

JAN 8 1992

Shaughnessy No.: 103601

Date Out of EFGWB:

DP Barcode: D160647, D169254, D169582, D163175, ~~D169199~~, ~~D166397~~

To: Eric Feris
Product Manager #74
Registration Division (H5707C)

From: Akiva Abramovitch, Chief
Environmental Chemistry Review Section #3
Environmental Fate and Ground Water Branch/EFED (H7507C)

Through: Henry Jacoby, Chief
Environmental Fate and Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of . . .

Submission/case# : S389534/819374, S404111/819374, S400641/281730, S393865/003372

Identifying No: 524-308,524

Common Name : Glyphosate.

Type Product : Herbicide.

Product Name : Rattler, Glifonox, Weedoff, Glycel, Rodeo, Roundup, Lider.

Company Name : Monsanto Agricultural Company.

Purpose : Response to the registrants Minutes to a meeting, response to a request for a deletion in a crop rotation interval as well as a review of an aqueous photolysis, aerobic soil metabolism, aerobic and aquatic metabolism, accumulation in confined rotational crops, and laboratory accumulation in fish studies.

Date Received: 3/24/91 EFGWB # (s): 90-0745, ~~90-0763~~, 92-0032

Action Code : 660

Date completed: 12/16/91

90-0753, 91-0356, 92-0011
91-0506

Deferrals to: _____ Ecological Effects Branch, EFED
_____ Science Integration and Policy Staff, EFED
_____ Non-Dietary Exposure Branch, HED
_____ Dietary Exposure Branch, HED
_____ Toxicology Branch I, HED
_____ Toxicology Branch II, HED

1. CHEMICAL: Common name:

Glyphosate.

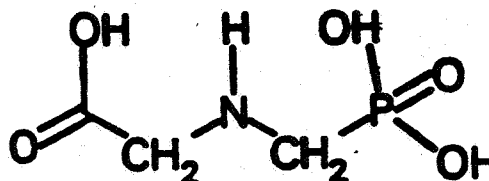
Chemical name:

Isopropylamine salt of N-(phosphono-methyl) glycine.

Trade name(s):

Rattler, Glifonox, Weedoff, Glycel, Rodeo, Roundup, Lider.

Structure:



Formulations:

See individual DER's.

Physical/Chemical properties:

Molecular formula: C₃H₈NO₅P.

Molecular weight: 169.1 g/mole.

Physical state: Zwitterion structure which forms colorless crystals.

Melting point: 200 C.

Bulk density: 0.5 g/cm³.

Solubility (25 C): 12 g/l water; insoluble in common organic solvents.

2. TEST MATERIAL:

Studies 1-4, 6: Active ingredient.

Study 5,7: Soluble concentrate.

3. STUDY/ACTION TYPE:

Response to the registrants Minutes to a meeting, response to a request for a deletion in a crop rotation interval as well as a review of an aqueous photolysis, aerobic soil metabolism, aerobic and aquatic metabolism, accumulation in confined rotational crops, and laboratory accumulation in fish studies.

4. STUDY IDENTIFICATION:

MRID #41689101: Castle, S., L.O. Ruze, and K. Shepler. 1990. Degradation study: Photodegradation of [¹⁴C] glyphosate in a buffered aqueous solution at pH 5, 7 and 9 by natural sunlight. PTRL Report No. 233W-1. PTRL Project No. 233W. R.D. No. 1020. Performed by Pharmacology and Toxicology Research Laboratory, Inc., Richmond, CA, and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #41742901: Kesterson, A.L. and R.H. Atkins. 1991. Aerobic metabolism of [¹⁴C]glyphosate in sandy loam and silt loam soils with biometer flask. PTRL Report No. 1301. PTRL Study No 368. R.D. No. 1031. Performed by Pharmacology and Toxicology Research Laboratory East, Inc., Richmond, KY, and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #41723701: Kesterson, A. and S.B. Jackson. 1990. Anaerobic aquatic metabolism of [¹⁴C]glyphosate. PTRL Report No. 1304. PTRL Study No. 367. Performed by Pharmacology and Toxicology Research Laboratory East, Inc., Richmond, KY, and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #41723601: Kesterson, A. and S.B. Jackson. 1990. Aerobic aquatic metabolism of [¹⁴C]glyphosate. PTRL Report No. 1300. PTRL Study No. 366. Performed by Pharmacology and Toxicology Research Laboratory East, Inc., Richmond, KY, and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #4153201: Nicholls, R.G. 1990. Confined rotational crop study of glyphosate. Part I: In-field portion. Pan-Agricultural Project No. Amended Report EF-88-22. R.D. No. 991. Monsanto Report No. MSL-9810. Performed by Pan-Agricultural Laboratories, Inc., Madera, CA, and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #41543202: McMullan, P.C., J.L. Honegger, and E.W. Logusch. 1990. Confined rotational crop study of glyphosate. Part II: Quantitation, characterization, and identification of glyphosate and its metabolites in rotational crops. (Part I: MSL-9810). Laboratory Project No. MSL-9811. R.D. No. 991. Performed by and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #41228301: Forbis, A.D. 1989. Uptake, depuration and bioconcentration of ¹⁴C glyphosate to bluegill sunfish (Lepomis macrochirus). Part I: MSL-9304. Laboratory Project No. MSL-9304. R.D. No. 955. Performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #41228302: Ridley, W.P. and K.A. Chott. 1989. Uptake, depuration and bioconcentration of ¹⁴C glyphosate to bluegill sunfish (Lepomis macrochirus). Part II: Characterization and quantitation of glyphosate and its metabolites. Laboratory Project No. MSL-9303. R.D. No. 955. Performed and submitted by Monsanto Agricultural Company, St. Louis, MO.

MRID #40541305: Kuntsman J.L., February 1988. Irrigated Crops Study- Determination of Glyphosate Residues in Crops, Irrigation Water, Sediment, and Soil Following Treatment of Irrigation Source With Rodeo. Laboratory Project No. MSL-7633. R.D. No. 856. Performed and submitted by Monsanto Agricultural Company St. Louis MO.

No MRID #: Letter from Lydia A. Suba: dated December 4, 1990. Regulatory Affairs Manager, Monsanto Agricultural Company, 800 N. Lindbergh Boulevard, St. Louis Missouri 63167. Regarding removal of preplant crop rotational restriction.

No MRID #: Letter from William Ronald Landis: dated May 20, 1991. Landis International, INC. 3025 Madison Highway P.O. box 5126, Valdosta Georgia 31603-5126. Regarding Cheminova glyphosate registration pre-regulatory conferences held on May 14, 1991.

5. REVIEWED BY:

Kevin Poff
EFGWB/EFED/OPP
Review Section #3

Signature: _____

Date: _____

DEC 17 1991

6. APPROVED BY:

Akiva Abramovitch
Chief
EFGWB/EFED/OPP
Review Section #3

Signature: Akiva Abramovitch

Date: DEC 17 1991

7. CONCLUSION:

Letter from Lydia Suba regarding removal of preplant crop rotational restriction.

1. EFGWB does not concur with the removal of preplant crop rotational restriction from the label of glyphosate for the following reason:

a) Studies MRID #41543201 and MRID #41543202 indicate that total residues (glyphosate, metabolite I, and aminomethylphosphonic acid, AMPA) in the 30 day after treatment (DAT) subplot ranged from 0.188 ppm (barley grain from 125 DAT) to 0.037 ppm (carrot root from 154 DAT).

Letter from William Ronald Landis regarding Cheminova glyphosate registration pre-regulatory conferences held on May 14, 1991.

1. EFGWB has read the "Minutes of the Meeting" as recorded by the registrant and concurs with the registrant's summary. However, other studies or data may be required of the registrant after EFGWB reviews the discussed studies.

Photodegradation in Water (161-2) MRID # 41689100 (DER 1)

1. Study MRID #41689100 completely satisfies the Photodegradation in Water (161-2) data requirement for glyphosate.

2. Glyphosate did not photodegrade (half-life > 410 days) in sterile aqueous buffered solutions (pH 5, 7, and 9) irradiated with natural sunlight at 14.7-28.6°C.

Aerobic Soil Metabolism (162-1) MRID #41742901 (DER 2)

1. Study MRID #41742901 can be used for supplemental information but does not satisfy the Photodegradation in Water (161-2) data requirement for glyphosate for the following reasons.

a) In the day 0 soil extracts, parent glyphosate comprised only 44.5-50.6% of the applied radiocarbon in the sandy loam soil and 64.3-82.2% in the silt loam soil.

b) Freezer storage stability data were not provided.

c) Three degradates that comprised up to 3.5% of the applied (0.140 ppm), 3.6% (0.144 ppm), and 0.6% (0.024 ppm) were not identified.

2. A new aerobic soil metabolism study (162-1) needs to be completed.

3. Glyphosate degraded rapidly with half-lives of < 1 day in sandy loam soil and 1-3 days in silt loam soil that were incubated in the dark at 25°C and 75% of the 0.33 bar moisture. The major nonvolatile degradate was aminomethylphosphonic acid and reached a maximum conc. of 26.3-28.7% at 14 days. At 12 months posttreatment, ¹⁴CO₂ was the major degradate and totaled ≥ 70.5% of the applied.

Anaerobic Aquatic Metabolism (162-3) MRID #41723701 (DER 3)

1. Study MRID #41723701 does not satisfy the anaerobic aquatic metabolism (162-3) data requirement for the following reasons:

- a) An accurate assessment of the dissipation pattern of glyphosate and the formation and dissipation of its degradates could not be made because the concentrations of glyphosate and its degradate AMPA were too variable between 15 and 90 days posttreatment.
- b) Freezer storage stability data were not provided.
- c) Two degradates that comprised up to 1.4% of the applied (0.05 ppm) and 6.2% (0.24 ppm) were not identified.

2. A new anaerobic aquatic metabolism (162-3) study needs to be completed.

Aerobic Aquatic Metabolism (162-4) MRID #41723601 (DER 4)

1. Study MRID #41723601 does not satisfy the aerobic aquatic metabolism (162-3) data requirement at this time for the following reason:

- a) Two degradates that comprised up to 2.0% of the applied (0.08 ppm) and 2.8% (0.11 ppm) were not identified.

2. Glyphosate degraded with a half-life of approximately 7 days in flooded silty clay loam sediment that was incubated in the dark at 25°C. The major nonvolatile degradate was aminomethylphosphonic acid. At 30 days posttreatment, $^{14}\text{CO}_2$ totaled 22.8% of the applied.

Confined Accumulation in rotational crops (165-1) MRID #41543201, 41543202 (DER 5)

1. Studies MRID #41543201 and 41543202 do not satisfy the confined accumulation in rotational crop (165-1) data requirement at this time for the following reasons:

- a) Freezer storage stability data on glyphosate and its degradates in the plant and soil substrates must be provided.

b) The test substance was incompletely characterized.

2. ^{14}C -Glyphosate residues (expressed as fresh weight) accumulated in lettuce, carrots, and barley planted 30, 119, and 364 days after sandy loam soil was treated with glyphosate at 3.71 lb ai/A. Accumulation decreased as the length of the rotation increased. In crops planted at 30 days posttreatment, [^{14}C]residues at harvest were 0.097 ppm in lettuce, 0.051 and 0.037 ppm in carrot tops and roots, respectively, and 0.188 and 0.175 ppm in barley grain and straw, respectively. In immature lettuce harvested at 40 and 60 days postplanting, [^{14}C]residues were 0.108 and 0.048 ppm, respectively (Table 7). In crops planted at 119 days posttreatment, [^{14}C]residues at harvest were 0.037 ppm in lettuce, 0.028 and 0.017 ppm in carrot tops and roots, respectively, and 0.078 and 0.056 ppm in barley grain and straw, respectively. In immature lettuce harvested at 28 and 48 days postplanting, [^{14}C]residues were 0.059 and 0.055 ppm, respectively (Table 7). In crops planted at 364 days posttreatment, [^{14}C]residues at harvest were 0.028 ppm in lettuce, 0.018 and 0.0096 ppm in carrot tops and roots, respectively, and 0.047 and 0.061 ppm in barley grain and straw, respectively. In immature lettuce harvested at 35 and 61 days postplanting, [^{14}C]residues were 0.057 and 0.043 ppm, respectively; in barley forage harvested at 48 days postplanting, [^{14}C]residues were 0.056 ppm.

Accumulation in Irrigated Crops (165-3) MRID #40541305 (DER 6)

1. Study MRID #40541305 does not satisfy the accumulation in irrigated crops (165-3) data requirement at this time for the following reason:
2. The registrant must explain the disparity between the accumulation in the confined rotational crop (165-1) and the apparent lack of accumulation in the irrigated crops (165-3); also, the rapid decline in glyphosate concentration in the pond water from Day 0 to Day 1 was not explained.
3. Alfalfa, corn (grain and forage), grass (fescue or sudan) and lettuce were irrigated five to eight times during the 1987 growing season with glyphosate treated water containing a maximum of 21.3 ppm (on treatment day then fell to 0.46 ppm by 1 day after treatment) of glyphosate. Residues in the sediment beneath the treated water reached a maximum of 3.5 ppm at 14 days after treatment. Residues of glyphosate in the sprinkler water at the pond site were the highest 7 days after treatment at 0.12 ppm. One lettuce sample from the MO location (the pond site) at 29 days after treatment (of water source) and 5 irrigation events was found to contain 0.06 ppm glyphosate.

Bioaccumulation in Fish (165-4) MRID #41228301, 41228302 (DER 7)

1. Studies MRID #41228301 and 41228302 completely satisfy the bioaccumulation in fish (165-4) data requirement for glyphosate.
2. Glyphosate residues did not significantly accumulate in bluegill sunfish exposed to glyphosate at 12 ppm for 35 days. Maximum bioconcentration factors were 0.38X for edible tissues, 0.63X for nonedible tissues, and 0.52X for whole fish. Only parent glyphosate was detected in aqueous extracts from edible and nonedible tissues; glyphosate and aminomethylphosphonic acid were detected in aqueous extracts from whole fish. A significant portion of total sample radioactivity was found to be incorporated into proteins. Residues accumulated by day 35 of the exposure period were depurated gradually with 35% elimination from edible tissues, 57% from nonedible tissues, and 52% from whole fish after 21 days of depuration.

8. RECOMMENDATIONS:

Inform the registrant that the photodegradation in water (161-2), and the bioaccumulation in fish (165-3) data requirements are satisfied; the aerobic aquatic metabolism (162-4), confined accumulation in rotational crops (165-1) and the accumulation in irrigated crops (165-3) studies may be upgraded; and that the aerobic soil metabolism (162-1), anaerobic aquatic metabolism (162-3) studies must be repeated. Also inform the registrant that EFGWB does not concur with the removal of preplant crop rotational restriction from the label of glyphosate.

The current status of environmental fate data requirements to support terrestrial food crop (field, vegetable, and tree fruit and nut crops), aquatic food crop (cranberries and rice), greenhouse nonfood crop, terrestrial nonfood crop (ornamental including turf), terrestrial nonfood (fallow and fence rows, highways and roadsides, railroad rights-of-way), aquatic non-food, domestic outdoor, and forestry (including Christmas tree plantations) sites is as follows:

(1) Satisfied :

Hydrolysis (161-1): File or reg # 524-308, 6/30/78; Stable at pH 3, 6, 9 at 5 and 35°C

Photodegradation in Water (161-2): This review; Stable

Photodegradation on Soil (161-3): EFGWB # 90374, 6/28/90; Stable

Leaching/ Adsorption/Desorption (163-1): EFGWB # 70727-29 (data taken from Dynamac review 6/7/85) (aged batch equilibrium) K_d values of 62, 90, 70, 22, and 175 were reported for Drummer silty clay loam, Ray silt, Spinks sandy loam, Lintonia sandy loam, and Cattail Swamp sediment respectively. After leaching 7 soils with 20" of water the recovered radioactivity in the soils was 93-100% of the applied.

Bioaccumulation in Fish (165-4): This review; Maximum bioconcentration factors were 0.38X for edible tissues, 0.63X for nonedible tissues, and 0.52X for whole fish.

(2) The following could be made acceptable by the submission of supplemental data.

Aerobic aquatic metabolism (162-4),
Confined accumulation in rotational crops (165-1)
Accumulation in irrigated crops (165-3)

(3) Not Satisfied :

Aerobic soil metabolism (162-1),
Anaerobic Soil Metabolism (162-2), may be satisfied by the anaerobic aquatic metabolism study.
Anaerobic aquatic metabolism (162-3)
Laboratory Volatility (163-2)
Terrestrial Field Dissipation (164-1)
Aquatic Field Dissipation (164-2)
Forestry Dissipation Studies (164-3)

(4) Reserved :

Photodegradation in Air (161-4)
Field Volatility (163-3)
Long Term Field Dissipation (164-5)
Field Accumulation in Rotational Crops (165-2)
Field Accumulation in Aquatic non-target organisms (165-5)

ENVIRONMENTAL FATE ASSESSMENT

Available data are insufficient to fully assess the environmental fate and potential for groundwater contamination of glyphosate at this time. Some limited data indicate that glyphosate strongly adsorbs to soil and is very readily degraded by biotic processes which would limit its potential to contaminate groundwater. Glyphosate has the potential to contaminate surface waters due to its aquatic use patterns and its stability to hydrolysis and photodegradation.

9. BACKGROUND

Glyphosate is a non-selective, non-residual, postemergence herbicide registered for use to control annual weeds, herbaceous and woody perennial, aquatic weeds, and annual and perennial grasses in food and non-food crop sites. It may be applied (in spring, summer, or fall) as a direct application in established crops; as a recirculating or wiper application to control weeds that are taller than the crop; or as a broadcast spray before planting, before emergence of the crop, or to achieve total vegetation kill for turf renovation or site preparation. In some states in the U.S., aerial application is permitted. Glyphosate is applied with a non-ionic surfactant. Single active ingredient formulations include emulsifiable

concentrate, soluble concentrate, and ready-to-use. Glyphosate may be tank mixed with alachlor, simazine, linduron, metribuzin, and metolachlor.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

Refer to attached reviews.

11. COMPLETION OF ONE-LINER:

Attached.

12. CBI APPENDIX:

All data reviewed here are considered "company confidential" by the registrant and must be treated as such.