

US EPA ARCHIVE DOCUMENT

DATE: 5/Sept./2000

SUBJECT: TGA1 PRODUCT CHEMISTRY REVIEW / ACTION:165  
DP BARCODE No.:D268663 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 Pedall, Ph.D., Chemist *H. Pedall 9/7/2000*  
Technical Review Branch / RD(7505C)

INTRODUCTION\DESCRIPTION OF SUBMISSION:

A meeting was held on 8/2/2000 with Glen O'Brien of Albaugh Inc., Janelle Whitehouse (who is the applicant for Albaugh Inc.) of Pyxis Consultants, [REDACTED]

[REDACTED] (who is one of the two proposed manufacturers of Albaugh's Glyphosate technical) and with Jim Tompkins, PM Team 25 Team Leader of the Herbicide Branch, EPA, and myself, to discuss the concerns raised in my review of June 29, 2000 of the product chemistry submission (in D265050) of Albaugh in their application for registration of the subject technical. A summary of the results of the meeting, dated 8/17/2000, is attached. A detailed response to the remaining concerns was provided by Albaugh Inc. dated 8/15/2000. Information was also received from Jim Tompkins, which was a communication from Stephen Wratten of Monsanto to Jim Tompkins dated 8/24/2000, [REDACTED]

[REDACTED] which described "diagnostic" impurities which typify the "glycine" process (which produces a product containing Glyphosine (N,N-bis(phosphonomethyl)glycine) as an impurity which has been linked to a "potential for crop injury" in Monsanto's greenhouse testing with Roundup Ready crops. [REDACTED]

SUMMARY OF FINDINGS:

1. [REDACTED] process for producing Albaugh's Glyphosate technical is very similar, [REDACTED] Cheminova/Monsanto's process, and is not likely to produce the undesired glyphosine impurity referred to in the letter from Stephen Wratten of Monsanto to Jim Tompkins.

2. The Six Pack Acute Toxicity Profile tests for Albaugh's Glyphosate technical, which was claimed to demonstrate the absence of any impurity of toxicological concern, was found to be acceptable by the EPA (c.f. letter of 5/24/2000 to Ms. Whitehouse of Pyxis Consulting who is the applicant for Albaugh Inc).

3. The information provided by Pyxis Consulting, i.e., copies of the U.S. Patents relevant to the manufacturing process of

MANUFACTURING PROCESS AND SOURCE INFORMATION NOT INCLUDED

[REDACTED]

confirmed that the steps of the processes in question were acceptable.

4. The chromatograms of [REDACTED] could not be compared to that of Monsanto/Cheminova's product because of the difference in the chromatogram's conditions used to obtain the chromatograms in question. However, based on the similarity of the manufacturing processes, in part the preliminary analyses, and in part the physical and chemical properties which were provided, it appears that the products are comparable/ or similar.

5. The other concerns, specifically on the CSP and on the physical/chemical properties (specifically on the technical's density), these were satisfactorily addressed at the 8/2/2000 meeting referred to in the Introduction above and in the response from Pyxis Consulting, dated 8/15/2000.

CONCLUSIONS/RECOMMENDATIONS:

Based on above Summary of Findings, all of the critical concerns raised in my review of 6/29/2000 have been satisfactorily addressed. Accordingly, the product chemistry information provided by Albaugh Inc., of [REDACTED], may be considered acceptable.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED