

## NICEATM Poster Presentation

### Society of Toxicology 45th Annual Meeting

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#### Evaluation of the Relationship Between *In Vivo* Rabbit Eye Test Scores and Their Reversibility

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The United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) utilizes a single hazard category (i.e., Category 1) to identify substances that cause serious/irreversible effects on the eye, based on results in the Draize rabbit eye test. The GHS mandates that the observation period during the Draize test be sufficient to evaluate reversibility or irreversibility of any observed effects, but not to exceed 21 days post-exposure. Early termination (prior to day 21) is considered acceptable for humane reasons (e.g., severe distress), when a corneal opacity score of 4 is recorded at any time, when at least 2 out of 3 animals tested have a mean score (days 1 to 3) for corneal opacity  $\geq 3$  or iritis  $> 1.5$ , or when reversal of observed effects is established (i.e., zero score for all endpoints). The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) conducted an analysis of available Draize eye test data (n=3924 rabbits) to evaluate the relationship between an adverse ocular effect and reversibility within 21 days. Based on this analysis, individual rabbit corneal opacity scores of 4 on days 1, 2, 3, 7, or 14 (n=74 rabbits) resolved (i.e., reversed to zero within 21 days) 24% (6/19), 28% (8/29), 15% (5/29), 4% (2/49), and 0% (0/69) of the time, respectively, while corneal opacity scores of 3 on days 1, 2, 3, 7, or 14 (n=110 rabbits) resolved 40% (26/65), 39% (29/74), 36% (30/84), 11% (6/56), and 0% (0/39) of the time, respectively. Mean corneal opacity scores  $\geq 3$  for days 1, 2, and 3 resolved 18% (12/65) 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% (53/75), 66% (45/68), 57% (29/51), 36% (16/45), and 7% (2/30) of the time, respectively. Mean iritis scores  $\geq 1.5$  on days 1, 2, and 3 resolved 60% (36/60) of the time. Supported by NIEHS contract N01-ES-35504.

#### **SOT Itinerary Information:**

ID# 909  
Location: Exhibit Hall (Convention Center)  
Date/Time: March 7, 2006 / 9:00 am – 12:00 noon  
Category: Regulatory/Policy, (Alternatives to Mammalian Models)