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Carbopol® Style 21 Polymer Toxicology Studies

The toxicology studies summarized below were performed on polymers with chemical compositions representative of the Carbopol® Style 21 polymer. Therefore, the toxicology data below is expected to be valid for the commercial grades of Carbopol® Style 21 polymer.

Human Repeated Insult Patch Tests

The test material (25 mg) 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 140 human volunteers[1] 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]140 subjects were identified for the study and received the baseline exam. 137 subject participated in the induction phase, and 120 participated in the challenge phase.

Skin Irritation

The skin irritation potential of the test material was evaluated undiluted in rabbits according to international OECD guidelines. 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 did not produce any evidence of skin irritation (Primary Irritation Index 0.0).

Eye Irritation

The eye irritation potential of the test material was evaluated undiluted according to international OECD guidelines. A standard amount of the test material (0.1 ml or the weight equivalent, 0.03g) 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 15.3 out of 110 at 1 hour; class 5 on a 1 to 8 scale) which cleared by the study termination (day 7).

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