

Relationship Between Adverse Ocular Effects and Their Reversibility.

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The GHS includes a single category (Category 1) to identify substances that cause corrosive/irreversible effects on the eye in the Draize test. A post-exposure observation period of up to 21 days is required to determine reversibility of any effects. Early termination is considered acceptable under certain circumstances. Using available Draize eye test data (n=3924 rabbits), NICEATM evaluated the relationship between an adverse ocular effect and its reversibility. Individual rabbit CO scores of 4 on days 1, 2, 3, 7, or 14 (n=74 rabbits) resolved 24%, 28%, 15%, 4%, and 3% of the time, respectively, while CO scores of 3 on days 1, 2, 3, 7, or 14 (n=110 rabbits) resolved 40%, 39%, 35%, 11%, and 9% of the time, respectively. Mean CO scores ≥ 3 for days 1, 2, and 3 resolved 18% of the time. With regard to iris effects, an iris score of 2 on days 1, 2, 3, 7, or 14 (n=83 rabbits) resolved 71%, 66%, 57%, 36%, and 7% of the time, respectively. Mean iritis scores ≥ 1.5 on days 1, 2, and 3 resolved 60% of the time. These data should assist in identifying earlier endpoints to terminate ocular toxicity studies sooner, and thus reduce animal pain and distress. Supported by NIEHS contract N01-ES-35504.