

# Carbopol<sup>®</sup>\* Ultrez 10 NF Polymer Toxicology Studies

The toxicology studies summarized below were performed on polymers with chemical compositions representative of Carbopol<sup>®</sup> Ultrez 10 NF polymer. Therefore, the toxicology data below is expected to be valid for the commercial grades of Carbopol<sup>®</sup> Ultrez 10 NF polymer.

## Human Repeated Insult Patch Tests

Carbopol<sup>®</sup> polymer (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<sup>1</sup> 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 Carbopol<sup>®</sup> 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<sup>®</sup> Ultrez 10 NF polymer.

<sup>1</sup>101 and 110 participated in the skin irritation and skin sensitization evaluation phases, respectively.

## Skin Irritation

The skin irritation potential of Carbopol<sup>®</sup> polymers 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, Carbopol<sup>®</sup> polymers did not produce any evidence of skin irritation (Primary Irritation Index 0.0).

## Eye Irritation

The eye irritation potential of Carbopol<sup>®</sup> polymer 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, Carbopol<sup>®</sup> polymers (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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