Topical Anesthetic Pre-treatment in the Draize Eye Test: Impact on Hazard Classification

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The Draize rabbit eye test has been used in ocular hazard evaluations since 1944. To reduce the number of severely irritating or corrosive substances that require animal testing, alternative approaches have been developed (e.g., weight-of-evidence approach). This evaluation assesses the effect of the anesthetic tetracaine hydrochloride on the irritancy potential of 97 proprietary formulations. A sequential testing scheme was used, where the first rabbit did not receive anesthesia. If a rabbit exhibited signs of pain or suffering after formulation administration, subsequent rabbits received anesthetic pre-treatment. Irritancy classifications were assigned to each rabbit according to the EU, EPA, and GHS hazard classification systems. Analyses indicated that rabbits pre-treated with anesthesia produced slightly more severe hazard classification categories than rabbits that were not pre-treated for all three classification systems. However, the differences were not statistically significant ($p > 0.05$). Analyses also indicated that anesthetic pre-treatment did not impact the variability of rabbit irritancy classifications for the same formulation and did not significantly increase the number of days needed for lesions to fully reverse. These findings support the routine use of 0.5% (w/v) tetracaine hydrochloride pre-treatment in the Draize rabbit eye test. Supported by NIEHS contract N01-ES-35504.