

# Carbopol<sup>®</sup> Ultrez 21 Polymer Toxicology Studies

*The toxicology studies summarized below were performed on polymers with chemical compositions representative of the Carbopol<sup>®</sup> Ultrez 21 polymer. Therefore, the toxicology data below is expected to be predictive of the toxicity of the commercial grades of Carbopol Ultrez 21 polymer.*

## Human Repeated Insult Patch Tests

The test material<sup>1</sup> 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<sup>2</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 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.

## 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.

<sup>1</sup> 150 mg of a 10% distilled water paste

<sup>2</sup> 111 subjects participated in the skin irritation and skin sensitization evaluation phases, respectively.

Lubrizol Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000

The information contained herein is being furnished for informational purposes only, upon the express condition that the User makes its own assessment of the appropriate use of such information. While the information contained herein is believed to be reliable, no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for a particular application or the results to be obtained herefrom. Lubrizol Advanced Materials, Inc. ("Lubrizol") cannot guarantee how any products associated with this information will perform in

combination with other substances or in the User's process. Due to variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the information or products for the applications disclosed. Lubrizol shall not be liable and the User assumes all risk and responsibility for any use or handling of any material beyond Lubrizol's direct control. LUBRIZOL MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO,

THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. It is the User's sole responsibility to determine if there are any issues relating to patent infringement of any component or combination of components relating to the supplied information. **Nothing contained herein is to be considered as permission, recommendation, nor as an inducement to practice any patented invention without permission of the patent owner.**

For further information, please visit: [www.lubrizol.com/personalcare](http://www.lubrizol.com/personalcare)