

DATE OUT: 30/JAN/2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]

DP BARCODE No.: 279115 EPA RECEIVED DATE: 05/OCT/2001 REG./File Symbol No.: 42750-AA PRODUCT NAME: Gly Star Ready-to-Use Grass and Weed Killer, 1.9% Glyphosate, isopropylamine salt COMPANY NAME: Albaugh, Inc. MRIDs: 455181-01 to -02 Action Code: 165

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

TO: 25 Jim Tompkins/Juanita Gilchrist
Herbicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 04/OCT/2001, Pyxis Regulatory Consulting of Gig Harbor, Washington on behalf of the applicant, requested registration of subject product as per the regulations of FIFRA sec. 3(c)(5). Included with this submission for review and acceptability were: product chemistry data, a proposed basic and two alternate formulations, Alt 1 & 2, all dated 04/OCT/2001, a proposed label EPA received 05/OCT/2001, Certificate With Respect to Citation of Data, and Data Matrix.

FINDINGS:

- 1a. The subject product is produced by a non-integrated formulation system, meaning that the active source in each of the submitted three formulations is registered. The product contains 1.92% isopropylamine salt of glyphosate: N-(phosphonemethyl)glycine. [REDACTED]
- 1b. The subject product, ready-to-use liquid herbicide, is intended for control of grass and weeds in non-crop areas, lawn replacement/renovation, and in garden plot preparation.
- 1c. The submitted product's two alternate formulations, Alt 1 & 2, CSFs both dated 04/OCT/2002, are substantially similar in composition to the submitted basic formulation, also dated 04/OCT/2001. Exception: the use of a different technical source in each formulation as shown in Finding 1(a) above.
2. The submitted/referenced product chemistry data is adequate and support a FIFRA Section 3(c)(5) registration of subject product.
3. Adequate analytical method is available for enforcement. [REDACTED]
[REDACTED] Reference method in this submission, MRID #455181-01, is entitled "Glyphosate (Technical) and Pesticide Formulations, Liquid Chromatographic Method, Revised 1995", Chapter 7, page 88.
4. The label claim nominal concentrations of 1.92% glyphosate, isopropylamine salt is consistent with that on the CSFs, all 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.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

5. The submitted product's basic and two alternate formulations, Alt 1 & 2 CSFs all dated 04/OCT/2001 were 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.

CONCLUSIONS:

We have no objections for a FIFRA sec. 3(c)(5) registration of subject product. The submitted product's basic and two alternate formulations, Alt 1 & 2 CSFs all dated 04/OCT/2001, and label are acceptable as per Findings 4 & 5 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 04/OCT/2001 was included with this submission claiming confidentiality of some of the submitted data the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data is to be found in Confidential Appendix A.
2. A GLP statement dated 20/SEP/2001 was included with this submission to the effect that some of the submitted studies were conducted in compliance with GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #455181-01 The submitted study entitled: "Product Identity and Composition, Description of Materials Used, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Analytical Methods to verify Certified Limits for Gly Star Ready-to Use Grass and weed Killer" Data Requirements of 40CFR§158, OPPTS Product Chemistry Properties Test Guidelines, 830.1550, 830.1600, 830.1650, 830.1670, 830.1750 & 830.1800." The studies were authored by Michael R. Kellogg; Sponsored by Albaugh, Inc. of Ankeny, Iowa; Completed on 04/OCT/2001 (12 pages).

MRID #455181-02 The submitted studies entitled: "Physical and Chemical Characteristics: Physical state, oxidation/reduction, pH, viscosity, and density" Data Requirements of OPPTS Product Chemistry Properties Test Guidelines, 830.1550, 830.6303, 830.6314, 830.7000, 830.7100 & 830.7300." The studies were authored by Catherine Wi; Performed by Product Safety Labs of Dayton, New jersey; Completed on 13/SEP/2001 (17 pages).

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

830-1550 Product Identity and Composition

Each of the submitted formulations, a basic and Alt 1 & 2, contains one registered technical grade of active ingredient plus cleared inert ingredients (refer to product's CSFs, all dated 04/OCT/2001).

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

830-1650 Description of Formulation 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

Reference method in this submission, MRID #455181-01, is entitled "Glyphosate (Technical) and Pesticide Formulations, Liquid Chromatographic Method, Revised 1995", Chapter 7, page 88.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190):

GUIDELINE REFERENCE NO.(GRN 830-)/TITLE	VALUE OR QUALITATIVE DESCRIPTION
-6302 Color	Light yellow.
-6303 Physical State	Liquid.
-6304 Odor	NA as per PR Notice 92-5.
-6314 Oxidation/Reduction: Incompatibility	Does not contain oxidizing/reducing agent.
-6315 Flammability/Flame Extension	NA. Water-base.
-6316 Explodability	Not considered to be potentially explosive.
-6317 Storage Stability	NA as per PR Notice 92-5.
-6319 Miscibility	NA. Ready-to-use product.
-6320 Corrosion Characteristics	Non considered to be corrosive.
-6321 Dielectric Breakdown Voltage	Not recommended for use around electrical equipment.
-7000 pH	4.59
-7100 Viscosity	1.092 centistokes @20°C, 1.099 centipoises @20°C, 1.066 centistokes @20°C.
-7300 Density/Relative Density Bulk Density	1.006 g/ml @20°C

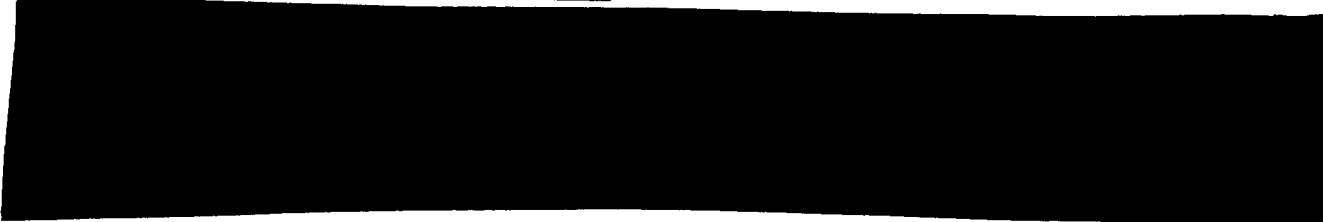
PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product:

Each of the submitted formulations, a basic and Alt 1 & 2, contains one registered technical grade of active ingredient plus cleared inert ingredients (refer to product's CSFs, all dated 04/OCT/2001).

830-1650 Description of Formulation Process:



830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities $\geq 0.1\%$ by weight were known to be formed during formulation and storage of the product.

830-1700 Preliminary Analysis:

NA for this non-integrated product.

830-1750 Certified Limits:

The applicant reported the same ingredients at percentages and low/upper limits as those reported on product's CSF.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

S. Malak and Central File (Reg. No. 42750-AA).
7505C:RD:TRB:CM-2:Rm.268:s.m.:30/JAN/2002:703-308-9365:<42750-AA>.