

SUBJECT:

DATE: February 11, 1974

FROM:

TO: Mr. Lee TerBush, Acting Chief
Coordination Branch
Registration Division

Registration No.: 524-GNI

Product Name: Roundup

Mr. L.H. Hannah's letter of 11/5/73 protested our recommendation that the signal word "Warning" on the label of the 3 lbs/gal formulation (CP-70139) be changed to "Danger".

Our action in this case was based on the degree of ocular irritation at various periods during the ten day study. As noted in my review, a irritation score of 64.3 was recorded on day seven in the animals receiving the undiluted material with no post administration treatment. It is also pointed out that on day ten, three days past scoring day — adverse eye irritation was still in evidence. Mr. John B. Ritch Jr.'s "Policy for Assigning Categories of Hazard to the Eyes for Irritating and Corrosive Substance" states in part, "Danger" - This signal word, without skull and crossbones is required when data indicate that 100 mg or 0.10 ml of the undiluted product when tested in rabbit eyes either with or without washing is corrosive or causes corneal opacity to the extent that the damage is not completely reversible within seven days.

If the registrant desires to reproduce the eye irritation study under question, we will be happy to review the additional data. The registrant's statement, "This we would attribute, at least in part, to a secondary infection in the previously irritated eyes" when referring to score of 64.3 at 168 hours cannot be quantitatively used to reduce the category of irritation.

Conclusion

Our May 24, 1973 recommendation concerning the use of the precautionary word danger rather than the word warning remains unchanged.


Robert D. Coberly, Biologist
Toxicology Branch
Registration Division

cc: Division File, Branch File

RDCoberly/km 02-11-74