

US EPA ARCHIVE DOCUMENT

Date: September 17, 2002

SUBJECT: Product Chemistry Review of Glyphosate Technical

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9-17-02
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DP BARCODE: D23790
EPA REG. NO.: 74530-G
REGISTRANT: Helm AG
USE: Herbicide

INTRODUCTION:

The registrant has submitted the product chemistry to support the registration of Glyphosate technical. The registrant has claimed that the proposed technical is substantially similar to the registered product with Reg. No. 336670-37. The product chemistry data have been submitted under MRID Nos. 456859-01 through 456859-03.

SUMMARY OF FINDINGS:

1. The registrant has submitted the Confidential Statement of Formula's for basic formulation (dated 05-22-0), for Glyphosate technical. The nominal concentration (97.0%) of the AI does not agree with the product label claim of 96.6%. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160. The registrant has provided the product specifications data on all the starting materials used for the production of this herbicide. [MRID No. 456859-01]
3. The product chemistry data submitted corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§158.162. The registrant has provided the details of the manufacturing process. [MRID No. 456859-01]
4. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.167. [MRID No. 456859-01]
5. The data were submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170. [REDACTED] [MRID No. 456859-02]
6. The data submitted corresponding the guideline reference 830.1800 (Enforcement Analytical method) satisfy the data requirements of 40CFR§158.180. [REDACTED] [MRID No. 456859-02]
7. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup B (Physical/Chemical properties) for the technical satisfy the data requirements of 40CFR 158.190, except for guideline 830.6313 (Stability), 830.7840 (Solubility), & 830.6320 (Corrosion characteristics). [MRID No. 456859-01]

QUALITY CONTROL INFORMATION IS NOT INCLUDED

BARCODE: D283790; Reg. No. : 74530-G PRODUCT: Glyphosate Technical

8. During the 5 batch analysis, the registrant also carried out the analysis for nitrosoamine in the technical Glyphosate. [REDACTED]

[MRID No. 456859-

03]

CONCLUSIONS:

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

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A and Subgroup B satisfy the data requirements of 40CFR§158.155 to 158.190 and are acceptable, except for the CSF for basic formulation, the product label and the corrosion characteristics (830.6320), stability (830.6313), and solubility (830.7840).

2. The CSF for basic formulation (dated 05-22-02) is not filled out correctly. It is not in compliance with PR Notice 91-2. The CSF for basic formulation is not acceptable for the following reasons:

A. The nominal concentration of the AI in the CSF (97.0%) does not concur with the product label claim of 96.6%.

B. Upper certified limit for the toxic impurity has not been provided. The registrant must provide the Upper certified limit in column 14a of the CSF for the toxic impurity nitrosoamine.

C. The registrant must delete the [REDACTED] from the column #12 of the CSF.

D. The registrant must submit a revised label with product label claim of 97.0%.

3. The substantial similarity issue of the proposed technical to the registered product with Reg. No. 336670-37 could not be addressed at this time, since the proposed upper certified limit for the toxic impurity nitrosoamine was not provided in the CSF.

4. The registrant must provide the data of glyphosate technical for the following guidelines:

830.6313. Stability: at room and elevated temperatures, and to metal and metal ions.

830.7840. Solubility in water and in organic solvents.

830.6320 . Corrosion characteristics.

QUALITY CONTROL INFORMATION IS NOT INCLUDED
MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

BARCODE: D283790; **Reg. No.:** 74530-G **PRODUCT:** Glyphosate Technical

830_1550 **Product Identity:** (MRID No. 456859-03)

Common Name: Glyphosate Technical

Chemical Name: N - (Phosphonomethyl)glycine

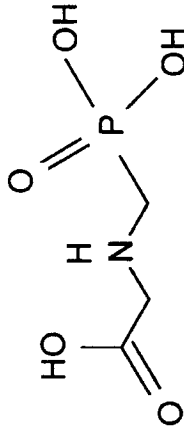
CAS No.: 1071 - 83 - 6

PC Code No.: 417300

Empirical formula: C₃ H₈ N O₅ P

Molecular Weight: 169.1

Structural formula:



ATTACHMENT II

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.) N - (Phosphonomethyl)glycine

Chemical Number (CAS; PC Code)	CAS No. 1071-83-6 PC Code No.: 417300
Registration/Symbol No.	74530-G
Type of Product (T, MP, EP)	97.0% TGAI / MP
DP Barcode	D283790
Reviewer	Shyam B. Mathur
Branch Chief	Deborah McCall

Table 1: Manufacturing and Impurity Data for the Thidiazuron Technical

GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product identity and composition	Basic CSF (5-22-02)	U	The product label claim is 96.6% does not concur with the nominal concentration of AI (97%) in the CSFs. The UCL for the toxic impurity was provided
830.1600	Description of materials used to produce product	456859-01	Y	The product specification sheets(MSDS) for all the starting materials have been provided
830.1620	Description of production process	456859-01	Y	The registrant has provided detailed information about the synthesis of the technical. The amounts of each starting material and conditions under which the reaction were performed are provided.
830.1670	Discussion of formation of impurities	456859-01	Y	The registrant has provided required information on the formation of impurities. The mechanisms for the formation of impurities during different stages of the production process have been submitted.
830.1700	Preliminary analysis	456859-02 456859-03	Y	Registrant has provided 5 batch analysis for the TGAI. Nitrosamine analysis was also submitted.
830.1750	Certified limits	Basic CSF (5-22-02)	U	The certified limits for the TGAI were within the standard certified limits. The limits were verified by 5 batch analysis. The UCL for nitrosamine was not provided
830.1800	Enforcement analytical method	456859-02	Y	

¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.
² Refer to CBI Appendix A for details.

QUALITY CONTROL INFORMATION IS NOT INCLUDED

Table 2: Physical and Chemical Properties of the Glyphosate Technical. *See Note for acceptance condition				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6302	Color	456859-01	Y	No color
830.6303	Physical state	" "	Y	Powder
830.6304	Odor	" "	Y	No odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	" "	U	TS is stable for 32 days at pH 5,7, & 9. No other data were provided.
830.6314	Oxidation/reduction: chemical incompatibility	" "	Y	None
830.6315	Flammability	" "	Y	Not Flammable
830.6316	Explosibility	" "	Y	TS is not classified as explosive material
830.6317	Storage stability	" "	I	Previous study indicate that TS is Stable under normal ware house conditions for at least 3 years. See Note 1
830.6319	Miscibility	NA		
830.6320	Corrosion characteristi	" "	I	To be reported. Study underway in conjunction with storage stability study
830.7000	pH	" "	Y	2.19 (1% solution in water)
830.7050	UV/Visible absorption	" "	Y	See Note 2
830.7100	Viscosity	NA		
830.7200	Melting point/ Melting range		Y	200 C with decomposition
830.7220	Boiling point/ Boiling range	" "	NA	
830.7300	Density/ relative density/ bulk density	" "	Y	1.74 g / ml. Loose packed bulk density: 54.08 lbs / cu. ft.
830.7370	Dissociation constants in water	" "	Y	pKa = 2.6, 5.6, 10.3
830.7550	Partition coefficient (n-octanol/water), shake flask method	" "	Y	K o/w = 0.0006 - 0.0017
830.7840	Water solubility: column elution method; shake flask method	" "	G	No data provided
830.7950	Vapor pressure	" "	Y	1.84 x 10 ⁽⁻⁷⁾ mm Hg at 45C

¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable ; G = Data gap
² For example, "brown" for 830.6302; "155° C" for 830.7200.
A* = The data are acceptable only if the registrant will provide information on the methods used to determine these properties.

Note 1. Storage stability (830.6317): (MRID No. 456859-01)

Glyphosate technical has been produced by Helm AG for many years and is known to be stable under normal warehouse storage conditions. To confirm the storage stability, 2 years study was conducted and the results are shown below:

Initial analysis: July 2, 1999

Present analysis: May 7, 2002

Glyphosate	96.30%	Glyphosate	96.1%
Moisture	0.20%	Moisture	0.1%
Appearance	White crystals	Appearance	White crystals

After nearly 3 years storage, the glyphosate content of Glyphosate technical production batch retain sample is still 99.8% of its original analysis. It is likely the slight drop in Glyphosate analysis is due to analytical variation and not product degradation.

Note 2. 830.7050. UV / VIS: (MRID No. 456589-01)

Medium	Wavelength (nm)	Absorbance	Molar Absorption coefficient
Acidic (pH 1.93)	201	1.742	322.6
	261	0.205	38.0
Neutral (pH 8.0)	201	0.880	160.0
	285	0.144	26.2
Basic (pH 10.2)	201	2.640	480.0
	261	0.207	37.6
	281	0.155	28.2

Page _____ is not included in this copy.

Pages 7 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.
