DATE OUT: 07 / FEB / 2005

FEE

SUBJECT: **FEE. PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.: D306058, D312253 **REG./File Symbol No.:** 80967-R
PRODUCT NAME: Meychem Glyphosate
COMPANY: Mey Corporation
PCC:103601; **Decision No.:** 344237 ; **FOOD USE [X]**
INTEGRATED FORMULATION: Yes [X] NO [ ]

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

02-08-05

TO: James Tompkins / Vickie Walters, RM 25
Herbicide Branch/RD(7505C)

INTRODUCTION:

On behalf of MEY Corporation, Technology Sciences Group Inc., is submitting the "Me-Too" application for the registration of the proposed end use product "Meychem Glyphosate". The active ingredient in the product is isopropylamine salt of glyphosate produced by integration formulation process. The glyphosate [N-(phosphonomethyl)glycine] was produced in-situ and then further reacted with isopropylamine to produce 41% isopropylamine salt of glyphosate as the active ingredient in the end use product Meychem Glyphosate. The registrant has submitted the product chemistry data corresponding to 830 series Subgroup A under MRID No. 462103-01. Initially no data on 830 series Subgroup B (physical-chemical properties) for the proposed end use was submitted. On 01-27-05, additional data was submitted which included Subgroup B data on the proposed product. The additional data were submitted under MRID Nos. 464566-01, 464566-02, and 464566-03. Also on the same date the applicant provided a revised CSF for basic formulation (dated 01-26-05) which will replace the previously submitted CSF for basic formulation (dated 02-27-04) and the product label. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 524-475. The TRB has been asked to review the product chemistry data submitted for the proposed end-use product and determine its similarity with the registered product.

SUMMARY OF FINDINGS

1. The proposed end-use product contains Isopropylamine salt of glyphosate as the active ingredient with product label claim of 41.0%. The active ingredient was produced by reacting the glyphosate (produced in-situ by chemical reactions) with isopropylamine.

2. The CSF for basic formulation (dated 01-26-05) is filled out correctly and completely. It is in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. The certified limits for the AI is based on the standard certified limits in compliance with 830.1750 . The proposed certified limits for the impurities are based on preliminary analysis of glyphosate acid and Meychem glyphosate. 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. 462103-01 and 464566-02].

3. The data submitted corresponding to the guideline reference 830.1650 (description of formulation process)and 830.1670 (discussion on the formation of impurities) satisfy the data requirements of 40CFR158.165 and 158.167 respectively [MRID No. 464566-02].

DP BARCODE No.:D306058, 312253 **REG./File Symbol No.:** 80967-R **PRODUCT NAME:** Meychem Glyphosate

4. The five representative batches of the end use product were analyzed for the IPA salt of glyphosate and for the glyphosate acid using HPLC/UV (195 nm) method (AOAC Method 983.10). The method uses ion exchange chromatography with UV detection. The quantitation was done by external standard technique. The method was validated for specificity, linearity, accuracy, and precision. The data submitted corresponding to the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.170 Additional information on 830.1700 (received on 01-27-05) The impurities were determined by HPLC/UV (208 nm) method, capillary GC method, and ion chromatography. Details of the method have been provided. The methods were validated for linearity, accuracy, and precision [MRID No. 462103-01 & 464566-02].

5. The AOAC Method 983.10 was found to be suitable for determining the content of the active ingredient in Meychem glyphosate. The method uses ion exchange chromatography with UV detection (195 nm) and external standard technique for the quantitation of the AI. The percent of glyphosate IPA salt in the test substance was calculated by multiplying the percent glyphosate by a constant derived from molecular weight (MW)of glyphosate & MW of IPA salt of glyphosate.

The data submitted corresponding to the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180 [462103-01].

6. The product chemistry data corresponding to 830 series subgroup B (physical-chemical properties) for the proposed end use product satisfy the data requirements of 40CFR§158.190 [MRID No. 464566-01]

7. The registrant has provided the results of accelerated storage stability study. The study was carried out for 14 days at 54°C and at cold temperatures. However, the registrant is required to generate one year storage stability for the proposed product. The registrant is recommended to carry out the corrosion characteristics study simultaneously with one year storage stability study. It is advised that the observations be made at 0. 3. 6, 9, & 12 months periods [MRID No. 464566-03]

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 guideline reference 830 Series Subgroup A satisfy the data requirements of 40CFR§158.150 to 158.180 and are acceptable.

2. The proposed product (File symbol No. 80967-R) was determined to be substantially similar to the registered product with Reg. No. 524-475 from the product chemistry point of view.

3. The product chemistry data submitted corresponding to 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).

4. The registrant has requested waiver for corrosion characteristics (830.6320) studies for the proposed end use product. Based on the justification provided, the Agency accepts the waiver request.

4. The CSF for basic formulation (dated 01-26-05) is acceptable.

5. The results of one storage stability (830.6317) study must be submitted to the Agency on completion. The registrant may request to the RM for the conditional registration of the product while the study is in progress.

DP BARCODE No.: D306058,312253 **REG./File Symbol No.:** 80967-R **PRODUCT NAME:** Meychem Glyphosate

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

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (basic CSF)	Y	01-26-05
830.1600. Beginning Materials	Y	462103-01 464566-02
830.1650. Formulation Process	Y	" " "
830.1670. Discussion of Impurities	Y	" " "
830.1700. Preliminary Analysis	Y	462103-01 464566-02
830.1750. Certified Limits (basic CSF)	Y	01-26-05
830.1800. Enforcement Analytical Method	Y	462103-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	yellow	464566-02
830.6303. Physical State	Y	liquid	" " "
830.6304. Odor	NA		
830.6314. Oxidation/Reduction Action	Y	Note 1	464566-02
830.6315. Flammability	NA		
830.6316. Explodability	Y	non-explosive	464566-02
830.6317. Storage stability	I	14 days	464566-03
830.6319. Miscibility	NA		
a830.6320. Corrosion Characteristics	Y	Waiver accepted	464566-01
830.6321. Dielec. Bkd. Vltg.	NA		
830.7000. pH	Y	4-6	464566-01
830.7100. Viscosity	Y	43 mPa 20	" " "
830.7000. Density/Bulk Density	Y	1.165	" " "

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(830.6314): Not to mix or store the product or spray solutions in galvanized or unlined steel containers or spray tanks. Avoid the contact with oxidizing or reducing agents.

DP BARCODE No.: D306058, 312253 **REG./File Symbol No.:** 80967-R **PRODUCT NAME:** Meychem Glyphosate

830.1800. Enforcement analytical method AOAC Method 983.10 [MRID No. 462103-01]

The method uses ion exchange chromatography with UV detection operating at 195 nm, and using external standard technique for quantitation of the active ingredient.

Summary: an accurately weighed amount of reference standard glyphosate was diluted with phosphate buffer mobile phase. The mobile phase consisted of aqueous potassium dihydrogen phosphate and methanol at pH 1.9. The portions of standard solution were injected directly into an ion exchange chromatographic system equipped with a loop injector, strip chart recorder, electronic integrator, and strong anion exchange column. An accurately weighed amount of test substance was similarly diluted and injected. After the system stability was assured, average peak areas from two successive injections from both standard and test solutions, along with the weights of test and reference substance used and the purity of the reference substance, were used to calculate the percent glyphosate in the test substance. The percent of glyphosate IPA salt in the test substance was calculated by multiplying the % glyphosate by salt factor.

Liquid chromatography: able to generate over 1000 psi and measure A at 195 nm.

Column: a strong anion exchange column like Partisil 10 SAX, 25 cm x 4.6 mm id, 1/4" (6.35 mm) od.

Column temperature: ambient

Mobile Phase: dissolve 0.8437 g potassium dihydrogen phosphate in 960 ml water. Add 40 ml methanol and mix well. Adjust the pH at 1.9 with 85% phosphoric acid.

Injection volume: 50 µL.

% Glyphosate = (R/R') x W'/W) x P

Where, R = average peak area of test solution; R' = average peak area of standard solution; W = mg test portion; W' = mg standard; P = % purity of standard. To convert % glyphosate to IPA salt, multiply by 1.3496.
Flow rate: 2.3 ml/min

CONFIDENTIAL APPENDIX
DP BARCODE No.:D306058,312253 REG./File Symbol No.: 80967-R PRODUCT NAME: Meychem Glyphosate

830.1550. Product Identity & Composition:[MRID No. 462103-01 & 464566-02]

Common Name: Meychem Glyphosate, IPA salt of glyphosate

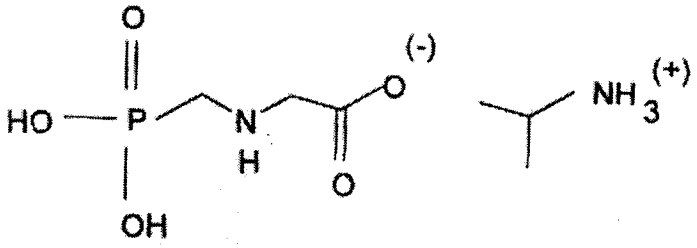
Chemical name: Glycine, N-(phosphonomethyl), isopropylamine salt

CAS No.: 38641-94-0

Molecular formula: $(HO)_2\ P(O)\ CH_2\ NH\ CH_2\ COO^{(-)}$ + $(Me)_2\ CH\ NH_3^{(+)}$

Molecular weight: 228.18

Structural formula:



830.1600. Description of materials used to produce the product: [MRID No. 462103-01 & 464566-02]

The registrant provided the MSDS's for all the starting materials used to produce the end use product Meychem glyphosate.

830.1620. Description of the production process: [MRID No. 462103-01 & 464566-02]

Meychem glyphosate is produced by an integrated formulation process and was produced in China by Shanghai Hujiang Biochemical Factory in Xinshi Town.

[redacted]

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Page _____ is not included in this copy.

Pages 6 through 11 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

__✓__ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.