2-3-92

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 3 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Monsanto Company: Response to the Glyphosate Reregistration Standard: Product and Residue Chemistry Data (MRID #'s 00156793 and 41886101, CBRS #'s 8196 and 8220, Barcode No.'s D166017 and D165705.)

FROM: R. B. Perfetti, Ph.D., Chemist
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: E. Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: W. Burnam, Acting Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

and

L. Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508C)

Attached please find a reviews of Monsanto Company's response to the glyphosate Reregistration Standard. These data were reviewed by Acurex Corporation under supervision of CBRS, HED.

This information has undergone secondary review in CBRS and has been revised to reflect the Branch policies.

Please see our conclusions in the attachment regarding the acceptability of the information submitted by the Registrant.

Revised Product Chemistry data Tables and a Residue Chemistry Summary Sheet have also been provided.

(1) 1
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If you need additional input please advise.

Attachment 1: Review of Glyphosate Product and Residue Chemistry Data.

cc (With Attachment 1): R. B. Perfetti, J. Burrell/C. Furlow (PIB/FOD), Glyphosate Reregistration Standard File, Glyphosate Subject File Circ. (7), RF and Acurex.

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GLYPHOSATE
(Chemical Code 099101)
(CBRS Nos. 8196 and 8220; DP Barcode D165705)
TASK 3

Registrant's Response to Residue Chemistry Data Requirements

November 8, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
4915 Prospectus Drive
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Research Triangle Park, NC 27709

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GLYPHOSATE

(Chemical Code 099101)

(CBRS Nos. 8196 and 8220; DP Barcode D165705)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

Task-3

BACKGROUND

The Glyphosate Guidance Document dated 6/86 cited residue chemistry data gaps for numerous crops. The status of the Guidance Document requirements was summarized in the Glyphosate Reregistration Standard Update dated 4/26/90. Monsanto Company submitted a response, dated 4/26/90, to several of the requirements that had been listed in a recent Agency correspondence (2/28/91) as still outstanding. In this response, Monsanto addressed requirements for storage stability data, residue data on peanuts and sugarcane and processing studies with corn grain, sorghum (milo) grain, soybeans, peanuts, olives, and wheat grain.

In response to the storage stability data requirement, Monsanto Company cited an 18-month interim report and indicated that the final report had been completed and would be submitted within 30 days. The Guidance Document requirements for data on corn, sorghum, and wheat grain included the need for separate tolerances to replace the established tolerance of 0.1 ppm for grain crops (40 CFR §180.364[a]). The registrant submitted the requested residue data with petitions for new tolerances. These data on corn grain (1987; MRID 40502604 and 1990; MRID 41478101), sorghum grain (1987; MRID 40502603 and 1990; 41472001), and wheat grain (1984; MRID 00150835 and 1990; 41484301) have undergone Agency review in conjunction with CBTS petition reviews. Data requested for soybean soapstock were provided from an older soybean processing study (1983; MRID 00156793). The registrant responded to requirements for data and/or tolerances for potatoes, olives, peanuts, and sugarcane with explanations of label changes, statements of intent to propose tolerances, or requests for waivers of data requirements. This CBRS review acknowledges these submissions as responses to requirements for reregistration and assesses their adequacy to fulfill outstanding data requirements.

The nature of glyphosate residues in plants is adequately understood. The residues of concern in plants are glyphosate and its aminomethylphosphonic acid metabolite (AMPA). Adequate analytical methodology is available for the enforcement of tolerances for residues in or on plant commodities. The accepted enforcement method is Method I, published in PAM, Vol. II.

CONCLUSIONS

1. CBRS will comment and make conclusions regarding storage stability data following receipt and review of Monsanto's forthcoming final report.

2. CBRS will comment and make conclusions regarding proposed food/feed tolerances for processed potato commodities following receipt and review of the registrant's forthcoming tolerance petition.

3. The data from the processing study on soybeans fulfill the requirements of the Guidance Document. The combined residues of glyphosate and AMPA did not concentrate in soapstock. A feed additive tolerance is not required for this commodity.

4. Data from the corn grain dry milling and wet milling studies fulfill the requirements of the Guidance Document. Residues of glyphosate did not concentrate in commodities of corn grain during processing. No food/feed additive tolerance is required.

5. Data from the sorghum grain processing studies satisfy the requirements of the Guidance Document. Residues of glyphosate did not concentrate in sorghum starch during processing. However, residues of glyphosate concentrated 5x in sorghum flour. Therefore, a food additive tolerance is required for this commodity. We note that tolerances of 5 ppm for sorghum and 25 ppm for milling fractions (except grits) are currently under consideration.

6. The data submitted for processed wheat commodities fulfill the requirements of the Guidance Document. Combined residues of glyphosate and AMPA concentrated ca. 3x in wheat milling fractions (excluding flour).

7a. The label directions for the use of glyphosate on olives are inadequate. A maximum number of applications per season or a maximum seasonal application rate are not specified and revised labels are needed to include these restrictions. If data are not available to reflect these specifications, additional data on processed olives and olive oil may be required. In addition, the labels must be amended to prohibit the harvesting of olives from the glyphosate-treated grove floor; otherwise, data are required to reflect this harvesting practice.

7b. The information on processing practices are sufficient to resolve Agency questions regarding whether or not the available data on processed olives reflect commercial practices. The requirement for additional data on processed olives will depend upon the nature of the labeling restrictions proposed.

8a. Because the registrant has removed the spot treatment use from the pertinent product labels, additional data on the raw agricultural commodities (RACs) of peanuts are not required.

8b. CBRS recommends against the registrant's request to waive the requirements for a peanut processing study. A processing study with peanuts must be conducted. Glyphosate applications should be made at the highest exaggerated rate that would not cause crop damage. Nutmeats must be processed whether or not residues are detected to determine the potential for concentration in processed commodities.

9. CBRS concludes that the registrant has adequately addressed the Guidance Document requirements for sugarcane. Because the label specifies that spot treatments are on volunteer or diseased cane, not on healthy cane, data reflecting this use are not required.

RECOMMENDATIONS

Food/feed additive tolerances must be proposed for wheat milling fractions (except flour). Based on the proposed tolerance of 4 ppm for wheat grain, a food/feed additive tolerance of 12 ppm would be appropriate for wheat milling fractions (except flour).

The labels bearing directions for use on olives in Greece, Italy, and Spain must be revised to specify a maximum number of applications per season or a maximum seasonal application rate. If data are not available to reflect these specifications, additional data on processed olives, processed olives, and olive oil may be required. In addition, the labels must be amended to prohibit the harvesting of olives from the glyphosate-treated grove floor; otherwise, data are required to reflect this harvesting practice.

A processing study with peanuts must be conducted. Glyphosate applications should be made at the highest exaggerated rate that would not cause crop damage. Nutmeats must be processed whether or not residues are detected to determine the potential for concentration in processed commodities. Data are required depicting glyphosate and AMPA residues in meal, crude oil, refined oil, and soapstock processed from treated peanuts. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

If the registrant wishes to register a late season preharvest use on wheat, data are required depicting the concentration of residues in grain dust processed from grain bearing measurable weathered residues.

DETAILED CONSIDERATIONS

Registrant's Response to Storage Stability Data Requirements. The registrant cited an 18-month interim report that was submitted and indicated that the final 2-year study will be forthcoming.

CBRS will comment and make conclusions following receipt and review of the final report.

Registrant's Response to the Requirement for Food/Feed additive tolerances: Potatoes. The registrant states that a food/feed additive petition for the necessary tolerances on the processed commodities of potatoes will be submitted.

CBRS will comment and make conclusions following receipt and review of the registrant's petition.

Registrant's Response to the Requirement for Processing Studies: Soybean Soapstock. In its response to the Registration Standard Update (letter dated 4/24/91), Monsanto indicated that an older processing study that included soapstock (1983; MRID 00156793) had been submitted to the Agency for review. Because these data were not previously considered in conjunction with reregistration, they are reviewed briefly here.

Soybean samples used for the processing study were harvested from a 1979 residue field trial conducted in MS. Soybean plants received two recirculating sprayer treatments of the 3 lb/gal SC/L formulation at 95 and 37 days prior to harvest for a combined application rate of 3.75 lb ai/A. An additional preharvest topical treatment at either 0.75, 1.5, 3 or 4.5 lb ai/A was also applied 15 days prior to harvest for total seasonal application rates of 4.5, 5.25, 6.75. or 8.25 lb ai/A, respectively.

Soybean samples were dehulled and seed fractions were finely ground with dry ice, and the dry ice was evaporated. The finely ground seed meal was extracted with hexane and filtered. The hexane was evaporated from the filtrate to produce the crude oil fraction. For preparation of soapstock, an aliquot of the crude oil was mixed with 10% aqueous NaOH. The soapstock was a thick yellowish gum that formed between the oil and aqueous layers after centrifugation. The soapstock fraction was analyzed using a high performance liquid chromatography (HPLC) method based on Method I in PAM, Vol. II. This HPLC method utilizes a post-column ninhydrin reaction with glyphosate and AMPA to produce chromophores that absorb at 546 nm. The detection limit was 0.2 ppm for each compound. Combined residues were <0.4 ppm (nondetectable) in soapstock processed from two samples of soybeans bearing combined residues of 10.99 and 13.64 ppm.

CBRS concludes that these data satisfy the requirement for data on soybean soapstock. This deficiency is resolved.

Registrant's Response to the Requirement for Processing Studies: Corn Grain. The registrant responded to data requirements concerning corn grain by citing data (1987; MRID 40502604) pertaining to residues of glyphosate and AMPA in processed corn commodities in conjunction with a proposal for a tolerance of 1 ppm for residues in or on corn grain (PP#8F6373). These data were reviewed by the Agency (M. T. Flood; CBTS No. 4289; 2/1/89), and it was concluded that residues did not concentrate in meal, crude oil, refined oil, or soapstock during dry milling of corn grain. However, data were requested on residues in corn grits and flour resulting from dry milling because no data were provided on these commodities. Based on the above dry milling data and on data from the partial wet milling of corn grain, the reviewer further concluded that glyphosate and AMPA residues would not be expected to concentrate in starch, crude oil, or refined oil during wet milling. Therefore, no additional data were required from wet-milled fractions of corn grain. In response to the deficiencies noted in the above dry-milling study, Monsanto submitted data (1990; MRID 41478101) pertaining to corn grits and flour fractions. These data were reviewed by CBTS (F. D. Griffith; CBTS Nos. 6745 and 6746; 7/13/90), and it was concluded that residues of glyphosate and AMPA did not concentrate in corn grits and flour. Therefore, no food/feed additive tolerance is required.

CBRS concludes that the available data fulfill the requirement of the Guidance Document for data on the wet and dry milling fractions of corn grain. This deficiency is resolved.

Registrant's Response to the Requirement for Processing Studies: Sorghum Grain. The registrant cited data (1987; MRID 40502603) pertaining to residues in commodities processed from sorghum grain that were submitted in conjunction with a petition (PP#8F3672/PP#8H5562) for a tolerance of 5 ppm for sorghum grain and a food/feed additive tolerance of 25 ppm for sorghum milling fractions (excluding grits). These data were reviewed by the Agency (S.H. Willett; CBTS Nos. 4357 and 4358; 11/18/88), and it was concluded that residues concentrated ca. 5x in sorghum flour. However, the above study was deemed incomplete because no data concerning residues in sorghum starch were included. Additional data regarding residues in sorghum starch were requested. In response to this data requirement, Monsanto submitted sorghum starch data, reviewed by CBTS (S. H. Willett; CBTS Nos. 6740, 6741, and 6742; 9/5/90). The Agency concluded that glyphosate and AMPA do not concentrate in sorghum starch.

CBRS concludes that these data fulfill the Guidance Document requirement for processing studies on sorghum grain. Residues of glyphosate did not concentrate in sorghum starch during processing. However, residues concentrated 5x in sorghum flour. The food/feed additive tolerance of 25 ppm proposed for the combined residues of glyphosate and AMPA in sorghum milling fractions (excluding grits) would be appropriate given a revised 5 ppm tolerance for grain.

Registrant's Response to the Requirement for Processing Studies: Wheat Grain. In its response to the Registration Standard Update (letter dated 4/24/91), Monsanto indicated that wheat grain processing data (1984; MRID 00150835) were previously submitted in support of

a proposed selective equipment application that was not pursued by the applicant. The Agency review of this petition (R. Cook; PP#3F2809/FAP#5H5450; 4/18/85) indicated that residues of glyphosate and AMPA concentrated ca. 3x in wheat bran and shorts. Therefore, food additive tolerances in wheat milling fractions (excluding flour) were required. Monsanto subsequently submitted data (1990; MRID 41484301) pertaining to glyphosate and AMPA residues in or on wheat grain and straw to support proposed tolerances for these residues in or on wheat grain (4 ppm) and straw (85 ppm) from the preharvest application of glyphosate. These data were reviewed by the Agency ([PP#0F3865] R.W. Cook; CBTS Nos. 6748, 6749, and 6750; 1/29/91), and it was concluded that glyphosate and AMPA residues were not likely to exceed the proposed tolerances for wheat grain (4 ppm) and straw (85 ppm). The reviewer further concluded that a food additive tolerance of 12 ppm should be proposed for wheat milling fractions (excluding flour), based on the proposed 4 ppm tolerance for wheat grain and on the data from the aforementioned wheat grain processing study. The processing data are again summarized below in Table 2.

Table 2. Residues of glyphosate and AMPA in wheat grain and processed wheat grain commodities (1984; MRID 00150835).

Location (rate)/ Fraction	Glyphosate (ppm)	AMPA (ppm)	Combined Residues (ppm)	Concentration Factor
TN (0.38 lb ae/A)				
Whole grain	0.67	<0.05[a]	0.67	-
Wheat bran	1.66	0.07	1.73	2.58x
Break flour	0.14	<0.05	0.14	0.21x
Reduction flour	0.12	<0.05	0.12	0.18x
Shorts	1.20	<0.05	1.20	1.79x
MO (3 lb ae/A)				
Whole grain	66.6	1.75	68.35	-
Bran	121.2	2.58	123.78	1.81x
Break flour	22.8	1.77	24.57	0.36x
Reduction flour	22.8	1.68	24.48	0.36x
Shorts	94.7	2.52	97.22	1.42x

[a]Detection limit was 0.05 ppm for both glyphosate and AMPA.

Monsanto stated the intent to propose a food/feed additive tolerance for wheat bran and shorts based on the available data.

CBRS concludes that the available data satisfy the requirements for a processing study on wheat grain. The registrant should propose a food/feed additive tolerance of 12 ppm for residues of glyphosate and AMPA in or on wheat milled fractions (excluding flour). It should be noted that data on grain dust would be required to support the proposed preharvest use.

Registrant's Response to Data Requirements for Olives. The Guidance Document required that the registrant provide documentation as to the uses registered in Greece, Italy, and Spain on olives in order to verify that the available data reflect the registered use. In addition, the registrant was required to verify procedures used for processing olives in these countries. Monsanto stated that they provided this information in a letter to the Agency dated 9/3/87; a copy of this information was included in the 4/26/91 submission.

Labels for the 3 lb/gal SC/L formulation used in Greece, Italy, and Spain specify a single application rate of 3.85 lb ai/A. No maximum number of applications per season or maximum seasonal use rate is stipulated. Moreover, there is no restriction stated prohibiting harvesting olives from the grove floor. These labels must be revised to specify these restrictions and limitations. There is no established PHI. However, the registrant stated that in Italy and Spain, glyphosate is applied to olive groves in the spring and summer, whereas harvest occurs during the winter. In Greece, the chemical is applied in late spring and summer and harvest begins in November and continues through March. Thus, the registrant contends, good agronomic practices in these countries prevent application of glyphosate within a month of olive harvest.

Regarding the processing of olives, Greek olives are soaked in brine (1% salt solution in water) after harvest, the salt concentration is increased progressively up to 8% in about 1 month, and thereafter, the olives are kept in brine of 11-12%. In Spain, the harvested olives are treated with sodium hydroxide (NaOH) for a few hours to remove the bitter flavor and the olives are rinsed to remove the NaOH prior to fermenting in brine. In Italy, 90% of olives are pressed mechanically for oil and the other 10% are processed in 5-7% salt at pH 4-5.

Regarding the need for data on olive oil from a processing study, a previous Agency review stated that owing to the water solubility of glyphosate, residues would not be expected in olive oil (memorandum on PP#3E2929, V.F. Boyd dated 12/19/83).

There are two separate tolerances established for glyphosate residues in or on olives. A tolerance of 0.2 ppm has been established for glyphosate residues in or on olives (40 CFR §180.364) covering fresh olives grown domestically. A food additive tolerance of 0.1 ppm has been established for glyphosate residues in imported olives (40 CFR §185.3500), applicable to processed imported olives, which are either preserved in brine or dried.

CBRS concludes that the label directions for the use of glyphosate on olives are inadequate. The registrant must revise the product labels from Greece, Italy, and Spain to specify a maximum number of applications per season or a maximum seasonal application rate. If data are not available to reflect these specifications, additional data on processed olives and olive oil may be required. In addition, the labels must be amended to prohibit the harvesting of olives from the glyphosate-treated grove floor; otherwise, data are required to reflect this harvesting practice.

The information on processing practices are sufficient to resolve the Agency's questions regarding whether or not the available data on processed olives reflect commercial practices.

Registrant's Response to the Requirement for Residue and Processing Studies: Peanuts. The Guidance Document required data on raw agricultural commodities of peanuts following registered spot treatments. Monsanto responded by stating that spot treatments were no longer permitted on the label and provided a copy of the label for EPA Reg. No. 524-308.

CBRS concludes that data on residues in or on peanut RACs following spot treatment are not required.

In addition, the Guidance Document requested data from a processing study with peanuts. Monsanto requested a waiver of this requirement based on nondetectable residues in or on nutmeats following registered preemergence use.

CBRS concludes that a processing study with peanuts must be conducted. Glyphosate applications should be made at the highest exaggerated rate that would not cause crop damage. Nutmeats must be processed whether or not residues are detected to determine the potential for concentration in processed commodities.

Registrant's Response to Data Requirements for Sugarcane. The Guidance Document required residue data on sugarcane and sugarcane forage, offering the option to revise the label to impose a feeding restriction in lieu of forage data. In response, Monsanto Co. revised the label to include a feeding restriction. The 1990 Glyphosate Reregistration Standard Update acknowledged the label revision but noted that data were still required on cane treated on the day of harvest. Monsanto's 4/24/91 response pointed out that the spot treatment in question is to control volunteer or diseased cane and that healthy cane is not treated less than 3 weeks before harvest. Copies of product labels stating that healthy cane should not be given spot treatments were provided as verification.

CBRS concludes that the registrant has adequately addressed the Guidance Document requirements. No additional data are required.

References (used)

00156793 Knudson, J.L. 1983. Glyphosate Residues in Soybeans and Soybean Fractions Following Recirculating Sprayer and Preharvest Topical Treatments with Roundup® Herbicide. Project No. MSL-3259. Unpublished Study submitted by Monsanto Agricultural Co. 126 p.

00150835 Monsanto Co. (1984) [Glyphosate Residues in Wheat Grain, Straw and Milling/Fractionation Products following Ropewick Wiper Treatment with Roundup Herbicide]. Unpublished compilation. 158 p.

40502603 Kuntsman, J. (1987) Glyphosate Residues in Milo Grain Fractions Following Preharvest Applications to Milo with Roundup Herbicide: MSL-7043. Unpublished study prepared by Monsanto Co. 138 p.

40502604 Kunstman, J. (1987) Glyphosate Residues in Corn Grain Fractions Following Preharvest Applications to Corn with Roundup Herbicide: MSL-6917. Unpublished study prepared by Monsanto Co. 195 p.

41478101 Kunda, U.S. 1990. Glyphosate Residues in or on Corn Grits and Flour Following Preharvest Application of Roundup® Herbicide to Corn. Project No. MSL-9797. Unpublished Study submitted by Monsanto Agricultural Co. 88 p.

41484301 Allin, J. (1989) Glyphosate Residues in Wheat Grain and Straw after Preharvest Treatment with Roundup Herbicide: R.D. No. 983. Unpublished study prepared by Monsanto Agricultural Co. 436 p.

Agency Memoranda

CBTS No(s): 4289
Subject: PP#8F6373 - Glyphosate on Field Corn
From: M. Flood
To: R. Taylor
Dated: 2/1/89
MRID(s): 40502604

CBTS No(s): 4357, 4358
Subject: PP#8F3672/8H5562 - Glyphosate on Grain Sorghum
From: S. Willett
To: R. Taylor
Dated: 11/18/88
MRID(s): 40502603

CBTS No(s): 6740, 6741, 6742
Subject: PP#8F3672/8H5562 - Glyphosate on Grain Sorghum
From: S. Willett
To: R. Taylor
Dated: 9/5/90
MRID(s):

CBTS No(s): 6745, 6746
Subject: PP#8F6373 - Glyphosate on Field Corn
From: F. Griffith
To: R. Taylor
Dated: 7/13/90
MRID(s): 41478101

CBTS No(s):
Subject: PP#3F2809/FAP#5H5450 - Glyphosate on Wheat
From: R. Cook
To: R. Taylor
Dated: 4/18/85
MRID(s): 00150835

CBTS No(s): 6748, 6749, 6750
Subject: PP#OF3865 - Glyphosate on Wheat Grain and Straw
From: R. Cook
To: R. Taylor
Dated: 1/29/91
MRID(s): 41484301

GLYPHOSATE (099101) RESIDUE CHEMISTRY DATA SUMMARY[1]		
Guideline Number and Topic[2]	Are data requirements satisfied?	MRID(s)[3]
171-3 Directions for use	N	N/A
171-4(a) Plant Metabolism	Y	
171-4(b) Animal Metabolism	Y	
171-4(c) Residue Analytical Methods - Plants	Y	
171-4(d) Residue Analytical Methods - Animals	Y	
171-4(e) Storage Stability	N	
171-4(k) Root and Tuber Vegetables Group		
Carrots	Y	
Beets, garden	Y	
Parsnips	Y	
Potatoes (Processed food/feed)	Y	
Radish	Y	
Rutabagas	Y	
Sugar beets (Processed food/feed)	Y	
Sweet potato	Y	
Turnips	Y	
171-4(k) Leaves of Root and Tuber Vegetables		
Beets, greens	Y	
Chicory leaves	Y	
Sugar beet tops	Y	
Turnip tops	Y	
171-4(k) Bulb Vegetables Group		
Onions (green and dry bulb)	Y	
171-4(k) Leafy Vegetables (except Brassica)		
Celery	Y	
Lettuce (leaf)	Y	
Lettuce (head)	Y	
Spinach	Y	
171-4(k) Brassica Leafy Vegetables Group		
Broccoli	Y	
Cabbage	Y	
Cauliflower	Y	
Kale	Y	
Mustard greens	Y	
171-4(k) Legume Vegetables (succulent/dried)		
Beans (succulent and dried)	Y	
Peas (succulent and dried)	Y	
Soybeans (Processed food/feed)	Y	
171-4(k) Foliage of Legume Vegetables		
Bean vines and hay	Y	
Soybean forage and hay	Y	
171-4(k) Fruiting Vegetables Group	Y	
171-4(k) Cucurbit Vegetables Group	Y	
171-4(k) Citrus Fruits Group (Processed food/feed)	Y	

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GLYPHOSATE (099101) RESIDUE CHEMISTRY DATA SUMMARY[1]		
Guideline Number and Topic[2]	Are data requirements satisfied?	MRID(s)[3]
171-4(k) Pome Fruits Group	Y	
171-4(k) Stone Fruits Group	Y	
Plums (fresh prunes) (Processed food/feed)	Y	
171-4(k) Small Fruits and Berries Group		
Grapes (Processed food/feed)	Y	
171-4(k) Tree Nuts Group		
Almonds	Y	
171-4(k) Cereal Grains Group		
Corn (field) (Processed food/feed)	Y[4]	
Corn (fresh) (Processed food/feed)	Y	
Corn (pop)	Y	
Sorghum (Processed food/feed)	Y[4]	
Wheat (Processed food/feed)	Y[4]	
171-4(k) Forage, Fodder, and Straw of Cereal Grains		
Corn (field and pop) forage and fodder	Y	
Corn (fresh) forage	Y	
Sorghum forage and fodder	Y	
171-4(k) Grass Forage, Fodder, and Hay Group	Y	
171-4(k) Non-grass Animal Feeds		
Alfalfa (Processed food/feed)	Y	
171-4(k) Miscellaneous Commodities		
Acerola	Y	
Asparagus	Y	
Avocados	Y	
Bananas	Y	
Coffee (Processed food/feed)	Y	
Cotton (Processed food/feed)	Y	
Figs (Processed food/feed)	Y	
Kiwi	Y	
Mangoes	Y	
Olives (Processed food/feed)	N	
Papayas	Y	
Peanuts (Processed food/feed)	Y	
Pineapple (Processed food/feed)	Y	
Pistachio	Y	
Sugarcane (Processed food/feed)	Y[4]	
Tea (Processed food/feed)	Y	
171-4(l) Processed Food/Feed		
Corn	Y[4]	
Olives	N	
Peanuts	N	
Sorghum	Y[4]	
Soybeans	Y[4]	00156793
Wheat	Y[4]	
171-4(j) Meat/Milk/Poultry/Eggs	Yes	
171-4(f) Potable Water	Yes	

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GLYPHOSATE (099101) RESIDUE CHEMISTRY DATA SUMMARY[1]		
Guideline Number and Topic[2]	**Are data requirements satisfied?**	**MRID(s)[3]**
171-4(g) Fish	Yes	
171-4(h) Irrigated Crops	Yes	
171-4(i) Food Handling Establishments	N/R	
171-5 Reduction of Residues	N/R	

[1]Registration Standard issued 6/86. Reregistration Standard Update issued 4/26/90.

[2]N/A = Guideline requirement not applicable.

[3]Underlining designates MRIDs that were reviewed in the current submission.

[4]CBRS No. 8196 and 8220 dated 1/31/92 by R. Perfetti. The registrant has responded to the deficiencies noted in the Update for these crops. No additional data are required.

GLYPHOSATE
(Chemical Code No. 103601)
(CBRS No. 8196; DP Barcode D165705)

TASK 3

Registrant's Response to Product Chemistry Data Requirements

November 8, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

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Environmental Systems Division
4915 Prospectus Drive
P.O. Box 13109
Research Triangle Park, NC 27709

GLYPHOSATE

(Chemical Code 099101)

(CBRS No. 8196; DP Barcode D165705)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task 3

BACKGROUND

A Product Search Listing conducted on 7/23/91 identified five manufacturing use products of glyphosate. All five products, the 75% technical (T) (EPA Reg. No. 524-421), 94% FI (EPA Reg. No. 524-420), 62% FI (EPA Reg. No. 524-333), 53.5% FI (EPA Reg. No. 524-318) and 41% FI (EPA Reg. No. 524-339) are registered by Monsanto Agricultural Company and contain the isopropylamine (IPA) salt of glyphosate. The Agency (J. Stokes; 9/1/87; CBRS Nos. 2346 and 2347) determined that the 62% IPA salt FI would be more appropriately designated as the technical isopropylamine salt, and that the 41% and 53.5% IPA salt FIs (EPA Reg. Nos. 524-339 and 524-318, respectively) are end-use products.

The Glyphosate Guidance Document (6/86) requires generic and product-specific data for all product chemistry topics. In response, Monsanto submitted data (1986; MRIDs 00161333, 40155801, 40155802 and 40155803; 1987; MRID 40405401; 1988; 41096101) pertaining to the 62% IPA salt FI (EPA Reg. No. 524-333) and the unregistered glyphosate acid technical. The Agency (W. Chin; 7/6/87; CBRS Nos. 1686 and 1687; J.Stokes; 9/1/87; CBRS Nos. 2346 and 2347; W. Chin; 2/25/88; CBRS No. 3007; R. Schmitt; 4/26/90; no CBRS No.) reviewed the submissions and concluded that all the requirements for the unregistered glyphosate acid technical and the 62% IPA salt FI (EPA Reg. No. 524-333), with the exception of the latter's storage stability and corrosion characteristics (Guideline Ref. Nos. 63-17 and -20, respectively) are satisfied.

In response to the Agency review, Monsanto Agricultural Company submitted additional data (1991; MRID 41886101) which are reviewed here for adequacy in fulfilling the requirements for the 62% IPA salt FI.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients
61-2. Description of Beginning Materials and Manufacturing Process
61-3. Discussion of Formation of Impurities

The Glyphosate Guidance Document (6/86) requires additional generic and product-specific chemistry data pertaining to product identity and composition. In response, Monsanto

submitted data (1986; MRIDs 00161333 and 40155801) for the unregistered glyphosate acid technical and the 62% IPA salt FI (EPA Reg. No. 524-333). The Agency (W. Chin; 7/6/87; CBRS Nos. 1686 and 1687; J. Stokes; 9/1/87; CBRS Nos. 2346 and 2347) reviewed the submissions and concluded that all requirements of these topics are completely satisfied. **No additional data are required.**

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis
62-2. Certification of limits
62-3. Enforcement Analytical Methods

The Glyphosate Guidance Document (6/86) requires additional generic and product-specific chemistry data pertaining to the analysis and certification of product ingredients. In response, Monsanto submitted data (1986; MRIDs 00161333 and 40155802; 1987; MRID 40405401)) for the unregistered glyphosate acid technical and the 62% IPA salt FI (EPA Reg. No. 524-333). The Agency (W. Chin; 7/6/87; CBRS Nos. 1686 and 1687; J. Stokes; 9/1/87; CBRS Nos. 2346 and 2347; W. Chin; 2/25/88; CBRS No. 3007)) reviewed the submissions and concluded that all requirements of these topics are completely satisfied. **No additional data are required.**

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Glyphosate Guidance Document (6/86) requires generic and product-specific data pertaining to physicochemical properties. In response, Monsanto submitted data (1986; MRIDs 00161333 and 40155803; 1988; MRID 41096101) for the unregistered glyphosate acid technical and the 62% IPA salt FI (EPA Reg. No. 524-333). The Agency (W. Chin; 7/6/87; CBRS Nos. 1486 and 1487; R. Schmitt; 4/26/90; no CBRS No.; K. Dockter; 5/31/91; CBRS No. 7742) reviewed the submission and concluded that all the requirements for the unregistered glyphosate acid technical and the 62% IPA salt FI (EPA Reg. No. 524-333) with the exception of the latter's storage stability and corrosion characteristics (Guideline Ref. Nos. 63-17 and -20, respectively), are satisfied.

Monsanto submitted additional data (1991; MRID 41886101) for the corrosion characteristics (Guideline Ref. No. 63-20). Twenty-five ml bottles made of high density polyethylene and high density polyethylene caps lined with an unspecified metal foil and a pulp backing were used for the corrosion study of the 62% IPA salt FI (EPA Reg. No. 524-333). The corrosion study lasted for four and a half years. According to the registrant, the focus of the investigation rested on the body of the bottle itself. The registrant claims that there was no evidence of deterioration or hardening of the high density polyethylene bottles. However, the registrant observed that there were some discoloration of the liner. A thin yellow film was also visible. The discoloration of the liner and formation of the thin yellow film were

disregarded by the registrant since the liner was not a part of the commercial container of commerce. The actual commercial packaging used for the 62% IPA salt FI (EPA Reg. No. 524-333) is a 55-gallon high density polyethylene drums with high density polyethylene caps. The bottles and caps used for the corrosion study and commercial packaging are identical.

The storage stability requirement (Guideline Ref. No. 63-17) for the 62% IPA salt FI (EPA Reg. No. 524-333) remains outstanding. For details of the specific requirements regarding storage stability, the registrant is referred to the Pesticide Assessment Guidelines Subdivision D - Product Chemistry Series 63.

The data provided by Monsanto do not fully satisfy the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-20) regarding physical and chemical characteristics of the 62% IPA salt FI (EPA Reg. No. 524-333). Data for the storage stability (Guideline Ref. No. 63-17) must be provided. Additional data are required.

MASTER RECORD IDENTIFICATION NUMBERS:

MRID documents containing data which have been previously reviewed by the Agency are designated in shaded print in the following bibliographic listing of Product Chemistry Citations (used). A summary of the subject memoranda and their associated MRID documents is presented below.

Product Chemistry Citations (used):

00161333 Hammon, J. (1986) Product Chemistry Data to Support the Continued Registration of Glyphosate (n-phosphonomethylglycine): Report No. MSL-5066 (Revised): Project No. 7663. Unpublished study prepared by Monsanto Co. 172 p.

40158801 Barclay J. (1986) Product Chemistry to Support the Registration of the Isopropylamine Salt of N-Phosphonomethylglycine (62% Solution): Product Identity and Composition: Laboratory Project No. MSL-6196. Unpublished study prepared by Monsanto Co. 37 p.

40158802 Barclay, J. (1986) Product Chemistry to Support the Registration of the Isopropylamine Salt of N-phosphonomethylglycine (62% Solution). Analysis and Certification of Product Ingredients: Laboratory Project No. MSL-6197. Unpublished study prepared by Monsanto Co. 61 p.

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40158803 Barclay, J. (1986) Product Chemistry to Support the Registration of the Isopropylamine Salt of N-phosphonomethylglycine (62% Solution). Physical and Chemical Characteristics: Laboratory Project No. MSL-6198. Unpublished study prepared Monsanto Co. 16 p.

40405401 Hirsch, R. ; Augustin, D. (1987) Nitrosamine Analyses of Roundup Herbicide, Rodeo Herbicide, MON 0139 and Polado Technical: Laboratory Project ID R. D. No. 835. Unpublished study prepared by Monsanto Ag. Co. 212 p.

41096101 Leiber, M. (1988) Vapor Pressure Determinations for Glyphosate and MON-7200/15100; Project No. MSL-7642; R.D. No. 924. Unpublished study by Monsanto Agricultural co. 59 p.

41886101 LaMonica, R. (1991) Guideline Series 63-20. Corrosion Characteristics. Study No. 0463-91-5-D prepared by Monsanto Agricultural Company. 23 p.

Agency Memoranda:

CBRS Nos.	1686, 1687
Subject:	PP#6F3380/6H5502. Glyphosate (Roundup®) in or on Soybeans. Amendment of 9/18/86 (Acc. #263795 and #262896).
From:	W. Chin
To:	R. Taylor and Toxicology Branch
Dated:	7/6/87
MRID(s):	00161333

CBRS Nos.	2346, 2347
Subject:	PP#6F3380/6H5502. Glyphosate in/on Soybeans. Amendment from Monsanto 2/20/87.
From:	J. Stokes
To:	R. Taylor and Toxicology Branch
Dated:	9/1/87
MRID(s):	40155801, 40155802, 40155803

CBRS No.	3007
Subject:	PP#6E3424: Re-evaluation of Nitrosamine Contaminants in Glyphosate Products.
From:	W. Chin
To:	H. Jamerson and Toxicology Branch
Dated:	2/25/88
MRID(s):	40405401

CBRS No.	None
Subject:	Glyphosate Product Chemistry and Residue Chemistry Registration Standard Update.
From:	R. Schmitt
To:	L. Rossi and R. Engler
Dated:	4/26/90
MRIDs:	00161333, 40155801, 40155802, 40155803, 40405401

CBRS No.	7742
Subject:	Isopropylamine (IPA) Glyphosate. Product Chemistry Data (Storage Stability and Vapor Pressure) for Monsanto Product(s).
From:	K. Dockter
To:	L. Rossi and R. Engler
Dated:	5/31/91
MRIDs:	41395605, 40559301, 41096101

TABLE A. GENERIC DATA REQUIREMENTS FOR THE MONSANTO UNREGISTERED GLYPHOSATE ACID TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirements	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)? Yes	No	Bibliographic Citation[3]
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-2. Beginning Materials and Production Process	TGAI	R		X	00161333
61-3. Formation of Impurities	TGAI	R		X	00161333
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis of Product Samples	TGAI	CR		X	00161333 40405401
Physical and Chemical Characteristics					
63-2. Color	TGAI	R		X	00161333
63-3. Physical State	TGAI	R		X	00161333
63-4. Odor	TGAI	R		X	001613333
63-5. Melting Point	TGAI	N/A[4]		X	
63-6. Boiling Point	TGAI	R		X	00161333

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)? Yes	No	Bibliographic Citation[3]
63-7. Density, Bulk Density, or Specific Gravity	TGAI	R		X	001613333
63-8. Solubility	TGAI or PAI	R		X	00161333
63-9. Vapor Pressure	TGAI or PAI	R		X	41096101
63-10. Dissociation Constant	TGAI or PAI	R		X	00161333
63-11. Octanol/Water Partition Coefficient	PAI	CR		X	00161333
63-12. pH	TGAI	CR		X	00161333
63-13. Stability	TGAI	R		X	00161333
Other Requirements					
64-1. Submittal of Samples	TGAI or PAI	CR		X[5]	

[1]Data requirements pertain to the Monsanto unregistered glyphosate acid technical. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Monsanto Glyphosate Manufacturing Use Products."

[2]Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; MP = manufacturing use product.

TABLE A. (Continued)

[3]These references were submitted in response to the Glyphosate Guidance Document (6/86). Underlining indicates documents that have been reviewed for this single action review.

[4]N/A = not applicable, product is a liquid.

[5]If samples are needed, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE MONSANTO GLYPHOSATE MANUFACTURING-USE PRODUCTS.[1]

Data Requirements	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)? Yes	No	Bibliographic Citation[3]
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-1. Product Identity and Disclosure of Ingredients	MP	R		X	00161333 40155801
61-2. Beginning Materials and Production Process	MP	R		X	00161333 40155801
61-3. Formation of Impurities	MP	R		X	00161333 40155801
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis of Product Samples	MP	CR		X	00161333 40155802 40405401
62-2. Certification of Ingredient Limits	MP	R		X	00161333 40155802
62-3. Analytical Methods to Verify Certified Limits	MP	R		X	00161333 40155802
Physical and Chemical Characteristics					
63-2. Color	MP	R		X	00161333 40155803
63-3. Physical State	MP	R		X	00161333 40155803

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)? Yes	No	Bibliographic Citation[3]
63-4. Odor	MP	R		X	00161333 40155803
63-7. Density, Bulk Density, or Specific Gravity	MP	R		X	00161333 40155803
63-12. pH	MP	CR		X	00161333 40155803
63-14. Oxidizing or Reducing Action	MP	CR		X	00161333 40155803
63-15. Flammability	MP	CR		X	00161333 40155803
63-16. Explodability	MP	R		X	00161333 40155803
63-17. Storage Stability	MP	R	X[4]		
63-18. Viscosity	MP	CR		X	00161333 40155803
63-19. Miscibility	MP	CR		X	00161333
63-20. Corrosion Characteristics	MP	R		X	41886101
Other Requirements					
64-1. Submittal of Samples	MP	CR		X[5]	

(Continued, footnotes follow)

TABLE B. (Continued)

[1]Data requirements pertain to the Monsanto 62% IPA salt FI (EPA Reg. No. 524-333) and the unregistered acid technical. Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Monsanto Unregistered Glyphosate Acid Technical Grade of the Active Ingredient."

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the Glyphosate Guidance Document (6/86). Underlining indicates documents that have been reviewed for this single action review.

[4]Monsanto has not responded to the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-17) for the 62% IPA salt FI (EPA Reg. No. 524-333) regarding storage stability. This requirement remains outstanding. For details of the specific requirement, the registrant is referred to the Pesticide Assessment Guidelines Subdivision D - Product Chemistry Series 63. Additional data are required.

[5]If samples are needed, the Agency will request them.

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