

US EPA ARCHIVE DOCUMENT

DATE: 21/MAR/2001

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]**
BARCODE No.: D271243 EPA RECEIVED DATE: 07/DEC/2000 REG./File Symbol No.: 42750-56
PRODUCT NAME: Albaugh Technical Glyphosate Acid, 96.5% Glyphosate MRID: 451214-01C
COMPANY NAME: Albaugh, Inc. Action Code: 161

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

TO: 25 Jim Tompkins/Juanita Gilchrist
Herbicide Branch/RD (7505C)

INTRODUCTION:

PM Team 25 requested TRB to review for acceptability an additional supply source, [REDACTED] for Albaugh Technical Glyphosate Acid, Reg. No. 42750-56. In support of this action, the PM included some product chemistry data (blow-backs) and re-submitted the basic formulation, CSF dated 11/MAY/2000.

FINDINGS:

- 1a. According to the EPA's letter of 04/DEC/2000, the basic formulation, CSF dated 11/MAY/2000, for Albaugh Technical Glyphosate Acid, Reg. No. 42750-56 was not acceptable because the [REDACTED] source is unapproved.
- 1b. In the same EPA's letter of 04/DEC/2000, the alternate formulation CSF dated 11/MAY/2000 reflecting the [REDACTED] source, was accepted, reviewed in connection with DP #269710, H. Podall, 23/OCT/2000.
2. Based on the preliminary analysis of the [REDACTED] source which is comparable to Monsanto/Cheminova technicals, it was concluded that [REDACTED] source is also comparable to that of Cheminova (H. Podall, DP #269710, 23/OCT/2000).
3. Adequate analytical methods are described in this submission for the determination of glyphosate, per se, and impurities, also summarized in this memorandum. These are: Cation exchange column, HPLC, and Liquid Chromatography/Mass Spectrometry.
4. The submitted five batch analysis for Albaugh Technical Glyphosate Acid manufactured in [REDACTED] is adequate and support the basic formulation CSF dated 11/MAY/2000.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

CONCLUSIONS:

We have no objections for approval of the [REDACTED] source for Albaugh Technical Glyphosate Acid. Product's basic formulation, CSF dated 11/MAY/2000, is acceptable.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 11/MAY/2000 was included with this submission claiming confidentiality of the submitted data the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of this information is to be found in Appendix A.
2. A GLP statement dated 11/MAY/2000 was included with this submission to the effect that the submitted studies were conducted in compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #451214-01C The submitted study entitled: "Glyphosate Acid Technical: Preliminary Analysis and Enforcement Analytical Method, 40CFR§158.170 and 158.180, Product Identity, Composition and Analysis OPPTS GRNs 830-1700 and 830-1800." The studies were authored by David J. Sinning; Performed by Case Consulting Laboratories, Inc. of Whippany, NJ; [REDACTED] Completed on 10/MAY/2000 (26 + 77 pages).

Group A, Series 830-1700/1800

830-1700 Preliminary Analysis: Refer to Confidential Appendix A.

830-1800 Enforcement Analytical Method, MRID #451214-01C:

Adequate analytical methods are described in this submission for the determination of glyphosate, per se, and impurities. These are: Cation exchange column, HPLC, and Liquid Chromatography/Mass Spectrometry.

Due to the nature of the test substance, impurities were separated on both anion and cation exchange columns. The method involving the anion exchange column was used to assay glyphosate. Two replicates from each batch were analyzed.

The precision and accuracy of the analytical method were determined by performing ten replicate analyses of the same sample. The accuracy of the analytical method was assessed by comparing the analytical results with the true or accepted value of the test substance. Method precision was

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the coefficient of variation of the analytical results for the glyphosate assay.

Methods validation regarding linearity, precision, and accuracy were adequate. Sample calculation and chromatograms were included with this submission.

CONFIDENTIAL APPENDIX A

830-1620 Production Process:

No data was submitted. However, in the cover letter dated 11/MAY/2000, it was apparent that the alternate manufacturing process and the ingredients sources in [REDACTED] is identical to that manufactured [REDACTED] previously submitted to the Agency in MRID #450583-02.

830-1700 Preliminary Analysis:

This analysis was conducted by Case Consulting Laboratories, Inc. of Whippany, New Jersey. The test substance was Glyphosate Acid Technical I supplied by [REDACTED]

The results of five batch analysis for Albaugh Technical Glyphosate Acid manufactured in by [REDACTED] is adequate and support the basic formulation CSF dated 11/MAY/2000.

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