TOX-080
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Carbopol® Ultrez 20 Polymer Toxicology Studies

CTFA / INCI Name: Acrylates/C10-30 Alkyl Acrylate Crosspolymer

The toxicology studies summarized below were performed on polymers with chemical compositions representative of the Carbopol® Ultrez 20 polymer. Therefore, the toxicology data below is expected to be predictive of the toxicity of the commercial grades of Carbopol Ultrez 20 polymer.

Human Repeated Insult Patch Tests

The test material[1] was applied evenly over 2 cm x 2 cm surgical gauze pads which were moistened with distilled water just prior to application to the skin of 113 human volunteers[2] in order to evaluate its skin irritation and sensitization potential. A series of 12 applications were 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 did not produce any evidence of skin irritation or skin sensitization under the conditions of the test. The investigators concluded that the results furnish no basis for contraindicating skin contact with the test material.

[1] 150 mg of a 10% distilled water paste
[2] 111 subjects participated in the skin irritation and skin sensitization evaluation phases, respectively.

Skin Irritation

The skin irritation potential of the test material was evaluated undiluted in rabbits according to international OECD Guidelines No. 404, 1992; Method B4 of Commission Directive 92/69/EEC. The test material (0.5g of dry polymer, moistened with 0.5 ml distilled water) was applied to the intact skin on each of three animal backs. The dose was held in contact with the skin under a semi-occlusive binder for an exposure period of four hours. Following the exposure period, the binder was removed, and the remaining test article was wiped from the skin using tap water and paper towels. The test sites were subsequently examined and scored for dermal irritation for up to seven days following patch removal.

Under the test conditions, the test material caused mild skin irritation (Primary Irritation Index 0.3).

Eye Irritation

The eye irritation potential of the test material was evaluated undiluted and as a 5% dilution in distilled water according to international OECD Guidelines No. 405, 1987; Method B5 of Commission Directive 92/69/EEC. A standard amount of the test material (0.1 ml or the weight equivalent, 47 mg) was administered to groups of three 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. Under the test conditions, the test material (undiluted) produced moderate corneal irritation, and conjunctival irritation (maximum mean score 37.7 out of 110; class 5 on a 1 to 8 scale) which cleared by the study termination (day 21). The 5% dilution produced moderate conjunctival irritation (maximum mean score 9.3 out of 110; Class 3 on a 1 to 8 scale) and was classified as a minimal irritant.

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