DATE OUT: 30/DEC/2003

-01

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE TGAI [X]
DP BARCODE #:D295972 EPA RECEIVED DATE:17/OCT/2003 FILE SYMBOL/REG : 70829-5
PRODUCT NAME: Glyphosate Technical, 96.7% Glyphosate MRID: 460984-~~10~~ to -03
COMPANY NAME: Chemical Products Technologies, LLC FOOD & NON-FOODUSES [X]
PPC NUMBER OF THIS TGAI: 417300 ACTION CODE:345 DECISION NO.: 335403

FROM: Sami Malak, Chemist S. Malak 12/30/03
Technical Review Branch/RD (7505C)

TO: 25 James Tompkins/Vickie Walters
Herbicide Branch/RD (7505C)

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

INTRODUCTION:

In a letter dated 10/OCT/2003, John Wise & Associates, Ltd. an agent for the applicant requested review for acceptability an alternate CSF dated 10/OCT/2003 reflecting a new manufacturing site for glyphosate technical. Product chemistry data was included with this submission.

FINDINGS:

1. The subject product was produced by [redacted] in China for the applicant with a composition detailed in an alternate CSF dated 10/OCT/2003. The currently approved glyphosate technical is produced by [redacted] China for the same applicant with a composition detailed in the current basic CSF dated 07/JUL/2003.

2. The submitted alternate CSF dated 10/OCT/2003 is substantially similar in composition to the current basic CSF dated 07/JUL/2003. Both products contain the same nominal concentration of 96.7% glyphosate and same physical/chemical properties. The new manufacturing, however, resulted in less number of impurities relative to the registered glyphosate because of the presence of some unidentified impurities, each <0.1%.

3. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the basic formulation of subject product, glyphosate technical, Reg. No. 70829-5. The methods employed in the preliminary analysis in this submission are reviewed in this memorandum.

4. The label claim nominal concentration of 96.7% glyphosate is consistent with that in the alternate CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.10.

5a. The proposed alternate CSF dated 10/OCT/2003 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for food and non-food uses.

5b. The applicant should be advised to make minor editing to the submitted CSF: (a) for consistency with the results of batch analysis, retain only the 95.7% in Column 13(b) and move the 96.7% as a footnote to the CSF stating "label claim nominal concentration; (b) the upper/lower certified limits should be based on 95.7% calculated by this reviewer at

98.57/92.83% noting that the label claim nominal concentration of 96.7 falls between the these limits; and (c) no need to list lower certified limits for the impurities noting that total methods accountability for a TGAI is acceptable if ≥98%.

CONCLUSIONS:

TRB has no objections for accepting the submitted alternate formulation, CSF dated 10/OCT/2003, reflecting a new manufacturing site in China by [redacted]

NOTE TO PM:

Please note some minor corrections to the submitted alternate CSF (Finding 5b).

REVIEW OF PRODUCT CHEMISTRY DATA

1. A statement of data confidentiality dated 01/OCT/2003 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data has been removed to Confidential Appendix A.

2. A GLP statement dated 01/OCT/2003 was included with this submission to the effect that the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

This product was produced by [redacted] in China for the applicant with a composition detailed in an alternate CSF dated 10/OCT/2003. The currently approved glyphosate technical is produced by [redacted] in China for the same applicant with a composition detailed in the current basic CSF dated 07/JUL/2003.

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	460948-01
.1600 Description of materials used to produce the product	Y	460948-01
.1620 Description of production process	Y	460948-01
.1650 Description of formulation process	NA	
.1670 Discussion of formation of impurities	Y	460948-01
.1700 Preliminary analysis	Y	460948-02
.1750 Certified limits	Y	460948-01
.1800 Enforcement analytical method	Y	460948-02
		84

Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

830-1620 Description of Production Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

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

830-1750 Certified Limits:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the basic formulation of subject product, glyphosate technical, Reg. No. 70829-5.

Analysis of the active ingredient:

The analytical method employed in the preliminary analysis was based on the publication: Morlier, L. W., and Tomkins, D. F., entitled "Liquid Chromatographic determination of Glyphosate in Water-Soluble Granular Formulations" Journal of AOAC International, 80(3):464-468 (1997). In this method an aliquot from quantitation of the samples was based on a high-performance liquid chromatography (HPLC) method using UV detection and an external standard curve. A standard curve was calculated by linear regression analysis of the detector response and concentration of the analytical standard.

Analysis of Aminomethyl phosphoric Acid:

The method of analysis was based on EPA's method 547 employing a high-pressure liquid chromatography (HPLC) method with fluorescence detection and post column derivatization.

Methods validation data regarding recovery, precision, accuracy, and linearity are adequate. Sample calculations and chromatograms were included with this submission.

Page _____ is not included in this copy.

Pages 4 through 5 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.

830-1670 Discussion of Formation of Impurities:

Potential impurities presen in the reaction are generally carry over materials used in the production, unreacted intermediates, minor contaminants found in the raw materials that may included:

[redacted]

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

830-1700 Preliminary Analysis:

The results of triplicate analysis of five batches of technical glyphosate using the analytical methods discussed in this memorandum were reported. The nominal concentrations and upper/lower certified limits of the ingredients are consistent with those presented in the submitted alternate CSF, dated 10/OCT/2003.

GRN 1750 CertifiedLimits:

Reported certified limits are consistent with those in product's CSF, an alternate formulation dated 10/OCT/2003. The nominal concentration and upper/lower certified limits of the ingredients reflect the results of triplicate analysis of five batches of technical glyphosate using the analytical methods discussed in this memorandum.

cc:S. Malak and Central File (Reg. No.70829-5).
7505C:RD:TRB:CM-2:268:s.m.:30/DEC/2003:703-308-9365: < 70829-5 > .