

Date out of EAB: 6/18/87

Signature:

From: Michael Firestone, Acting Chief
Special Review Section #2
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Michael Firestone

Reg./File No.: 197169 to 197171

Chemical: Glyphosate

Type Product: herbicide

Product Name: Roundup, Rodeo, etc.

Company Name: Monsanto

Submission Purpose: Review Worker Safety Rules

Date In: 8 June 1987

Action Code: 655

Date Completed: 18 June 1987

EAB # 70724-26

Monitoring Requested:

<u>TAIS (level II)</u>	<u>Days</u>
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Monitoring Voluntarily Done

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Deferrals To:

Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

Benefits and Use Division

CHEMICAL NAME:

Hydrocarbons

(RD PROVIDE)
SHADNESSY NO.
103601-1

Identifying Number	Action Code	Reference Number	Record Number	Study Guideline or Narrative Description	Reg. Std. Review Submission Criteria (SEE BELOW)	Accession Number	(HED/BUD/TSS Complete) Study found to be Acceptable (A)/ Unacceptable (U) for review or reviewer comment
524-318	655	7	197169	Request to delete	2		
524-333	655	9	197170	Requestment for Work	2		
524-339	655	12	197171	Request Rules	2		

PRODUCT MANAGER (PM) or REVIEW MANAGER (RM) AND NUMBER:

Taylor

25

PM/RM TEAM MEMBER AND NUMBER:

VE Walter 25

DATE RECEIVED (EPA):

2/17/87

RD BRANCH CHIEF INITIALS:

F

CHECK APPLICABLE BOX:

- ☐ Adverse 6(a)(2) Data (405,406) ☒ Product Specific Data (Reregistration) (655,656)
☐ Suspect Data (415,416) ☐ Generic Data (Reregistration) (660,661)
☐ IBT Data (485,486) ☐ Special Review Data (870,871)

NUMBER OF INDIVIDUAL STUDIES SUBMITTED: 1

HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) If yes, please identify the study(ies):

TO BE COMPLETED BY RSERB

DATE SENT TO HED/BUD/TSS: *6-8-87*

PRIORITY NUMBER: *50*

PROJECTED RETURN DATE: *8-5-87*

DATE RETURNED TO RD (HED/BUD/TSS PROVIDE):

RELATED ACTIONS:

INSTRUCTIONS:

Request to delete requestment for worker safety studies

Please note add information so this subject is not turned over to EPA as it is not currently

REVIEWS SENT TO:

HED: ☐SIS ☐TB ☐RCB ☒EAB ☐EEB

RD: ☐TSS

BUD: ☐EAB ☐SSB

TO:	TYPE OF REVIEW	NUMBER OF ACTIONS		
		Reregistration	Special Review	Other
	Toxicology			
	Ecological Effects			
	Residue Chemistry			
☒	Exposure Assessment	3		
	Product Chemistry			
	Efficacy			
	Precautionary Labeling/Acute Tox.			
	Science Support			
	Economic Analysis			

FOR DATA SUBMITTED UNDER A REGISTRATION STANDARD: Review Submission Criteria

Policy Note #31

- 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
2 = data of particular concern
3 = data necessary to determine tiered testing requirements

NOTE TO TSS:
Return 1 Copy To RSERB

INCLUDE AN ORIGINAL AND FOUR (4) COPIES OF THIS COMPLETED FORM FOR EACH BRANCH CHECKED FOR REVIEW.

Monsanto

400856- 00

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

February 9, 1987

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Glyphosate Guidance Document,
Additional Information to Support
Roundup® Herbicide
EPA Registration No. 524-308
Shackle® Herbicide
EPA Registration No. 524-330
Shackle C® Herbicide
EPA Registration No. 524-339
Polado® Herbicide
EPA Registration No. 524-332
Rodeo® Herbicide
EPA Registration No. 524-343
Roundup L&G® Herbicide
EPA Registration No. 524-370
Landmaster® Herbicide
EPA Registration No. 524-351
Landmaster II® Herbicide
EPA Registration No. 524-376
MON-0139 (62% solution),
EPA Registration No. 524-333
Ranger® Herbicide
EPA Registration No. 524-382

Dear Sir:

In the glyphosate registration standard (issued August 11, 1986), the Agency requested that "Worker Safety Rules" appear on all glyphosate formulated products labeled for agricultural or aquatic uses (refer to pages 14, 21, 22, 28 and 29 of the Glyphosate Guidance Document). These rules required that specific protective clothing be worn to "reduce the risk of injury to skin".

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Mr. Robert J. Taylor
February 9, 1987
Page 2

Monsanto firmly believes that the Agency's requested "Worker Safety Rules" are unjustified, and they are neither necessary nor required for the safe use of glyphosate products. Our comments that support this position were previously submitted (November 7, 1986) to the the Agency as part of Monsanto's comments to the Glyphosate Guidance Document.

The purpose of this submission is to offer additional expert information which further supports our position that dermal exposure to glyphosate formulations (when used according to label instructions) does not cause skin injuries; and therefore that the requested addition of "Worker Safety Rules" to glyphosate product labels should be deleted.

Monsanto is now submitting a report entitled "Irritation, Sensitization, Photoirritation and Photosensitization Assays with Glyphosate Herbicide" by Dr. Howard I. Maibach of the University of California, San Francisco Medical Center (Contact Dermatitis 1986: 15:152-156). In this study glyphosate herbicide was evaluated for acute irritation, cumulative irritation, photoirritation and allergic and photoallergic potential in 346 human volunteers. These data show glyphosate herbicide was less irritating than a standard liquid dishwashing detergent and a general all purpose cleaner. There was no evidence for the induction of photoirritation, allergic potential or photoallergic contact dermatitis.

This report (Maibach, 1986), plus the glyphosate acute toxicology data presently on file with the Agency provides conclusive evidence that the requested "Worker Safety Rules" are not necessary. Therefore, Monsanto requests the Agency to do the following:

- A. Conclude that the glyphosate products currently registered are adequately labelled for dermal exposure.
- B. Delete the "Worker Safety Rules" labeling requirement that is requested in the glyphosate registration standard.

Should you have any questions concerning the enclosed glyphosate report, we would suggest that you contact Dr. Maibach. If you have any questions concerning this request, please contact Mr. Lyle Gingerich, or myself. Please inform us of the MRID number assigned to this submission.

Sincerely,


Thomas F. Armstrong
Registration Manager

Enclosure

/jjs

cc: L. L. Gingerich

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1.0 INTRODUCTION

Monsanto submitted a letter on 9 February 1987 requesting that the Agency reconsider its Worker Safety Rules for glyphosate products. These rules were published in the 11 August 1986 Glyphosate Registration Standard. As part of its request, Monsanto has submitted a study entitled "Irritation, Sensitization, Photoirritation, and Photosensitization Assays with Glyphosate Herbicide" (Maibach, H.I. Contact Dermatitis, 15:152-156, 1986). Monsanto believes that the worker safety Rules are unjustified and are not needed for the safe use of glyphosate products.

2.0 DISCUSSION

The Exposure Assessment Branch believes that some glyphosate products present a risk of injury and that label precautions are necessary. There are two sources for this concern. A review of the Toxicology Branch one-liners for Roundup indicate that Roundup is a eye irritant. A primary eye irritation study in rabbits conducted at Younger Labs (Study #YL-71-150, 7 October 1971, EPA Accession #009856) indicated that Roundup is a Toxicity Category I eye irritant. Another primary eye irritation study in rabbits conducted by Monsanto (Study #ML-80-362, 3 June 1981, EPA Accession #070170) indicated Roundup to be a Toxicity Category II eye irritant.

The results of these two studies are supported by poisoning incidents reported to the California Department of Food and Agriculture between 1981 and 1985. During this time period, a total of 64 applicator and 24 mixer/loader eye injuries were reported. In addition to the eye injuries, 52 applicator and 7 mixer/loader skin injuries were reported. A summary of the poisoning incidences (Blondell, J., 6 June 1986) is attached (Attachment 1).

The Toxicology Branch one-liners and the California data indicate that some glyphosate products are eye and skin irritants. Based on these data, EAB requested that worker safety rules be placed on some glyphosate labels to reduce the risk of injury. The safety rules were also intended to contain "common-sense" safety measures that the Agency is currently preparing to implement on all labels in addition to the use of goggles to prevent product from getting into the eye. The use of goggles was intended only for those glyphosate products that carried a "Warning" signal word because of eye irritation.

3.0 CONCLUSION

Based on the Toxicology Branch one-liners and poisoning incidences reported for glyphosate use in California, EAB concludes that some formulations of glyphosate are eye irritants and possibly skin irritants. To clarify possible ambiguities in the Registration Standard in regards to worker safety rules, EAB is proposing the two attached labels for non-home use products. Attachment 2 is

intended for all glyphosate products that contain the signal word "WARNING" based on either dermal irritation or eye irritation. Attachment 3 is intended for all glyphosate products that contain the signal word "CAUTION".


Curt Lunchick
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

JUN - 6 1986

Glyphosate Poisoning Statistics Summary

Prepared By Jerome Blondell

Acute hazards to glyphosate (round up) can be measured by counting or estimating the number of deaths, hospitalizations, and visits to physicians outside of the hospitals.

Mortality

During four years (1961, 1969, 1973, 1974), when all accidental deaths due to pesticides in the U.S. were counted, there were no deaths due to glyphosate.

Hospitalized Poisonings

Based on a 12% sample of the nation's hospitals, glyphosate was not found to have caused any hospitalizations during the time period 1971 through 1976.

Physician-treated Poisoning

Based on data obtained from California (the only state which enforces mandatory reporting of occupational pesticide incidents), physicians treated an average of 47 occupational illnesses each year from 1981 through 1985. 50% of the illnesses were due to eye injuries, 35% were injuries to the skin, 13% were systemic illnesses and 2% were a combination of the eye and skin injury. Glyphosate ranked third among all pesticides as a cause of occupational illnesses in California. None of the illnesses that occurred from 1981 to 1985 required hospitalization. Sulfur and Propargite the top two causes of California occupational illnesses caused mostly skin injuries. Only 20% of these injuries were to the eye. 48 people were disabled due to glyphosate illness during the 1981 to 1985 time period, making it the sixth largest cause of disability, accounting for a total of 179 days off of work.

Poisonings per Pounds Used

The number of California physician-treated occupational illnesses (average per year, 1981-1985) per million pounds of glyphosate reported sold in California in 1984 was 17.0. On average, for all pesticides, we find 1.3 poisonings per million pounds sold, per year in California.

Summary of Occupational Illness due to Glyphosate in California, 1982-1985.

<u>Type of Worker</u>	<u>Systemic</u>	<u>Eye</u>	<u>Skin</u>	<u>Eye and Skin</u>	<u>Total</u>
Ground Applicator	6	19	17	0	42
Hand Applicator	18	44	35	3	100
Other type Applicator	0	1	0	0	1
Subtotal Applicators	24	64	52	3	143
Mixer-Loader	1	24	7	0	32
Coincidental Exposure	3	7	2	0	12
Exposure to Field Residue	0	0	5	0	5
Other type Residue Exposure	1	0	0	0	1
Exposure to Concentrate	0	4	1	0	5
Subtotal other Workers	5	35	15	0	55
Grand total	29	99	67	3	198

Ground Applicator: Person exposed while applying by dust or spray rig.

Hand Applicator: Person exposed while applying by hand-pump, hose-end, or backpack sprayer, duster or aerosol can.

Coincidental Exposure: Person exposed to an application-strength dilution, not directly involved in handling the pesticide. Primarily includes persons exposed to spray drift.

Exposure to Field Residue: Person exposed to residues while working in a previously treated field.

Exposure to Concentrate: Persons involved in handling pesticide products between packaging and use (warehouses, truckers, retailers).

Attachment 2 WORKER SAFETY RULES FOR ALL GLYPHOSATE PRODUCTS
CONTAINING THE SIGNAL WORK "WARNING" FOR SKIN
OR EYE IRRITATION

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

Do not rub eyes with hands. See First Aid (Practical Treatment) Section.

HANDLE THE CONCENTRATE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT.

Wear chemical resistant gloves, chemical resistant apron, chemical resistant shoes, shoe coverings, or boots, long sleeve shirt, long legged pants, and a face shield or goggles.

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, CLEANING, DISPOSAL OF THE SPRAY SOLUTION, AND DURING REENTRY TO TREATED AREAS BEFORE THE SPRAY HAS DRIED.

Wear long sleeved shirt, long legged pants, chemical resistant gloves, and a face shield or goggles. A helmet with visor may be worn during open cockpit aerial application.

Only during application from a tractor with a completely enclosed cab or aerially with an enclosed cockpit will the face shield or goggles and gloves not be required. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK, wash protective clothing and equipment with soap and water after each use. Personal clothing worn during use should be laundered separately from household articles. Clothing or protective equipment heavily contaminated or drenched with glyphosate must be disposed of in accordance with state or local regulations.

HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

Attachment 3. WORKER SAFETY RULES FOR ALL GLYPHOSATE PRODUCTS
INTENDED FOR AGRICULTURAL USES AND CONTAINING
THE SIGNAL WORK "CAUTION"

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

When handling this product wear chemical resistant gloves, long sleeve shirt, and long legged pants.

Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating and drinking, or toileting.

After work: Wash clothing and gloves with soap and water after each use. Personal clothing worn during use should be laundered separately from household articles. Clothing or protective equipment heavily contaminated or drenched with glyphosate must be disposed of in accordance with state or local regulations. Heavily contaminated or drenched clothing cannot be adequately decontaminated.