DATE OUT: 29/APR/2003

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF TGAI/MP [X] EP [ ]**
DP BARCODE No.: D287869 **File Symbol No.:** 70829-L
PRODUCT NAME: Clearout Technical
COMPANY: Chemical Products Technologies
PCC: 417300
FOOD USE [X] **INTEGRATED FORMULATION [X]**

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

TO: Jim Tompkins/Vickie Walters, PM 25
Herbicide Branch/RD(7505C)

INTRODUCTION:

The registrant has submitted product chemistry data in support of the application for the registration of the proposed product. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 524-420. The registrant has provided a CSF for basic formulation dated July 29, 2002 and the product chemistry data under MRID No. 457453-01.

SUMMARY OF FINDINGS

1. The proposed technical is Glyphosate acid with nominal concentration and product label claim of 96.7%. This technical is produced in the facility based in China.

2. The CSF for basic formulation (dated July 29, 2002) is not filled out correctly. The nominal concentration of the active ingredient concurs with the product label claim nominal concentration. The CSF is not acceptable.

3. No data have been submitted corresponding to guideline 830 Series Subgroup A & B for the proposed technical.

4. The analytical data submitted (MRID No. 457453-01) for the identification and determination of one of the impurities partially satisfy the data requirements of 40CFR158.167. The amount for this impurity indicated in the CSF concurs with the analytical results. For more details, please refer to Confidential Appendix.

BARCODE No.:D287869**File Symbol No.:**70829-L **PRODUCT NAME:** Clearout Technical

5. The proposed technical was found to be substantially similar to the registered product with Reg. No. 524-420 from product chemistry view point. However, the registrant must submit the product chemistry data corresponding to Sub group A (830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, and 830.1800). The Subgroup B (Physical-Chemical properties) data can be cited from the registered product.

CONCLUSIONS:

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

1. The CSF for basic formulation (dated 07-29-02)is not acceptable for the following reasons:

i. The amounts provided in column 13a and the calculations in 13b are not correct. The registrant must check the calculations and accordingly correct the CSF and submit to the Agency.
ii. The total amount in Block #17 is not correct. This must be corrected.

The registrant must submit a revised & corrected CSF.

2. The proposed technical was found to be substantially similar to the registered product with Reg. No. 524-420 from product chemistry view point. However, the registrant must submit the product chemistry data corresponding to Sub group A (830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, and 830.1800). The Subgroup B (Physical-Chemical properties) data can be cited from the registered product.

3. The product chemistry data corresponding to following guidelines are required:

830.1550 (Product identity & composition)
830.1600 (Description of material used to produce the product)
830.1620 (Description of production process)
830.1670 (Discussion of the formation of impurities)
830.1700 (Preliminary analysis)
830.1750 (Certified limits)
830.1800 (Enforcement analytical method)

These data must be submitted for the Glyphosate technical produced in the facility located in China.

[redacted]

BARCODE No.:D287869 **File Symbol No.:**70829-L **PRODUCT NAME:** Clearout Technical

Determination of the impurity N-(Phosphonomethyl)iminodiacetic acid in Glyphosate acid TGAI: (MRID No. 457453-01)

Four representative lots of glyphostae acid TGAI were analyzed for N-(Phosphonomethyl)iminodiacetic acid impurity at LOD at 0.5% using titration method. [Repasi, J., (1993) Selective Complexometric Determination of Glyphostae and related compounds. *Pesticide Sciences,* 39:287-292]

The Precision of the method was determined by analyzing one lot of the test substance, in quadruplicate, on each of two different days. The RSD was 0.0% for the impurity on each day and both days combined.

The accuracy of the method was demonstrated by the analysis of one lot of the test substance fortified with N-(Phosphonomethyl) iminodiacetic at approximately the following ratios of LOD; 1x, 2x, 3x, 4x, and 5x (LOD or x = 0.5%). The assay was run in quadruplicate. The mean recoveries ranged between 99.0% and 104.6%.

Method: An aliquot from each of the four lots of the TS was dissolved in a total of 245 ml water and 5 ml of 1M NaOH. Four replicates (50 ml each) were transferred to 250 ml flasks then 1 ml of 10% w/w nitric acid was added followed by addition of 30 mg of methyl thymol blue mixture to each flask. The solution was mixed, then titrated with bismuth volumetric solution to a blue-purple color.

The concentration of N-(Phosphonomethyl)iminodiacetic in glyphosate was then calculated in the samples using the following equation:

$$\% \text{ acid (w/w) present} = \frac{F_2 \times V_2 \times 0.015 \times MW \times 5 \times 100}{M_s}$$

Where, F_2 = 1.0032
V_2 = Volume of bismuth volumetric solution consumed (ml)
MW = molecular weight of acid (227.11)
M_s = adjusted glyphosate technical weight + adjusted N-(Phosphonomethyl)iminodiacetic acid for AI (mg)

0.015 = Molarity of nitric acid

[redacted]

BARCODE No.:D287869**File Symbol No.:**70829-L **PRODUCT NAME:** Clearout Technical

The results of analysis are provided in the following table:

Lot Number	20023.7	20023.6	20023.1	20023.4
Replicate 1	1.2	1.6	1.4	1.9
Replicate 2	1.2	1.6	1.2	2.1
Replicate 3	1.2	1.6	1.4	2.1
Replicate 4	1.2	1.6	1.4	2.1
Average	1.2	1.6	1.4	2.1
SD	0.0	0.0	0.1	0.1
RSD(%)	0.0	0.0	7.1	4.8