Shaughnessy No.: 103601

Date Out of EAB: JAN 27 1988

To: R. Taylor
Product Manager 25
Registration Division (TS-767)

From: T. Dougherty, Chief
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

THRU: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS-769C)

Attached, please find the EAB review of...

Req./File # : 524-318, 524-333, 524-339

Chemical Name: Glyphosate

Type Product : Herbicide

Product Name : Roundup, Glifonox, Glycel, Rodeo, Rondo

Company Name : Monsanto Company

Purpose : Addendum to a Standard.

Action Code(s): 660

EAB #(s) : 70732-34

Date Received: 6/8/87

TAIS Code:

Date Completed: JAN 27 1988

Monitoring submitted:

Total EAB Reviewing Time: 3. days

Monitoring requested:

Deferrals to:

____ Ecological Effects Branch

____ Residue Chemistry Branch

____ Toxicology Branch

1. CHEMICAL: Common name:

Glyphosate

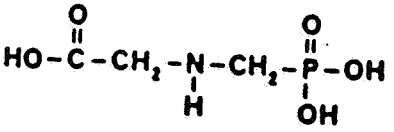
Chemical name:

N-(phosphonomethyl)glycine

Trade name(s):

Roundup, Glifonox, Glycel, Rodeo, Rondo

Structure:



Formulations:

0.42-4 lb ai/gal SC/L, 5-6.6% SC/L, 0.5-1% RTU, and 0.75% PrL.

Physical/Chemical properties:

Molecular formula: $C_3H_8O_4NP$.

2. TEST MATERIAL: N/A

3. STUDY/ACTION TYPE: Monsanto's comments to the Standard

4. STUDY IDENTIFICATION: N/A

5. REVIEWED BY:

S. Simko
Chemist
EAB/HED/OPP

Signature: S. Simko

Date: 1/[illegible]/88

6. APPROVED BY:

T. Dougherty
Chief, Section 1
EAB/HED/OPP

Signature: [signature]

Date: JAN 27 1988

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7. CONCLUSIONS:

For the photodegradation data gap, Monsanto responded that they will submit a study. For the photodegradation report FR 258, Monsanto should submit the spectrum of the light source used, then the study will evaluated later. The photodegradation in air study is deferred pending the results of the volatility study.

For the aerobic metabolism data gap, Monsanto claims that study MRID 108181 cannot be dismissed because of the variability of the data. They claim that this variability is inherent in nature and so should be acceptable. EAB's response is that for laboratory experiments, conditions should be sufficiently controled to be able to produce a residue decline curve. Monsanto also claims that the purpose of the metabolism studies is to identify the degradates. EAB's response is that the laboratory rate of metabolism is needed as well as the identification of residues.

For the anaerobic soil metabolism study, when an acceptable anaerobic aquatic metabolism study is submitted this anaerobic soil metabolism study may be waived.

For the aerobic aquatic metabolism data gap, the major problem with the study (MS-0207) was the missing data points as well as the time length of the study which was too short to demonsrate the pattern of formation and decline of the degradate MON 0453.

For the anaerobic aquatic metabolism data gap, Monsanto claims EAB should use study MSL-0207. EAB's response is that no information was given to show that MSL-0207 was carried out under anaerobic conditions. If the registrant has data to support the claim of anaerobic conditions, the information should be submitted. Otherwise, an appropriate study is requested.

The leaching data requirement for glyphosate is satisfied.

The reports cited by Monsanto for the rotational crop accumulation studies and fish accumulation studies should be submitted to EAB for consideration.

8. RECOMMENDATIONS:

The following data are required:

Photodegradation studies in water

Photodegradation studies on soil

Aerobic soil metabolism studies

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Anaerobic soil metabolism studies

Aerobic aquatic metabolism studies

Anaerobic aquatic metabolism studies

Laboratory volatility studies

Terrestrial field dissipation studies: Two studies were reviewed (EAB# 70727-29) for this addendum. One study (Danhous, 264343) is unacceptable because either the data were too variable to accurately assess the dissipation of glyphosate in soil, or else the sampling intervals were inadequate to establish the half-life of the test substance. This study does not fulfill data requirements because the test substance was not characterized, the pattern of formation and decline of degradates was not addressed in the orchard soil study, soil characteristics including textural analysis were not reported, field test data were not reported, and storage stability data were not reported. Portions of the other study (Danhous, 264332) were unacceptable because the data were too variable to accurately assess the dissipation of glyphosate in soil, insufficient material was present at any sampling interval to establish a residue decline curve, and sampling intervals were inadequate. Portions of this study were scientifically sound but do not fulfill data requirements because the test substance was not completely characterized, the test soils were not completely characterized, field test data were not provided, no pretreatment samples were taken, and no immediate posttreatment samples were taken at the IN and OH sites.

Aquatic field dissipation studies

Forestry dissipation studies: One study (Allan et al., 264343) was reviewed (EAB# 70727-29) and is scientifically sound. This study does not fulfill data requirements because dissipation of glyphosate in the forest canopy, understory, lakes, and streams was not addressed; the soil was not completely characterized; the test substance was not completely characterized; the treated soil and litter were not sampled deep enough to define the extent of leaching; and meteorological data were not provided.

Confined accumulation in rotational crops

Accumulation studies on irrigated crops

Laboratory studies of pesticide accumulation in fish

The following data requirements are fulfilled:

Hydrolysis studies

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Leaching and adsorption/desorption

The following data requirements are deferred or are not required for presently registered uses:

Photodegradation in air: Deferred pending the results of the volatility study.

Field volatility studies

Long-term field dissipation studies

Field accumulation studies on rotational crops

Field accumulation studies on aquatic nontarget organisms

9. BACKGROUND:

A. Introduction

B. Directions for Use

Glyphosate isopropylamine salt is a nonselective, postemergence systemic herbicide registered for use on a variety of terrestrial food crop (field, vegetable, and orchard crops), aquatic food crop (rice), greenhouse, terrestrial nonfood, aquatic nonfood, domestic outdoor, and forestry sites. Application rates range from 0.19 to 3.75 lb ai/A. Glyphosate may be formulated with alachlor or acifluorfen. Single active ingredient formulations consist of 0.42, 3, and 4 lb ai/gal, and 5 and 6.6% SC/L; 0.5, 0.96, and 1% RTU; and 0.75% PrL. Glyphosate may be applied foliarly, in a broadcast, using conventional ground equipment, hand-held and recirculating sprayers, and aerially. Applicators need not be certified or under the direct supervision of applicators certified to apply glyphosate.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: N/A

11. COMPLETION OF ONE-LINER: N/A.

12. CBI APPENDIX: None.