

US EPA ARCHIVE DOCUMENT

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SUBJECT: Application for registration of glyphosate (Roundup) formulation MON 0139 DATE: July 22, 1975

FROM: TB

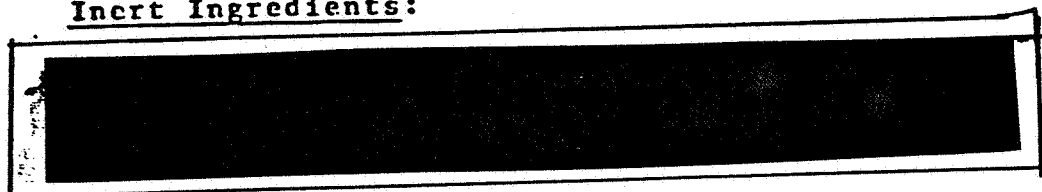
TO: Mr. Robert Taylor, PM 25

Registration #: 524-GRI  
 Related petitions: 5G1523; 5F1536  
 Formulation:

Active Ingredient:

Glyphosate (N-phosphonomethylglycine),  
 isopropylamine salt 53.5%

Inert Ingredients:



Recommendation:

Data on file for the 41% Roundup formulation (Reg.#: 524-308) were used to support the subject formulation. TB has no adverse comment regarding this registration.

The subject formulation (MON 0139) is identical to the Roundup formulation already registered (Reg.# 524-308), with the single exception that MON 0139 does not contain the surfactant [redacted]. Toxicity data on file was obtained with an submitted in support of the formulation with [redacted]. If the removal of the surfactant has any effect upon the toxicity of the formulation, one would expect such removal to decrease the toxicity. Therefore the data on file may be considered valid for evaluating the proposed formulation (eventually to be considered for home use).

INERT INGREDIENT INFORMATION DELETED

Pertinent acute data appear below and pertain to the formulation plus surfactant. (R. Landolt, 5G1523; 8-21-74)

Acute Oral LD50 (rat) - 4040 (3660-4460) mg/kg

Toxic signs: lethargy, diarrhea, weakness, collapse, hemorrhagic lungs and liver, GI inflammation.

Acute Dermal LD50 (rabbit) - >7940 mg/kg

Acute Inhalation (rat - 4 hr. exposure) - no signs of systemic toxicity at 12.2 mg/l

Primary Skin Irritation (rabbit - 24-hr. exposure) (0.5 ml)  
Mild Irritant. Draize score: 2.3/8.0

Eye Irritation (rabbit - 15 min. exposure) (0.1 ml)

Mild Irritant. Max. score 16/110 at 1 hr. Normal in 7 days.

Human Subacute Dermal (patch test)  
15 exposures; 1:9 dilution of 30% formulation.

Results: non-irritant; non-sensitizer.

New data submission:

Acute Oral LD50 (MON 0139) -

13,200 (11,750-14,900) mg/kg

Toxic signs: lung hyperemia, slight liver discoloration, GI inflammation.

*Diana M. Reisa*

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cc: Branch Reading File:DMReisa:gac:7/22/75:  
Initial:O.E. Paynter

*OEPS/11175*