Date: 29/June/2000

SUBJECT: Product Chemistry Review of Albaugh's Glyphosate Technical
FROM: Harold Podall, Ph.D.,Chemist H. Podall 7/17/2000
Product Chemistry Team
Technical Review Branch/RD (7505C)
TO: PM 25: Jim Tompkins/Jaunita Gilchrist, PM Team Reviewer
Herbicide Branch/ RD (7505C)

DP BARCODE: D265050
EPA File Symbol No.:042750-LA
REGISTRANT Albaugh Inc.
USE: Herbicide active ingredient for manufacturing use only (for food and non-food use)

MANUFACTURING PROCESS / SOURCE AS MARKED

INTRODUCTION:

The applicant, Janelle Whitehouse- Consultant agent for Albaugh, Inc., requests on behalf of Albaugh registration of "Glyphosate Acid Technical" (Box 3 of CSF should read as Glyphosate Technical - not Glyphosate Acid Technical) produced by [redacted] The products from these companies are considered to be substantially similar. They are also claimed to be substantially similar to Cheminova's product,EPA Reg.No. 4787-26. One label and one CSF, presumably covering both the [redacted] product, and reports on 1) the [redacted] manufacturing processes and discussion of the formation of impurities, prepared by Janelle Whitehouse and Michael Kellogg, Consultants for Albaugh,Inc. (MRIDs 450583-01 and -04), on 2) the preliminary analyses of each of these products, prepared by Charles V. Willis of the Case Consulting Laboratories,Inc., [redacted] (MRIDs 450583-02 and - 05), and on 3) the physical and chemical properties of only a [redacted] prepared also by Charles Willis of the Case Laboratories for [redacted] (MRID 450583-3), were provided in support of this registration.

SUMMARY OF FINDINGS:

General Comments:

1. The CSF for this product is unacceptable since 1) it does not list all of the impurities present (other than the one listed [redacted] their % by wt.content, and their UCLs (the total of all should be equal to (100 - the LCL of the active ingredient) or (100 - 93.6) or 6.4%), 2) the upper certified limit of the possible nitroso compounds present, particularly in the [redacted] (c.f. p.18, vol.1, MRID 450583-01 for their possible source), and 3) the inconsistency of the 5 batch analyses for the [redacted] (c.f., p.12 of vol.2, MRID 450583-02) and of the [redacted] (c.f., p.12 of vol.5, MRID 450583-05) with the values in the CSF.

2. In addition, the products produced by the [redacted] (CSF for "Albaugh Technical Glyphosate Acid" dated 2/28/00) do

not appear to be me-too products of EPA Reg.No.4787-26 Glyphosate Technical of Cheminova, Inc.(CSF dated 4/20/95) based on 1) the presence of different impurities cited in the respective CSFs, 2) comparison of some of the physical/chemical properties, such as the product's density, i.e., 0.883 g/ml for Albaugh's technical vs. 1.655 g/ml for Cheminova's technical, and 3) the fact that their given nominal concentration (NC) of the active ingredient of 96.5% is barely within the LCL of 96% and the NC of 98.3% for Cheminova's technical.

3. There are also significant differences in the process chemistry of the manufacturing processes of the [redacted] as well as the questionable viability of the processes per se, as described , from a process chemistry and engineering standpoint.

4. Finally, the values of some of the physical/chemical properties reported for the technical (vs. those required for the pure active ingredient) are questionable , let alone their comparison with those for the Cheminova 's product. Thus, it is not clear that the product supplied by [redacted] is representative of the technical produced by [redacted]

The Technical Product Produced by [redacted]

1. The proposed CSF is a) inconsistent with the preliminary analyses (vol. 2, p.12) where the average conc. of the a.i of the 5 batch analyses was [redacted] (vs. the NC of 96.5% in the CSF), b) except for one impurity [redacted] it does not identify the other impurities present at 0.1% or greater, totaling [redacted] (such as discussed in vol.1, p.16 -18), and c) it appears to have a different impurity profile than that of the Cheminova product - arising possibly from a different manufacturing process than the latter (c.f. also the General Comments above, items 1 & 2.

2. The structure given for the impurity, [redacted] on p.16, vol.1 is not consistent with that given on p.11 which is the intermediate produced in the 2nd step of the manufacturing process.

3. According to the reaction, shown on p.18 of vol. 1, [redacted] The presence or absence of nitroso compounds should be discussed with a possible listing given in the CSF (see 1st item under the General Comments above).

4. a) [redacted]

MANUFACTURING PROCESS / SOURCE AS MARKED

2

[redacted]

5. Literature or patent references (and copies of the articles) for [redacted] steps of the manufacturing process should be provided to document their viability.

6. [redacted]

7. The reasons for omitting provision of the values for the storage stability, miscibility (in petroleum ether solvents), corrosivity to its packaging material, dielectric breakdown voltage, and solubility in solvents of varying polarity (such as ethanol, acetone, benzene, and n–hexane) should be stated or the values provided.

The Technical Product Produced by [redacted]

1. Similar concerns to the 1st finding for [redacted], relevant to the applicability of the CSF to this product, and regarding its substantial similarity to [redacted] and to the Cheminova product ,are applicable here.

2. [redacted]

3. Accordingly, one can expect significant differences in the composition of the glyphosate product, specifically in its purity and in the impurities present; hence requiring a different CSF for each source and determination of their respective chemical and physical properties.

4. Literature and/or patent references should be provided here as well, particularly for [redacted]

CONCLUSIONS:

Based on the above considerations, this submission by Albaugh, Inc. for registration of Albaugh Technical Glyphosate Acid is not acceptable. Key concerns relate to 1) the viability of the described manufacturing processes for production of the glyphosate technical, 2) apparent use of purified samples of the technical rather than the technicals per se from the indicated sources in the 5 batch analyses,

MANUFACTURING PROCESS/ SOURCE AS MARKED

3

and 3) use of only a purified grade of the technical for all of the chemical and physical properties rather than use of the purified grade only for those properties where the PAI is called for and the technical per se from each source where the properties of the TGAI are required as per the Table of 40 CFR 158.190.

Page 5 is not included in this copy.

Pages _____ through _____ 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.