5-17-76

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Temporary and food additive tolerances for the combined residues of the herbicide N-phosphonomethylglycine (glyphosate) and its metabolite, aminomethylphosphonic acid. Also, label safety review for an Experimental Use Permit.

DATE: MAY 17 1976

FROM: Toxicology Branch

TO: Libby Zink (SRS)

Petitioner: Monsanto Agricultural Prod. Co.
800 N. Lindbergh Blvd.
St. Louis, Missouri

Pesticide Petition No. 6G1757

File Symbol No. 524-EUP

Food Additive Petition No. 6H5125

Chemical Name: Isopropylamine salt of N-phosphonomethylglycine

Common Name: Glyphosate (Isopropylamine salt)

Product Name: CP70139

Proposed Temporary Tolerances:

Cotton seed	5.0 ppm
Cotton forage, hay, and trash	20.0 ppm
Soybean grain	10.0 ppm
Soybean forage and hay	10.0 ppm
Liver and kidney of cattle, goats, hogs, horses, poultry, and sheep	0.05 ppm

Proposed Food Additive Tolerance

Soybean hulls	20.0 ppm

RECOMMENDATION:

TOX finds that data supports the proposed temporary tolerances and food additive tolerance.

In reference to the EUP, TOX notes the letter of Robert J. Taylor, PM, 4/5/76 (Reg. No. 524-GRI) that states this formulation (MON 0139) will be tested for eye irritation in our Beltsville, Md., laboratory. The letter also mentioned that eye irritation studies on a very similar formulation indicated Category II (WARNING) requirements. The signal word 'WARNING' will therefore be required for this Experimental Use Permit (524-EUP). Labeling should be revised as per the S-76B enclosure.

EPA Form 1320-6 (Rev. 6-72)

TOX recognizes the possibility that when the registrant requests registration of this product, the signal word 'CAUTION' may be appropriate depending upon results of this Beltsville study.

Furthermore, TOX notes that the label recommendation and proposed program suggest addition of surfactants, anti-foaming agents, and drift control agents to varying degrees. In response, TOX has determined that since they are to be added to the spray use dilution of CP70139, increased irritation potential (surfactant) should be slight. In addition, this is not under our purview because they are not ingredients of the formulated product. On the other hand, if these adjuvants are to be added to this product for registration, toxicology studies for this new formulation must be submitted.

Cholinesterase inhibition data must be submitted for registration (stated to be available in April 7 meeting with R. Coberly). Also, rationale for lack of general organophosphate effects should be submitted in lieu of neurotoxicity study.

Experimental Program:

Request for 850 gallons of CP-70139 for treatment of soybeans and 625 gallons on cotton via the recirculating sprayer system. One to 5 quarts are to be used per acre/treatment. Maximum treatments are 3 applications X 8.0 lb. ae/acre. Calculation based upon:

A. Average of 5 treatments per location

B. 2.0 quarts/acre/treatment

C. 2 repeated applications of treatments/location

D. Treatments applied in 1 acre plots

Glyphosate is a non-selective herbicide (postemergence foliar-applied).

Formulation: CP-70139

Active Ingredient	% by wt.
Glyphosate (N-phosphonomethyl-glycine) isopropylamine salt	53.5%
Inert Ingredients	[redacted]

Note: Formulation does not contain the surfactant [redacted]

Related Petitions:

PP# 4G1444 - Temporary tolerances granted in or on corn, soybeans, and wheat grain, forage, and straw at 0.1 ppm.

PP# 5F1536 - Tolerances proposed at 0.2 ppm in or on forage grasses, soybean forage and hay and 0.1 ppm in or on various grains and soybeans.

PP# 5G1561 - Temporary tolerance requested at 0.1 ppm on grapes.

PP# 5F1560 - Permanent tolerance proposed at 0.1 ppm on grapes.

PP# 5G1523 - TOX recommended favorably for temporary tolerances of 0.2 ppm in or on forage hay, and straw of barley, buckwheat, oats, rice, rye, and sorghum (milo).

and 0.1 ppm in or on grain of barley, buckwheat, oats, rice, rye, and sorghum (milo);

and 0.05 ppm in or on animal liver and kidney.

Toxicological Review

The following studies were reviewed in conjunction with PP No. 5G1523, 8/21/74, R. E. Landolt. See review for additional studies.

Species	Route	Exposure	Formulation	LD_{50} or Dose mg/kg	Observations
Dog	Feeding	90 days	Tech.	0, 200, 600, and 2,000 ppm	'NEL' > 2000 ppm
Rat	Feeding	90 days	Tech.	0, 200, 600, and 2000 ppm	'NEL' > 2,000 ppm
Mouse	Carcinogenic feeding	18 month	Tech.	0, 100, 300 ppm	Not tumorigenic or carcinogenic at 300 ppm
Rat	Reproduction feeding		Tech.	0, 30, 100, 300 ppm	'NEL' > 300 ppm
Mouse	Mutagenic (dominant lethal)		Tech.	5 and 10 mg/kg	Not mutagenic at 10 mg/kg
Rabbit	Teratogenic (day 6-18 gestation)		Tech.	10 and 30 mg/kg	Not teratogenic at 30 mg/kg

Data submitted in conjunction with this action

Species	Test Rate	Formulation	LD_{50} Dose mg/kg	Observations
Rat	Oral	MON-0139 4 lb/gal	13,200	
Rat	Dermal	CP-70139	>7,940	
Rabbit	Dermal Irrit.	CP-70139	None	Not an irritant
Rabbit	Eye Irrit.	CP-70139	10.6/110 at	1 hour (max.)
Rat	Oral	MON-0139	>15,800	Reduced activity
Rabbit	Eye Irrit.	MON-0139	11.0/110 at	1 hour (max.)
Rabbit	Dermal Irrit.	MON-0139	0.6/8.0	

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E for OEP 5/17/76