A	09-21-04
830.1600. Beginning Materials	A	464389-01
830.1650. Formulation Process	A	" " "
830.1670. Discussion of Impurities	A	" " "
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	A	09-21-04
830.1800. Enforcement Analytical Method	A	464389-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	A	Yellow	464342-02
830.6303. Physical State	A	Clear Liquid	464342-02
830.6304. Odor	A	Waxy odor	464342-02
830.6314. Oxidation/Reduction Action	A	See Note 1	464342-02
830.6315. Flammability	A	150°F	464342-02
830.6316. Explodability	A	See Note 2	464342-02
830.6317. Storage stability	G		
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	G		
830.6321. Dielectric Breakdown Voltage	NA		
830.7000. pH	A	6.5 @ 20°C	464342-02
830.7100. Viscosity	A	See Note 3	464342-02
830.7000. Density/Bulk Density	A	0.993 @ 20^0C	464342-02

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.

Note1. Oxidation/Reduction (830.6314): A significant rise (7.1°C) in temperature upon addition of potassium permanganate solution. No significant temperature change was noted for monoammonium phosphate, zinc metal (dust) and water.

Note 2. Explodability (830.6316): Impact Explodability – Not impact sensitive; Thermal explodability – No exothermic events observed over temperature range.

Note 3. Viscosity (830.7100): Kinematic Viscosity at 40°C (m^2/sec) was 0.0000057

Enforcement analytical method: (MRID No. 464389-01)

HPLC/UV method for the determination of Fluroxypyr MHE and aminopyralid in the formulations

Fluroxypyr MHE and aminopyralid were determined by HPLC using a Zorbax SB Phenyl column. A phosphate buffered aqueous acetonitrile eluent was used and the detection was monitored with a UV detector at 270 nm. Quantification was carried out by peak height measurement using an internal standard calculation.

Equipment & Parameters

HPLC system: Agilent 100HPLC system consisting of a binary gradient pump, autosampler and a vacuum degassing unit.

Column: Zorbax SB Phenyl 5 µm, 250 mm x 4.6 mm id
Column temperature: ambient
Mobile phase A: Dissolve 1.25 g potassium dihydrogen phosphate in 550 ml distilled water, add 450 ml acetonitrile, mix well and adjust the pH to 2.5 with phosphoric acid.
Mobile phase B: Acetonitrile
Flow rate: 1.5 ml/min
Injection volume: 10 µL
Gradient program:

Time (min)	% A	% B
0	100	0
3.5	100	0
8.0	50	50
16.0	50	50
17.0	100	0

Wave length: 270 nm
Approximate retention time: Aminopyralid – 2.3 minutes; Diehylphthalate – 7.1 minute; Fluroxypyr MHE – 11.8 minutes
UV wavelength: 270 nm
Internal standard: Diethylphthalate
Approximate retention time: Aminopyralid – 2.3 min; 2, 4-D – 5.3 min; Diethylphthalate – 7.3 min

The method was validated for linearity, accuracy, and precision.

Inert ingredient information may be entitled to confidential treatment

CONFIDENTIAL APPENDIX
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The name of the inert ingredient for which the food use tolerance exemption is yet established is [redacted].

The tolerance is not established presently, but tolerance exemption can be granted when Kerry Leifer returns back from his training in Denver, Colorado.