







"Acute Eye Irritation/Corrosion"

For some substances shown to be irritating by this test, additional tests using rabbits with eyes washed soon after instillation of the substance may be indicated. In these cases it is recommended that 6 rabbits be used. Four seconds after instillation of the test substance, the eyes of 3 rabbits are washed, and 30 seconds after instillation the eyes of the other 3 rabbits are washed. For both groups, the eyes are washed for 5 minutes using a volume and velocity of flow which will not cause injury.

° C l i n i c a l   o b s e r v a t i o n s  
a n d   s c o r i n g

The eyes should be examined at 1, 24, 48 and 72 hours. If there is no evidence of irritation at 72 hours the study may be ended. Extended observation may be necessary if there is persistent corneal involvement or other ocular irritation in order to determine the progress of the lesions and their reversibility or irreversibility. In addition to the observations of the cornea, iris and conjunctivae, any other lesions which are noted should be recorded and reported. The grades of ocular reaction (Table I) should be recorded at each examination.

Examination of reactions can be facilitated by use of a binocular loupe, hand slit-lamp, biomicroscope, or other suitable devices. After recording the observations at 24 hours, the eyes of any or all rabbits may be further examined with the aid of fluorescein.

The grading of ocular responses is subject to various interpretations. To promote harmonization and to assist testing laboratories and those involved in making and interpreting the observations an illustrated guide in grading eye irritation should be used. (Such an illustrated guide is in use in the United States and can be obtained from the Consumer Product Safety Commission, Washington D.C.)

3. D A T A   A N D   R E P O R T I N G

° T r e a t m e n t   o f   r e s u l t s

Data may be summarised in tabular form, showing for each individual animal the irritation scores at the designated observation time; a description of the degree and nature of irritation; the presence of serious lesions and any effects other than ocular which were observed.

TABLE 1: GRADES FOR OCULAR LESIONS

CORNEA	CONJUNCTIVAE
Opacity : degree of density (area most dense taken for reading).	Redness (refers to palpebral and bulbar conjunctivae, cornea and iris).
No ulceration or opacity ..... 0	Blood vessels normal ..... 0
Scattered or diffuse areas of opacity (other than slight dulling of normal lustre), details of iris clearly visible ..... 1*	Some blood vessels definitely hyperaemic (injected)..... 1
Easily discernible translucent area, details of iris slightly obscured ..... 2*	Diffuse, crimson colour, individual vessels not easily discernible ..... 2*
	Diffuse beefy red ..... 3*
Nacrous area, no details of iris visible, size of pupil barely discernible ..... 3*	Chemosis: lids and/or nictating membranes
Opaque cornea, iris not discernible through the opacity ..... 4*	No swelling ..... 0
	Any swelling above normal (includes nictating membranes) ..... 1
IRIS	Obvious swelling with partial eversion of lids ..... 2*
Normal ..... 0	Swelling with lids about half closed ..... 3*
Markedly deepened rugae, congestion, swelling, moderate circumcorneal hyperaemia, or injection, any of these or combination of any thereof, iris still reacting to light (sluggish reaction is positive) ..... 1*	Swelling with lids more than, half closed ..... 4*
No reaction to light, haemorrhage, gross destruction (any or all of these) ..... 2*	

\* Starred figures indicate positive effect

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° E v a l u a t i o n o f t h e r e s u l t s

The ocular irritation scores should be evaluated in conjunction with the nature and reversibility or otherwise of the responses observed. The individual scores do not represent an absolute standard for the irritant properties of a material. They should be viewed as reference values and are only meaningful when supported by a full description and evaluation of the observations.

° T e s t r e p o r t

The test report should include the following information:

- species/strain used;
- physical nature and, where applicable, concentration and pH value for the test substance;
- tabulation of irritant/corrosive response data for each individual animal at each observation time (e.g. 1, 24, 48 and 72 hours);
- description of any serious lesions observed;
- narrative description of the degree and nature of irritation or corrosion observed;
- description of the method used to score the irritation at 1, 24, 48 and 72 hours (e.g. hand slit-lamp, biomicroscope, fluorescein); and
- description of any non-ocular topical effects noted.

° I n t e r p r e t a t i o n o f t h e r e s u l t s

Extrapolation of the results of eye irritation studies in animals to man is valid only to a limited degree. The albino rabbit is more sensitive than man to ocular irritants or corrosives in most cases. Similar results in tests on other animal species can give more weight to extrapolation from animal studies to man.

Care should be taken in the interpretation of data to exclude irritation resulting from secondary infection.

4. L I T E R A T U R E

(1) WHO Publication: Environmental Health Criteria 6, Principles and Methods for Evaluating the Toxicity of Chemicals. Part II, (in preparation).

(2) United States National Academy of Sciences, Committee for the Revision of NAS Publication 1138, Principles and Procedures for Evaluating the Toxicity of Household Substances, Washington, 1977.

(3) Draize, J.H. Woodward, G. and Calvery, H.O., J. Pharmacol. Exp. Ther. 83 : 377-390, 1944.

(4) Draize, J.H. Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics - Dermal Toxicity, pp. 49-52. Assoc. of Food and Drug Officials of the United States, Topeka, Kansas 1965.

(5) Draize, J.H. The Appraisal of Chemicals in Foods, Drugs and Cosmetics, pp 36-45. Association of Food and Drug Officials of the United States, Austin, Texas 1965.

(6) United States Federal Hazardous Substances Act Regulations. Title 16, Code of Federal Regulations, 38 FR 27012, Sept. 27, 1973; 38 FR 30105, Nov. 1, 1973.

(7) Loomis, T.A. Essentials of Toxicology. 2nd Ed. pp. 207-213. Lea & Febiger, Philadelphia, 1974.

