TOX-039
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Fixate™ G-100 PR Polymer
Toxicology Profile

The following tests were performed on either one or both of the products SDR EX-752 and EX-SDR 26, experimental acrylic copolymers.

EX SDR-26 is a 100% active dry polymer. SDR EX-752 is a 26% active, water dispersion of the SDR-26 polymer that has been partially neutralized with Amino-methyl propanol.

Acute Dermal Toxicity

A group of ten rats (five males and five females) was given a single 24-hour, semi-occluded dermal application to intact skin. The acute dermal median lethal dose (LD_{50}) of the 100% active polymer in the Sprague-Dawley CD strain rat wa s found to be greater than 2000 mg/kg bodyweight. There were no deaths, and no signs of systemic toxicity noted during the study.

Acute Dermal Irritation

The skin irritation potential of both “neat” and 12% neutralized solutions of the dry form of the polymer were evaluated. The polymer was evaluated using albino rabbits, following the OECD Guidelines for Testing of Chemicals No. 404 “Acute Dermal Irritation/Corrosion” and Method B5 Commission Directive 92/69/EEC.

Prior to application of the test substance, the backs of three rabbits were clipped. In the study of the “neat” material, a 0.5 g sample was moistened with 0.5 ml of distilled water, then applied to the skin of each animal; in the 12%-dispersion study, 0.5 ml of the dispersion was applied to the skin of each animal. The test areas were then covered with gauze patches followed by an impervious material wrapping to hold the patch and sample in place.

At the end of 4 hours, the wrapping was removed and the sites were wiped (not washed). The treated areas were then examined for evidence of primary irritation at 1 hour and 24, 48 and 72 hours. Two of the three animals exposed to the “neat” polymer appeared normal at the 48-hour observation and the remaining treated skin site appeared normal at the 72-hour observation. The “neat” test material produced a primary irritation index of 0.5 and was classified as a mild irritant to rabbit skin according to the Draize classification scheme (maximum score 8.0).

There was no evidence of skin irritation with the 12% neutralized solution of the polymer. The dispersion of test material produced a primary irritation index of 0.0 and was classified as a non-irritant to rabbit skin according to the Draize classification scheme (maximum score 8.0).

Eye Irritation

The eye irritation potential of the polymer and dilute dispersions were assessed using OECD Guideline 405 (1987) and Method B5 Commission Directive 92/69/EEC.

A volume of 0.1 ml of each test material was administered to 3 New Zealand White rabbits. The respective test material was instilled into the conjunctival sac of one eye of the test animals while the other eye served as control. The eyes were not washed after instillation.

The eyes were examined at 1 hour and 24, 48 and 72 hours following treatment, according to the method of Draize.

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The liquid form of the polymer (SDR EX-752), exhibited mild to minimal eye irritation responses and had a maximum group mean scores of 12.7[1] out of a maximum of 110. No corneal or iridial effects were noted. Conjunctival irritation ranged from mild to moderate. All eyes appeared normal at 72-hour observation or earlier.

A 12% dispersion and a 12% neutralized dispersion were classified as minimal irritants with a maximum mean score of 6.0 out of a maximum of 110.

Based on these results the polymer SDR EX-752, was found to not meet the criteria for classification as an irritant according to EU labeling regulations Commission Directive 93/21/EEC.

Human Dermatologic Investigation

The dry polymer was applied to the skin of 107 human volunteers in order to evaluate the skin irritation and sensitization potential of this product. A series of 11 applications (0.2 g) 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. A challenge phase was conducted in week 5, with 4 applications of the test material on a virgin site of each volunteer.

Application of the polymer to the skin of humans did not cause any skin irritation or sensitization. It was concluded that this product should be well tolerated and that the hazard of sensitization is exceedingly small.

[1] Class 4 on a 1 to 8 scale; Kay and Calandra classification system