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

SEP 29 1981

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

PR NOTICE 81-3
NOTICE TO MANUFACTURERS, FORMULATORS, DISTRIBUTORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticides

SUBJECT: Label Improvement Program: Change in Test Methods for and Categorization of Eye Irritation

This Notice announces EPA's adoption of new testing methods for, and categorization of, eye irritation. Registrants will not be required to adhere to this policy until reregistration. Therefore, until that time, no action on the part of registrants to relabel current products will be required. Applicants, although not required, are encouraged to label their products in accordance with the new criteria in order to avoid relabeling for this purpose at the time of reregistration.

I. Background

In 1975, EPA established in 40 CFR 162.10(h) toxicity categories which are based on the results of acute toxicity tests. The criteria for eye irritation categorization in the 1975 regulation are based on a seven-day observation period.

In 1977, the National Academy of Science (NAS) published a revised version of its 1964 document entitled "Principles and Procedures for Evaluating Toxicity of Household Substances" commonly known as the NAS Publication 1138. NAS concluded, on the basis of studies submitted, that for adequate evaluation of the effects produced when chemicals are introduced into the eyes of animals, an observation period of three weeks was necessary. In addition to a classification scheme for eye irritation severity based on a three-week observation period, the NAS recommended that the reversibility of the effects within that period be considered in classifying substances.

II. Change in Methodology and Criteria for Toxicity Categories for Eye Irritation

The Agency is adopting the NAS recommendations and revising its 1975 eye irritation criteria accordingly. Studies will be evaluated, and categories assigned, based on a twenty-one day observation period including reversibility of effects over that period. Toxicity categories for eye irritation are now defined as follows:

I	II	III	IV
Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or irritation clearing in 8-21 days	Corneal involvement or irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours

III. Change in Precautionary Labeling for Eye Irritation

The Agency has also revised its precautionary labeling statements for eye irritation to reflect NAS criteria. These statements are in the Appendix.

IV. Optional Retesting and Amended Registrations

1. Registrants are not required at this time to retest their products or submit applications for amended registration. Only when a registration standard is issued for the active ingredient in a product will registrants be required to comply with this policy.

2. In certain cases registrants may have previously submitted studies that justify reclassification of products to a lower toxicity category (e.g., I to II, or II to III) due to the reversibility of effects. In such cases registrants are encouraged to refer the Agency to these existing tests and amend their labels accordingly.

3. Any registrant may conduct a new eye irritation study with a twenty-one day observation period and request that his product be recategorized according to the new criteria. This course might be chosen if the registrant believes that the twenty-one day observation period will permit assignment to a lesser toxicity category (e.g., I to II).

4. If a registrant wishes to have the Agency consider new data on eye irritation, and concomitant label changes, an application for amended registration must be submitted to the appropriate Product Manager in the Registration Division. This may be done at any time. An amended registration for this purpose must contain:

   a. EPA form 8570-11 (Application for Amended Registration);

   b. Two copies of new eye irritation studies; and

   c. Two copies of draft labeling incorporating revised precautionary statements. The Appendix to this notice provides precautionary statements that are to be used for this purpose.

V. Implementation

A. Testing

Applicants/registrants may proceed at this time with eye irritation studies based on the new testing criteria. The observation period must be such as to allow a conclusive demonstration as to whether eye effects are reversible within or persistent beyond 21 days.

B. Categorization of Products

1. The Agency will begin immediately to evaluate products according to the new criteria.

2. However, in many instances, new data will not be available immediately. Therefore, in the interim, products will be categorized on the basis of data presently available. That is, if

all effects are reversible within 7 days, the products will be assigned to Toxicity Category III. If any effects persist beyond 7 days, the product will be assigned to Toxicity Category II or I. No product, however, will be assigned to Toxicity Category II based on a study terminated on the 7th day, since the Agency is unable to distinguish Category I from II on the basis of seven-day studies.

VI. Further Information

For further information on the revised testing methodology, persons may contact Dr. Reto Engler, Registration Division (TS-767C), EPA, 401 M Street, S.W., Washington, DC 20460, phone number 202-557-7161.

For information on applications for amended registration, registrants may contact the appropriate Product Manager in the Registration Division.

Douglas D. Campt
Director
Registration Division (TS-767C)

APPENDIX

LABEL STATEMENTS REGARDING EYE IRRITATION HAZARDS DUE TO PESTICIDES

TOXICITY CATEGORY	SIGNAL WORD	SKULL AND CROSSBONES & "POISON" REQUIRED	PRECAUTIONARY STATEMENTS	PRACTICAL TREATMENT
I Corrosive; (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days.	DANGER	No	Corrosive.* Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear (goggles, face shield, or safety glasses).** Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.	If in eyes: Flush with plenty of water. Get medical attention. If swallowed: drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
II Corneal involvement or irritation clearing in 21 days or less.	WARNING	No	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear (goggles, f ce shield, or safety sses).** Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.	Same as above except omit NOTE TO PHYSICIAN statement.
III Corneal involvement or irritation clearing in 7 days or less.	CAUTION	No	Causes (moderate) eye injury (irritation). Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.	If in eyes: Flush with plenty of water. Get medical attention if irritation persists.
IV Minimal effects clearing in less than 24 hours.	CAUTION	No	None required.	None required.

*The term "corrosive" may be omitted if the product is not actually corrosive.

**Choose appropriate form of eye protection. Recommendation for goggles or face shield is more appropriate for industrial, commercial, or non-domestic uses. Safety glasses may be recommended for domestic or residential uses.