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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Application for Experimental Permit for Roundup DATE: 6/3/75

FROM: TB

TO: PM

Registration No: 524-EXP-22G

Registrant: Monsanto Co.

Action Requested: Experimental Permit

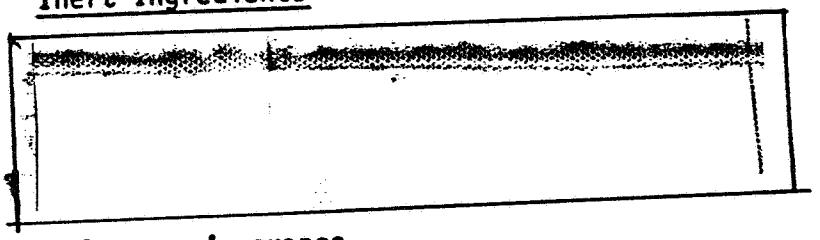
Recommendation: ~~No adverse comment~~ Register with letter
1) Use "~~Caution~~ Danger" as precautionary word.
~~2) Provide sample of formulation for governmental testing~~

Related Petition: 5G1561

Formulation: Roundup

41.0% Glyphosate (N-phosphonomethyl glycine), isopropylamine salt.

Inert Ingredients



INERT INGREDIENT INFORMATION DELETED

Use: Herbicide for use in grapes

Application Rate: one to five quarts per acre

Application Method: Spray

Application Frequency: Not more than three times a year.

Toxicity Data

The following data were submitted with prior registrations.

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

Acute Toxicity

Rat Oral LD_{50}*	4040 mg/kg
Rat Oral LD_{50} (3 lbs/gal)	4900 mg/kg
Rat Oral LD_{50}*	4320 mg/kg
Rabbit Oral LD_{50}*	3800 mg/kg
Rabbit Dermal MLD*	>7940 mg/kg in females >5010 mg/kg in males
Rabbit Dermal MLD (3 lbs/gal)	>7940 mg/kg
Rat Inhalation LC_{50}*	>12.2 mg/L
Rabbit Dermal Irritation*	no irritation was reported
Rabbit Dermal Irritation (3 lbs/gal)	mild irritation
Rabbit Eye Irritation *	no irritation was reported
Rabbit Eye Irritation (3 lbs/gal)	producted severe irritation but data was effected by bacterial infection.
Rabbit Eye Irritation (3 lbs/gal)	produced slight to mild irritation

Subacute Toxicity

Mice Mutagenic*	negative at 10 mg/kg
Rabbit Teratogenic*	negative at 30 mg/kg
90 Day Dog Feeding*	NEL 2000 ppm
90 Day Rat Feeding*	NEL 2000 ppm
21 Day Rabbit Dermal (3 lbs/gal)	NEL <37.9 mg/kg

Special Study

Human Patch Test (3 lbs/gal)	no irritation noted

The following toxicity data were submitted for review to enforce the belief that the eye irritation displayed in a prior study was due to infection rather than the formulation.

* N-phosphonomethyl glycine

Acute Rabbit Eye Irritation (3 lbs/gal)-Younger Lab-3/15/74

Exactly 0.1 ml of the undiluted test material was instilled directly into the conjunctival sac of each of six rabbits.

Results: The formulation produced a PII of 9.1, indicating a slight irritant. No corneal or iris involvement was reported. The conjunctivaewas involved to the extend of severe erythema and moderate edema. All scores were zero at 7 days.

Acute Rabbit Dermal Irritation (3 lbs gal)-Younger Lab 3/15/74

Exactly 0.5 ml of the undiluted test material was applied to the backs of six rabbits. Length of contact was 24 hrs.

Results: A PII score of 1.3 was reported, indicating only slight irritation

Acute Eye Irritation (3 lbs gal)-Younger Lab-3/15/74

Exactly 0.1 ml of the undiluted test material was instilled into the conjunctival sac of each of six rabbits.

Results: The formulation produced a PII of 9.6, indicating a slight irritant. No corneal or iris involvement was reported. The conjuctival was involved to the extend of severe erythema and slight edema. All scores were zero on day 7.

Conclusion: Three of the four eye irritation studies provided by the registrant indicate an overall PII of under 10, (slight irritation). The corneal opacity observed in the fourth study was reported as being caused by infection rather than chemical action.

In the interest of obtaining another insight into the ocular effects caused by this formulation, this reviewer requests that a sample of the formulation being registered be tested at our government testing laboratory in Beltsville. The sample should also be identified quantitatively.

Robert D. Coberly, Biologist
Toxicology Branch
Registration Division

cc: Branch Reading file
RCoberly:ir:6/3/75
Initial O.E. Paynter