PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

DATE OUT: 15/FEB/2004

FEE: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE TGAI [X] -01
DP BARCODE #:D310768 EPA RECEIVED DATE:22/NOV/2004 FILE SYMBOL/REG : 70829-5
PRODUCT NAME: Glyphosate Technical, 97.1% Glyphosate **MRID:** 463917-00 to -02
COMPANY NAME: Chemical Products Technologies, LLC **FOOD & NON-FOODUSES [X]**
PPC NUMBER OF THIS TGAI: 417300 **ACTION CODE:**R34 **DECISION NO.:** 350410

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

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

INTRODUCTION:

In a letter dated 21/OCT/2004 the applicant requested review for acceptability an alternate CSF dated 21/OCT/2004 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] with a composition detailed in an alternate CSF dated 21/OCT/2004. The currently approved glyphosate technical is produced by [redacted] in [redacted] for the same applicant with a composition detailed in the current basic CSF dated 07/JUL/2003.

2. The submitted alternate CSF dated 21/OCT/2004 is substantially similar in composition to the current basic CSF dated 07/JUL/2003. The nominal concentration in the submitted alternate formulation is 97.1% as falling within the upper/lower certified limits of the current nominal concentration of 96.7%. The physical/chemical properties are the same in both products. 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 nominal concentration of 96.7% glyphosate is consistent with that in the current basic CSF and slightly below the nominal concentration of the submitted alternate formulation.

5. The proposed alternate CSF dated 21/OCT/2004 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.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

CONCLUSIONS:

The TRB has no objections for accepting the submitted alternate formulation, CSF dated 21/OCT/2004 reflecting a new manufacturing site [redacted]

REVIEW OF PRODUCT CHEMISTRY DATA

1. A statement of data confidentiality dated 21/OCT/2004 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 21/OCT/2004 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] for the applicant with a composition detailed in an alternate CSF dated 21/OCT/2004. The currently approved glyphosate technical is produced by [redacted] 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	463917-01
.1600 Description of materials used to produce the product	Y	463917-01
.1620 Description of production process	Y	463917-01
.1650 Description of formulation process	NA	
.1670 Discussion of formation of impurities	Y	463917-01
.1700 Preliminary analysis	Y	463917-01
.1750 Certified limits	Y	463917-01
.1800 Enforcement analytical method	Y	463917-01

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.

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

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.

Attachment:

Confidential Appendix A (pages 4-6).

Page _____ is not included in this copy.

Pages 4 through 6 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.