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Novemer™ EC-1 Polymer Toxicology Studies

The toxicology studies summarized below were performed on polymers with chemical compositions representative of Novemer™ EC-1 polymer. Therefore, this toxicology data is expected to be predictive of the toxicity of the commercial grades of Novemer EC-1 polymer.

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 cotton gauze patch that was held in place with a strip of surgical tape. 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 and on day 7. The test material produced a primary irritation index score of 2.3 and was classified as a moderate irritant.

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 conjuntival sac of the right eye of each of three animals. The left eye served as an untreated control. The eyes were evaluated 1, 24, 48, and 72 hours following treatment. The test material produced minimal to moderate conjunctival irritation which returned to normal in all animals by 48 hours. The test material produced a maximum mean score of 7.3 out of 110 and was classified as a minimal irritant (Class 3 on a 1 to 8 scale).

Skin Sensitization

The skin sensitization potential of a number of samples of the test material was evaluated in mice. The method used was that described by Kimber, I., Hilton, J. and Weisenberger, C. (1989) "The Murine Local Lymph Node Assay for Identification of Contact Allergens: A Preliminary Evaluation of *in situ* Measurements of Lymphocyte Proliferation", Contact Dermatitis 21, 215-220 and Basketter, D.A. and Scholes, E.W. (1992) "Comparison of the Local Lymph Node Assay with the Guinea Pig Maximization Test for the Detection of a Range of Contact Allergens, Food and Chemical Toxicology", 30, 65-69. Groups of four mice were treated with the test material at concentrations of 0%, 5%, 15%, or 25% w/v in dimethyl formamide 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 250 µl of phosphate buffered saline containing 3H-methyl thymidine (^{3}HTdr: 80µCi/ml, specific activity 2.0 Ci/mmol) via tail vein giving a total dose of 20 µCi to each mouse. A single cell suspension of pooled lymph node cells was prepared by mechanical disaggregation through a 200 mesh steel gauze. After completing the washing and centrifuging steps, the precipitates were incubated over night at 4°C, were re-centrifuged, and measured for ^{3}HTdr incorporation. While some of the test samples with higher residuals had positive responses (test/control ratio > 3) at high doses, the samples with the low residuals were negative at all concentrations tested. These results indicated that the low residual test materials that are similar to commercial grades of Novemer EC-1 polymer have a low skin sensitization potential.

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