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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3380/6H5502. Glyphosate (Roundup®) in or on Soybeans. Amendment of 9/18/86 (Acc. #263795 and #262896; RCB #1686 and #1687).

FROM: W. T. Chin, Chemist *W. T. Chin*
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Philip V. Errico, Section Head *Philip V. Errico*
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Robert J. Taylor, PM #25
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Monsanto Agricultural Products Company has proposed to increase the tolerances as established under 40 CFR §180.364 for the combined residues of the herbicide glyphosate [N-(phosphonomethyl)glycine] and its metabolite aminomethylphosphonic acid (AMPA) for soybeans at 20 ppm (now 6 ppm), soybean hay at 200 ppm (now 15 ppm) and for soybean hulls at 100 ppm (now 20 ppm) under 40 CFR §561.253 based on preharvest applications.

RCB has recommended against the proposed tolerances for the deficiencies specified in Conclusions 1b, 2a, 2b, 2c, 3b, 5, and 6a of W. T. Chin's 10/24/86 memo.

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In response to the deficiencies identified above, Thomas F. Armstrong of Monsanto Agricultural Products Company submitted an amendment which includes a cover letter dated 9/18/86 to Robert J. Taylor of EPA; revising Sections B and F; a volume of updated Product Chemistry data of glyphosate technical and its end-use product, Roundup® Herbicide (Acc. #263795); and a report entitled "Validation of New Residue Method and Re-analysis of Glyphosate in Water" (Acc. #262896). The deficiencies specified above are restated below, followed by the petitioner's responses and RCB's comments/conclusions.

Deficiency "1b"

"The petitioner has to fill the following data gaps specified in the Product Chemistry Chapter of Glyphosate Registration Standard issued by RCB on 7/15/85: §61-2. Description of beginning materials and manufacturing process. §61-3. Discussion of formation of impurities. §62-1. Preliminary analysis of products. §62-2. Certification of ingredient limits. §62-3. Analytical methods to verify certified limits. §63-4. Oder. §63-7. Density. §63-8. Solubility. §63-9. Vapor pressure. §63-11. Octanol/water partition coefficient. §63-12. pH and §63-13. Stability."

The Petitioner's Response to Deficiency "1b"

In order to fill the data gaps identified above, the petitioner submitted a volume of data (Acc. #263795) composed of two parts: Part A: "Product Chemistry Data to Support the Continued Registration of Glyphosate, N-(Phosphonomethyl)glycine, and Part B: "Product Chemistry Data to Support Registration of Mon-2139 (Roundup® Herbicide), A Formulation of N-(Phosphonomethyl)glycine in the Form of Its Isopropylamine Salt."

RCB's Comment/Conclusion on the Petitioner's Response to Deficiency "1b"

In Part A of Acc. #263795, a complete Product Chemistry Chapter of the Glyphosate Registration Standard was submitted. These data were prepared in accordance with EPA's Pesticide Assessment Guidelines, Subdivision D, Product Chemistry (October, 1982). RCB concludes that these data are adequate to fill all the data gaps identified in deficiency "1b".

The data of §63 Physical and Chemical Characteristics of Glyphosate Technical are shown in Appendix 1; and the Generic Data Requirement for Glyphosate Technical is up-dated and shown in Appendix 2.

In Part B of Acc. #263795, Product Chemistry data of an end use product of glyphosate, Mon-2139 (Roundup® Herbicide), was provided. It has been agreed that RD will do the Product Chemistry review for end use products.

Deficiency "2a"

"The petitioner is requested to submit detailed information regarding specific rates and application instructions for the current petition. The complete Roundup® label should be provided."

The Petitioner's Response to Deficiency "2a"

The petitioner did submit a brochure entitled "Roundup® Herbicide, Complete Discussion for Use" but did not give specific rates and application instructions for the current petition.

RCB's Comment/Conclusion on the Petitioner's Response to Deficiency "2a"

RCB concludes that deficiency "2a" is still outstanding.

Deficiency "2b"

"In the submitted "Directions for Use", the sentence "Do not feed or graze treated areas within 25 days after preharvest application" should be modified to read "Do not graze or harvest treated crop for livestock feed within 25 days of last preharvest application."

The Petitioner's Response to Deficiency "2b"

The petitioner submitted a revised Section B which contains the following statement: "After preharvest application, do not feed or graze soybean hay or forage from the preharvest treated area." The petitioner also mentioned in the cover letter: "This proposed preharvest label restriction is realistic because the grower can control it and preharvest treated soybean forage or hay is not of a major economic importance (see Table II of subdivision O, Residue chemistry guidelines, page 54)."

RCB's Comment/Conclusion on the Petitioner's Response to Deficiency "2b"

RCB has no doubt that the grower can control it. However, the intent of the recommended restriction is not to restrict any feeding of treated soybean forage and hay, but only to restrict the harvesting

for livestock feed within 25 days after treatment. With a clarification requested under deficiency "2c" below, adequate tolerances could be established or are established for treated soybean plant material. In the "Directions for Use", the following restriction should be specified: "Do not graze or harvest treated crop for livestock feed within 25 days of last preharvest application." Therefore, RCB concludes that deficiency "2b" is still outstanding.

Deficiency "2c"

"The so-called "soybean hay" which the petitioner is proposing a tolerance at 200 ppm is understood to be "soybean straw", the dried plant residue remaining on the ground after harvest of the soybeans. The petitioner is requested to clarify this point by submitting a revised Section F."

The Petitioner's Response to Deficiency "2c"

The petitioner submitted a revised Section F to amend the 2/21/86 petition by deleting the 200 ppm glyphosate soybean hay tolerance request.

RCB's Comment/Conclusion on the Petitioner's Response to Deficiency "2c"

In the revised Section F, the petitioner failed to clarify the term "soybean straw" discussed above. The petitioner is requested to clarify "soybean straw" and should establish a tolerance for it. RCB, therefore, concludes that deficiency "2c" is still outstanding.

Deficiency "3b"

"As indicated in Glyphosate Registration Standard (7/15/85), metabolism studies using ruminants and poultry are required. Animals must be dosed for at least three days with ¹⁴C-glyphosate at a concentration in the total diet which will result in sufficient residues in the tissues, milk, and eggs for characterization. Animals must be sacrificed within 24 hours of the final dose (milk and eggs must be collected twice daily). The distribution, characterization, and quantification of residues must be determined in eggs, milk, muscle, fat, kidney and liver."

The Petitioner's Response to Deficiency "3b"

In this amendment, no information responding to deficiency "3b" was submitted.

RCB's Comment/Conclusion on the Petitioner's Response to Deficiency "3b"

RCB concludes that deficiency "3b" is still outstanding.

Deficiency 5

"Since the field trials were conducted in 1979 and the dates of analysis of the samples are not given, RCB cannot determine the storage periods of the samples analyzed. Therefore, RCB is unable to determine the adequacy of the residue data submitted for the requested tolerance changes without the support of adequate storage stability data. The petitioner should submit information on the conditions and period of sample storage."

The Petitioner's Response to Deficiency 5

In this amendment, no information responding to deficiency 5 was submitted.

RCB's Comment/Conclusion on the Petitioner's Response to Deficiency 5

RCB concludes that deficiency 5 is still outstanding.

Deficiency "6a"

"Previous feeding studies on cattle, poultry and swines using a 3:1 ratio of glyphosate and AMPA at dietary levels of 10, 30 and 100 ppm indicated that no detectable (<0.025 ppm) residues of glyphosate and AMPA were found in milk or eggs and none (<0.05 ppm) were found in muscle or fat of cattle, swine or poultry from the 100 ppm feeding level (PP#5F1536). However, if the metabolism studies requested in Conclusion "3b" above identify additional residues of toxicological concern, new feeding studies may be needed."

The Petitioner's Response to Deficiency "6a"

In this amendment, no information responding to deficiency "6a" was submitted.

RCB's Comment/Conclusion on the Petitioner's Response to Deficiency "6a"

RCB concludes that deficiency "6a" is still outstanding.

OTHER CONSIDERATIONS

A report (Acc. #262896) entitled "Validation of New Residue Method and Re-analysis of Glyphosate in Water" was also submitted in the current amendment. In the cover letter (5/19/86) of this report, Thomas F. Armstrong of Monsanto indicates that they request EPA to use this new method to support their glyphosate residue analysis and that "Monsanto also gives permission for this HPLC method to be made available in PAM for enforcement purposes."

The petitioner has submitted this analytical method in response to conclusion 4a in RCB's 10/24/86 memo (W. T. Chin, PP#6F3380/6H5502). This method is considered better and faster than the present enforcement method, and a MTO will be requested. A tolerance recommendation will not be held up for the results on this MTO.

RECOMMENDATION

RCB continues to recommend against the proposed increase in the established tolerances for the combined residues of glyphosate and AMPA in soybeans at 20 ppm (now 6 ppm), soybean hay at 200 ppm (now 15 ppm) and soybean hulls at 100 ppm (now 20 ppm) for the deficiencies identified in the Conclusions 2a, 2b, 2c, 3b, 5 and 6a of W. T. Chin's 10/24/86 memo.

Attachments: Appendix 1: §63, Physical and Chemical Characteristics of Glyphosate Technical

Appendix 2: Generic Data Requirements for Glyphosate Technical

cc with attachments: R.F., Circu., EAB, EEB, Glyphosate Reg. Std., PP#6F3380/6H5502, PM#25, W.T.Chin, W.J.Boodee, TOX and PMSD-ISB

RDI: P.V.Errico(6/30/87), R.D.Schmitt(6/30/87)

TS-769: RCB: CM#2, RM812,557-4352, W.T.Chin,wc(6/30/87)

(Cited from Acc. #263795, p. 49-51)

§63. Physical and Chemical Characteristics of Glyphosate Technical

<u>Guideline</u>	<u>Test</u>	<u>Glyphosate</u>
63-2	Color	White (TGAI)
63-3	Physical state	Powder (TGAI)
63-4	Odor	None (TGAI)
63-5	Melting point	200°C with decomposition (FAI)
63-6	Boiling point	Not required since it is not a liquid at room temperature
63-7	Bulk density	0.50 g/mL (TGAI)
63-8	Solubility - in water	1.16 g/100 mL @ 25°C (FAI)
	- in organic solvents	Insoluble in acetone, benzene and ethanol (FAI)
63-9	Vapor pressure	1.84×10^{-7} mmHg @ 45°C (FAI)
63-10	Dissociation constant	pKa ₁ =2.6 pKa ₂ =5.6 pKa ₃ =10.6 (TGAI)
63-11	Octanol/water partition coefficient	0.0006-0.0017 (FAI)
63-12	pH	2.5, 1% solution (TGAI)
63-13	Stability	No assay loss when stored with Fe, Zn or Cu or when stored in sunlight or @ 50°C (TGAI)
63-14	Oxidizing or reducing action	No reaction with H ₂ O, CO ₂ , (NH ₄) ₂ PO ₄ and Zn; oxidized by KMnO ₄
63-15	Flammability	Not combustible (TGAI)
63-16	Explosibility	Not explosive (FAI)
63-17	Storage stability	No assay change after 1 year storage (TGAI)
63-18	Viscosity	Not required since it is a solid.
63-19	Miscibility	Not required since it is not an emulsifiable liquid.
63-20	Corrosion characteristics	Not corrosive to polyethylene containers (FAI)
63-21	Dielectric breakdown voltage	Not required for FAI or TGAI

TABLE 2. GENERIC DATA REQUIREMENTS FOR GLYPHOSATE TECHNICAL (Updated on 9/18/86)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Ref. Cited
			[YES]	[NO]	
<u>Product Identity and Composition</u>					
§61-1. Product identity and disclosure of ingredients	TGAI	R	[]	[X]	Acc.#263795
§61-2. Description of beginning materials and manufacturing process	TGAI	R	[]	[X]	Acc.#263795
§61-3. Discussion of formation of impurities	TGAI	R	[]	[X]	Acc.#263795
<u>Analysis and Certification of Product Ingredients</u>					
§62-1. Preliminary analysis	TGAI	R	[]	[X]	Acc.#263795
§62-2. Certification of ingredient limits	TGAI	R	[]	[X]	Acc.#263795
§62-3. Methods to verify certified limits	TGAI	R	[]	[X]	Acc.#263795
<u>Physical and Chemical Characteristics</u>					
§63-2. Color	TGAI	R	[]	[X]	Acc.#263795
§63-3. Physical state	TGAI	R	[]	[X]	Acc.#263795
§63-4. Odor	TGAI	R	[]	[X]	Acc.#263795
§63-5. Melting point	TGAI	R	[]	[X]	Acc.#263795
§63-6. Boiling point	TGAI	NA	[]	[X]	Acc.#263795
§63-7. Specific gravity	TGAI	R	[]	[X]	Acc.#263795
§63-8. Solubility	TGAI/PAI	R	[]	[X]	Acc.#263795
§63-9. Vapor pressure	TGAI/PAI	R	[]	[X]	Acc.#263795
§63-10. Dissociation constant	TGAI/PAI	NA	[]	[X]	Acc.#263795
§63-11. Octanol/water partition coef.	TGAI/PAI	R	[]	[X]	Acc.#263795
§63-12. pH	TGAI	R	[]	[X]	Acc.#263795
§63-13. Stability	TGAI	R	[]	[X]	Acc.#263795

TGAI: Technical grade active ingredient (94.0%-99.8% pure); PAI: Pure active ingredient; R: Required; NA: Not applicable.