

US EPA ARCHIVE DOCUMENT

DATE: 23/Oct./2000

SUBJECT: TGAI PRODUCT CHEMISTRY REVIEW / ACTION: 166
DP BARCODE No.: D269710 EPA File Symbol No.: 42750-LA
CHEMICAL: Albaugh Technical Glyphosate Acid
COMPANY: ALBAUGH INC.

TO: PM 25: Jim Tompkins/Jaunita Gilchrist, PM Team Reviewer
Branch: Herbicide
Registration Division (7505C)

FROM: Harold Podall, Ph.D., Chemist *H. Podall*
Technical Review Branch / RD(7505C)

INTRODUCTION\DESCRIPTION OF SUBMISSION:

The Applicant, Janelle Whitehouse of Pyxis Regulatory Consulting, for Albaugh Inc. has submitted information (attached) relevant to the latter's 2nd manufacturing source T the [redacted] for the subject technical, in response to the concerns raised in our product chem. review of 6/29/2000 (D265050) and meeting at the EPA on 8/27/2000 (attached). The information submitted pertained to 1) an explanation of why the product should not contain any nitrosoamines, 2) provision of chromatograms of the technical produced by [redacted] (the manufacturing source that was accepted, c.f. product chem. review of 9/5/2000, D268663), 3) solubility data in different solvents of the technical, and 4) the octanol/water partition coefficient of the active ingredient.

In addition, information received from Mr. S. Wratten of Monsanto, via Jim Tompkins, PM Team 25, Herbicide Branch, regarding the possible presence of an impurity (Glyphosine) (which can cause injury to crops) in Glyphosate technicals produced abroad, was reviewed with respect to the [redacted] was previously reviewed for the [redacted] for D268663).

SUMMARY OF FINDINGS:

1. The explanation for the absence of nitrosoamines in the [redacted] is technically acceptable.
2. The chromatograms of the [redacted] match those of the [redacted]. Accordingly, based on this information, in conjunction with the preliminary analyses of the two products and the previous conclusion that the [redacted] technical is comparable/similar to the Monsanto/Cheminova technical (in my product chem report of 9/5/2000 cited above), one can conclude that the [redacted] technical is also comparable to that of Cheminova.
3. The attached summary of the physical/chemical properties of Albaugh's technical (produced in [redacted] and, where required, for the active ingredient per se, i.e. for Glyphosate, is

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technically acceptable and meets the chemistry requirements for registration of the product.

4. Albaugh's sources of its technical are not produced by the "glycine" process nor do the former's processes involve glycine as a reactant or intermediate. In addition, based on the chemistry of the [REDACTED] manufacturing processes the respective technicals should not contain the Glyphosine impurity referred to in the letter from Mr. Wratten of Monsanto.

CONCLUSIONS/RECOMMENDATIONS:

1. This submission has adequately addressed the concerns of this reviewer in the cited chemistry reports of 6/29/2000 and 9/5/2000 as well as the concern raised by Mr. Wratten of Monsanto regarding the possible presence of an impurity (Glyphosine) that is very harmful to crops in technicals produced abroad, particularly in India and in China.

2. With this submission, Albaugh Inc. has fulfilled the product chemistry requirements for registration of the subject technical.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED