TOX-001
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Carbopol® 980 and 981 Polymer Toxicology Studies

The following tests were performed on polymers with chemical compositions representative of Carbopol® 980 and Carbopol 981 polymers. This toxicology data is expected to be predictive of the toxicity of Carbopol 980 and 981.

Human Repeated Insult Patch Tests

Test material was impregnated into a 1" x 1" square piece of surgical gauze and moistened with 0.2 ml distilled water just prior to application to the skin of 54 human volunteers.

In order to evaluate the skin irritation and sensitization potential of this product, a series of 12 applications was conducted with each panelist during the primary/induction phase. On four consecutive days of weeks 1, 2 and 3, the patch containing the test material was applied to its designated site. The patches were removed and the contact sites were examined 24 hours after each application. Following a one week rest period (week 4) a challenge phase was conducted on week 5 with 4 applications of the test material on a virgin site of each volunteer.

The test material produced no visible effects in 41 subjects out of 54 during the primary irritation/ activation period. Faint or moderate reddening of the skin occurred on one occasion in 10 subjects, 2 times on one subject and 4 times on another subject. These effects would put the test material in the category of a weak skin irritant. Two subjects out of 53 displayed solitary episodes of faint or moderate reddening in the challenge phase; however, the investigators concluded they did not display a sensitizing reaction.

It was concluded that the results furnish no basis for contraindicating skin contact with the test material under similar or less stringent conditions than the testing conditions used.

Skin Irritation

The skin irritation potential of the test material was evaluated in rabbits in accordance with FHSH regulations. Each of six rabbits received a 0.5g dose of the test article as a dermal application to both an intact and 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. The test sites were subsequently examined and scored for dermal irritation for up to three days following patch removal.

Although slight well-defined erythema (redness of the skin) was noted at 25 hours, all responses had subsided by the 72-hour observation. No edema (swelling) was noted at any test site.

Under the test conditions, the test material is considered a slight irritant to rabbit skin. The calculated Primary Irritation Index for the test material is 0.58.

Eye Irritation

The eye irritation potential of the test material was evaluated. A standard amount, 0.1 g (or 0.1 ml of the dilute solution) of the test material was administered to groups of six albino rabbits. The respective test material was instilled into the conjunctival sac of one eye of the test animals while the other eye served as a control. The eyes were not washed after instillation. A similar procedure was followed on an additional three animals, with the exception that a saline rinse was used.

In the no-rinse group, the test material produced minimal conjuctivitis in 6 of 6 test animals at 24 hours. Redness and swelling persisted to the study termination (7 days) in 4 of 6 rabbits. Similar responses were seen in the rinse group.

It was concluded that the test material was not considered to be an eye irritant (rabbit) based on the no-rinse group according to FHSA evaluation criteria.

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