

Carbopol[®] ETD Polymer Toxicology Studies

The toxicology studies summarized below were performed on polymers with chemical compositions representative of the Carbopol[®] ETD polymer family. Therefore, the toxicology data below is expected to be valid for the commercial grades of Carbopol ETD 2001, 2020 and 2050 polymers.

Human Repeated Insult Patch Tests

Carbopol polymer 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 100 human volunteers in order to evaluate its skin irritation and sensitization potential. 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 Carbopol polymer 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 Carbopol polymers.

Skin Irritation

The skin irritation potential of Carbopol polymers was evaluated undiluted and as a 1% neutralized solution in rabbits according to international OECD guidelines. The test material (0.5 g of dry polymer or 0.5 ml of 1% neutralized solution) 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 4 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.

Although very slight erythema (redness of the skin) and edema (swelling) were noted with the undiluted lots, all responses had subsided by the day 7 observation. Very slight erythema also was noted with one lot of the 1% test solution. However, even with this lot, the observation was limited to one of the three animals and was only seen at the 4 hour observation.

Under the test conditions, Carbopol ETD polymers would be considered a non-irritant to a slight irritant to rabbit skin when undiluted (Primary Irritation Index 0.0 - 1.5), and a non-irritant to a very slight irritant when tested as a 1% solution (Primary Irritation Index 0.0 - 0.1).

Eye Irritation

The eye irritation potential of Carbopol ETD polymer was evaluated undiluted and as a 1% neutralized solution according to international OECD guidelines. A standard amount of the test material (0.1 ml or the weight equivalent, 0.04 g) 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, Carbopol ETD polymers (undiluted) produced slight to moderate corneal irritation, and conjunctival irritation which cleared by the study termination (day 7). Only slight iridal and conjunctival irritation was noted with the 1% solution and all irritation was found to clear by 72 hours.

Note: The 1% solutions were neutralized to pH 6.9 - 7.0.

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