

Toxicology Studies of Carbopol[®] Aqua CC Polymer

The toxicology studies summarized below were performed on a polymer with a chemical composition similar to Carbopol[®] Aqua CC polymer. Structure activity assessments of the limited compositional differences indicate that this toxicology data is expected to be predictive of the toxicity of Carbopol Aqua CC polymer.

Acute Oral Toxicity

The oral toxicity of the test material was evaluated in rats according to OECD Guideline 423; Method B1 of Commission Directive 2004/73/EC. The test material was administered orally as a gel in dimethyl sulphoxide to two groups of three female Sprague-Dawley CD strain rats at 2000 mg/kg body weight. Animals were subject to daily observations and weekly determination of body weight. Macroscopic examinations were performed after terminal sacrifice on day 14. No mortality occurred. There were no signs of systemic toxicity or abnormalities detected at necropsy. The oral LD50 value was determined to be greater than 2500 mg/kg bodyweight.

Skin Irritation

The skin irritation of the undiluted test material was evaluated in rabbits according to OECD Guideline No. 404, 1992; Method B4 of Commission Directive 92/69/EEC. The test material (0.5 ml) was applied to the intact skin on the backs of three animals under a semi-occlusive dressing. Four hours after the application of the test material, the patches were removed, and the test material was gently removed from the skin. The test sites were evaluated one hour after removal of the patches and at 24, 48, and 72 hours. The test material produced a primary irritation index score of 0.33 and was classified as negligibly irritating. Therefore, Carbopol Aqua CC polymer is expected to have a low potential to cause skin irritation.

Skin Sensitization

The skin sensitization potential of a number of samples of the test material was evaluated in the mouse using the Local Lymph Node Assay based on the guidelines described in OECD, Section 4, Health Effects, No. 429 (Draft), Paris Cedex, 2000, EC, Council Directive 67/548/EEC, Annex IV C, B.42 (Draft), June 2001 and ICCVAM, NIH publication, No. 99-4494, February 1999. Groups of four mice were treated with the test material a concentrations of 0, 1, 25, and 100% w/v in acetone:corn oil (4:1 v/v) 25 µl/ear by daily application to the dorsal surface of each ear for three consecutive days. Five days following the first topical application, all mice were injected with 25 µl of phosphate buffered saline containing 3H-methyl thymidine via tail vein giving a total dose of 20 uCi to each mouse. A single cell suspension of pooled lymph node cells was prepared by mechanical disaggregation through stainless steel gauze (125µm diameter). The cells were washed and centrifuged, precipitated, and re-centrifuged at 4°C, and then were measured for ³HTdr incorporation. Solutions of 5%, 10%, and 25% alpha-hexylcinnamic aldehyde in acetone:corn oil (4:1 v/v) were used as the positive control.

Very slight erythema was noted among the animals. All lymph nodes were enlarged. No other macroscopic abnormalities of the lymph nodes were noted. The stimulation index (SI) for the test substance was determined to be 2.50, 1.37, and 0.59 at 1%, 25%, and 100%, respectively. Because this SI value was below the criteria for a positive response (test/control ratio > 3), the test substance was determined not to cause a sensitization response under the conditions of this test. Therefore, Carbopol Aqua CC polymer is expected to have a low potential to cause skin sensitization.

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Eye Irritation

The eye irritation of the undiluted test material was evaluated in rabbits according to OECD Guideline No. 405, 1987; Method B5 of Commission Directive 92/69/EEC. The test material (0.1 ml) was placed in the conjunctival sac of the one eye of each of three animals. The other eye served as an untreated control. The eyes were evaluated 1, 24, 48, and 72 hours following treatment. The test material produced a maximum mean score of 10 out of 110 and was classified as mildly irritating. Therefore, Carbopol Aqua CC polymer is expected to have a low potential to cause eye irritation.