DATE OUT: 19 / MAY / 2003

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF TGAI/MP [X] & Unregistered TGAI as source AI**
DP BARCODE No.: D 287872 **REG./File Symbol No.:** 70829-U
PRODUCT NAME: Clearout 62 Formulation Concentrate
PCC: 103601
FOOD USE [X] **INTEGRATED FORMULATION [X]**

FROM: Shyam Mathur, Team Leader /s/ S. B. Mathur
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Technical Review Branch/RD (7505C)

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Herbicide Branch / RD(7505C)

INTRODUCTION:

The product chemistry data for the proposed product were reviewed previously (see PCR dated 07/31/02, D282730). The registrant was advised to: (i) to conduct sample or batch analysis of the proposed product and identify carryover impurities from the un-registered glyphosate acid used for its production and list all impurities ≥ 0.1% w/w and those of toxicological concern at the LOQ in the CSF of the proposed product, (ii) submit data corresponding to guideline reference 830.1670 (Discussion on the formation of impurities), 830.1700 (Preliminary analysis), and 830.1750 (certified limits). The registrant responded on November 22, 2002 and provided the required data along with the revised CSF for basic formulation (dated 11-22-02). The product chemistry data for Clearout 62 have been submitted under MRID Nos. 458071-01, 451929-02, 451929-03, 448831-21, and 448831-22. For the un-registered glyphosate acid the product chemistry data have been submitted under MRID Nos. 452798-01, 448831-19, 448831-20, and 451929-01.

The previous review (dated 07/31/02, D282730) also determined that the proposed product is substantially similar to the registered product with Reg. No. 524-333 from product chemistry view.

The TRB has been asked to evaluate the product chemistry data submitted for the proposed end-use product Clearout 62 and the unregistered glyphosate acid.

SUMMARY OF FINDINGS

A. Clearout 62 Formulation concentrate

1. The proposed end-use product contains IPA salt of glyphosate as the active ingredient with product label claim of 62.0%. The IPA salt was prepared by the reaction of glyphosate acid (unregistered, 96.7%) and isopropylamine.

2. 830.1550. Product identity & composition:

The CSF for the basic formulation (dated 11-22-02) is filled out correctly and completely. It is in compliance with PR Notice 91-2. The CSF included all the carryover impurities (≥ 0.1%) from the unregistered glyphosate acid, none of the impurities present are of toxicological concern. The data submitted corresponding to the guideline reference 830.1550(Product Identity & composition) satisfy the data requirements of 40CFR§158.155.

Concentrate

3. 830.1670. Discussion on the formation of impurities: (MRID No. 458071-01)

The registrant has reported all the impurities present in the manufacturing use product including the carryover impurities from the unregistered glyphosate acid. For more details please refer to Confidential Appendix. The data submitted corresponding to guideline reference 830.1670 satisfy the data requirements of 40CFR§158.167.

4. 830.1700. Preliminary analysis: (MRID No. 448831-21)

Five representative lots of Clearout 62 were analyzed for glyphosate IPA salt content using a modified version of method described in the *Journal of AOAC International,* 80 (3): 464-468 (1997). The HPLC / UV (195 nm) technique was used for this determination. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170.

5. Determination of N-nitrosoglyphosate in Clearout 62: (MRID No. 451929-02)

Five lots of Clearout 62 were analyzed for N-nitrosoglyphosate using the HPLC/UV validated method. The method detection limit was 1.0 ppm. No N-nitrosoglyphosate was detected in the un-spiked samples at or above 1.0 ppm. Although the recoveries of the spiked samples were less than the lowest acceptable range (70 to 120%) the method was capable to detect peak for N-nitrosoglyphosate samples at 1.0 ppm or higher. For more details please refer to Confidential Appendix.

6. Subgroup B (Physical-Chemical) properties: (MRID No. 448831-22 and 451929-03)

The product was found to stable for one year (830.6317) under warehouse conditions for one year. The data submitted corresponding to 830 series subgroup B (Physical-Chemical properties) satisfy the data requirements of 40CFR§158.190.

B. Unregistered Glyphosate acid:

1. The data submitted corresponding to guideline reference 830.1550 (Product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

2. The data submitted corresponding to guideline reference 830.1600 (description of materials used to produce the product), 830.1620 (Description of production process) and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.160, 158.162 and 158.170 respectively. [MRID No. 452798-01]

3. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis) and 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.170 and 158.180 respectively. The active ingredient was determined by HPLC/UV method. The product was also analyzed for the impurities present at the levels of $\geq$ 0.1% . For more details please refer to Confidential Appendix. [MRID No. 448831-19]

4. The data submitted corresponding to 830 Series subgroup B (Physical-Chemical properties) satisfy the data requirements of 40 CFR§158.190, except for one year storage stability (830.6317), corrosion characteristics (830.6320), dissociation constant (830.7370), partition coefficient (830.7550), water & organic solvent solubility (830.7840), and vapor pressure (830.7950). [MRID No. 448831-20 & 451929-01]

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end-use product and the unregistered glyphosate acid and has concluded that:

Clearout 62 Formulation Concentrate

1. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup A and Subgroup B were found to be acceptable.

2. The revised CSF for basic formulation (dated 11-22-02) is acceptable.

Unregistered Glyphosate acid

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 were found to be acceptable, except for storage stability (830.6317), corrosion characteristics (830.6320), dissociation constant (830.7370), partition coefficient (830.7550), water & organic solvent solubility (830.7840), and vapor pressure (830.7950).

2. The registrant must submit or cite(registered glyphosate technical with purity within ± 3% of 96.7%) the product chemistry data corresponding to the following guidelines:

one year storage stability (830.6317), corrosion characteristics (830.6320), dissociation constant (830.7370), partition coefficient (830.7550), water & organic solvent solubility (830.7840), and vapor pressure (830.7950).

DP BARCODE No.:D 287872**File Symbol No.:** 70829-U **PRODUCT NAME:** Clearout 62 Formulation Concentrate
PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B) Clearout 62

Subgroup A	Data Required Fulfilled	MRID No.

830.1550. Chemical Identity	Y	11-22-02-CSF
830.1600. Beginning Materials	Y	456578-07 Earlier report
830.1650. Formulation Process	Y	" "
830.1670. Discussion of Impurities	Y	458071-01
830.1700. Preliminary Analysis	Y	448831-21 451929-02
830.1750. Certified Limits	Y	11-22-02-CSF
830.1800. Enforcement Analytical Method	Y	456578-07 Earlier report

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Light gray with green tint	448831-22
830.6303. Physical State	Y	Viscous liquid	" "
830.6304. Odor	Y	odorless	" "
830.6314. Oxidation/Reduction Action	Y	Note 1	" "
830.6315. Flammability	NA		" "
830.6316. Explodability	NA		" "
830.6317. Storage stability	Y	1 yr Stable	451929-03
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	Y	non-corrosive	" "
830.6321. Dielec. Bkd. Vltg.	NA		" "
830.7000. pH	Y	4.40	448831-22
830.7100. Viscosity	Y	448.5 cps 20°C 126.3 cps 40°C	" "
830.7000. Specific gravity/Density	Y	1.2439 g/ml	" "

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 = Waiver

Note 1. Oxidation/Reduction: at the addition of Potassium Permanganate an immediate reaction occurred with fumes and color changed to pink with black tint. Temperature ± 32°C. Bubbling occurred and formed a single thick layer. At the end there was splatters on the side of the vessel, a black solid, bottom layer formed, and the surface had a white butter-like appearance

DP BARCODE No.:D 287872**File Symbol No.:** 70829-U **PRODUCT NAME:** Clearout 62 Formulation Concentrate

SUBJECT: Product Chemistry Review of **Unregistered Glyphosate acid**

830.1550. Product Identity: [MRID No.: 452798-01]

Common Name: Glyphosate

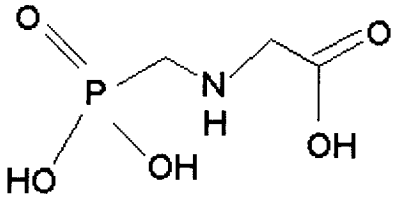
Chemical Name: N-(Phosphonomethyl)glycine

CAS No.: 1071-83-6

PC Code No.: 417300

Empirical formula: $C_3 H_8 N O_5 P$

Molecular Weight: 169.07



ATTACHMENT II

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, CAS)	Glyphosate
Chemical Number (CAS; PC Code)	CAS No. 1071-83-6 PC Code: 417300
Registration/Symbol No.	Unregistered (no registration planned by the applicant)
Type of Product (T, MP, EP)	96.7% TGAI/ MP
DP Barcode	287872
Reviewer	Shyam B. Mathur
Branch Chief	Deborah McCall

Table 1: Manufacturing and Impurity Data for the Glyphosate acid

GLN	Requirement	MRID	Status[1]	Details and/or Deficiency[2]
830.1550	Product identity and composition	452798-01	A	The applicant is not planning to register the TGAI, no CSF and product label are required. The 5 batch analysis confirmed 96.7% purity of glyphosate acid
830.1600	Description of materials used to produce product	452798-01	A	The data have been submitted for all the starting materials have been provided by registrant
830.1620	Description of production process	452798-01	A	The production process has been described in details
830.1670	Discussion of formation of impurities	452798-01	A	The 5 batch analysis indicated process related impurities of about 0.1%. The impurities have been identified.
830.1700	Preliminary analysis	448831-19	A	Registrant has provided 5 batch analysis for the
830.1750	Certified limits	" "	A	standard certified limits proposed
830.1800	Enforcement analytical method	" "	A	HPLC / U V method was used

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.; G = Data gap; I = In progress or need upgrade;

Table 2: Physical and Chemical Properties of the Unregistered TGAI / MUP Glyphosate

GLN	Requirement	MRID	Status[1]	Result[2] or Deficiency
830.6302	Color	448831-20	A	White
830.6303	Physical state	" "	"	Crystalline solid
830.6304	Odor	" "	"	odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	" "	A	Stable at ambient and elevated temperature (54°C), metal and metal ions and to sunlight
830.6314	Oxidation/reduction:	" "	A	None
830.6315	Flammability		NA	
830.6316	Explodability	" "	NA	
830.6317	Storage stability	" "	G	
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics	" "	G	
830.7000	pH	" "	A	1.72 @ 23°C (1% aqueous suspension using methods in CIPAC MT 75)
830.7050	UV/Visible absorption	" "	NA	
830.7100	Viscosity		NA	
830.7200	Melting point/	451929-01	A	Range of 202.3 °C to 203 °C
830.7220	Boiling point/	" " "	NA	
830.7300	Bulk Density	" " "	A	1.71 g / m l at 20 °C (CIPAC MT 3)
830.7370	Dissociation constants in water	"	G	
830.7550	Partition coefficient	"	G	
830.7840	Water solubility:	"	G	
830.7950	Vapor pressure	"	G	

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable ; G = Data gap W = waiver request
I = Incomplete or in progress; U = Needs upgrading

Page _____ is not included in this copy.

Pages 8 through 13 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.