TOX-002
Edition: November, 1993

Carbopol® 1382 Polymer Toxicology Studies

The toxicology studies summarized below were performed on EX-182, an experimental copolymer resin polymerized in an ethyl acetate/cyclohexane cosolvent system. Due to the similarity in chemistry of Carbopol® 1382 to EX-182, the toxicology profile is expected to be similar.

Skin Irritation

The potential irritant and/or corrosive effects of EX-182 were evaluated on New Zealand White rabbits. Each of six rabbits received a 0.59 dose of the test article as a dermal application to both an intact and an abraded test site. The dose was held in contact with the skin under a semi-occlusive binder for an exposure period of 24 hours. Following the exposure period, the binder was removed and the remaining test article was wiped from the skin using gauze and distilled water. Test sites were subsequently examined and scored for dermal irritation for up to three days following patch removal.

A very slight erythema was observed on the majority of intact and abraded test sites at the 25-hour scoring interval. By 72 hours, all dermal responses had resolved.

Under the test conditions, EX-182 would be considered to have a negligible irritation potential. The calculated Primary Irritation for EX-182 was 0.42 (maximum possible score 8.0).

Eye Irritation

The potential eye irritant and/or corrosive effects of EX-182 were evaluated in New Zealand White rabbits. Each of nine animals received a 0.021g dose (0.1 ml equivalent) of the test article (i.e., neat powder) in the conjunctival sac of the right eye. The contralateral eye of each animal remained untreated and served as a control. At 30 second postinstillation, both eyes of three rabbits were rinsed with 50 ml of physiological saline (rinse group); no rinsing procedure was utilized on the six remaining rabbits (no rinse group). Test and control eyes were examined for signs of irritation for up to 72 hours following dosing.

In the no rinse group, exposure to the test article produced significant ocular irritation in 3/6 test eyes. Corneal opacity (3/6 eyes) and iritis (1/6 eyes) was observed at the 24 hour scoring interval and resolved completely by 72 hours. Minimal conjunctivitis (conjunctival redness and swelling) was observed in 6/6 test eyes at 24 hours postdose and completely resolved by test termination (72 hours).

In the rinse group, exposure to the test article produced generally less severe responses than that noted in the no rinse group. Iritis was observed in 1/3 eyes at 24 hours and diminished completely at 48 hours. Conjunctivitis was observed in 3/3 eyes at 24 hours and diminished by test termination in 2/3 eyes.

Based on the no rinse test data, EX-182 is considered to be a borderline irritant to the ocular tissue of the rabbit according to the FHSA evaluation criteria.

Human Patch Test

The skin irritation and/or sensitizing potential of EX-182 was evaluated by the intensified version of the Shelanski and Shelanski Human Repeated Insult Patch test.

EX-182 was impregnated into strips of surgical gauze which were then cut into 1" x 1" squares. For each application, a patching device containing one of these squares on its webril pad was moistened and positioned directly on a designated site on the back of each subject with the gauze square in contact with the skin.

EX-182 produced no visible effects in 43 of 54 subjects during the primary irritation/activation test period. Faint or moderate redding (erythema) occurred once in 9 subjects and twice in 2 subjects. These effects would put EX-182 in the category of a very weak skin irritant.

Three of 53 subjects had solitary episodes of faint erythema during the challenge phase. The absence of responses significantly different than those obtained during the initial test phases indicates that EX-182 does not possess a skin-sensitizing potential which can attain clinical status under the test conditions.

It was concluded that the results of this test furnish no basis for contraindicating skin contact with EX-182 under similar or less stringent conditions than those used in this test.

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