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Avalure™ UR 450 Waterborne Polymer Toxicology Studies

The toxicology studies summarized below were performed on polymers with chemical compositions representative of the Avalure™ UR 450 waterborne polymer. Therefore, the toxicology data below is expected to be predictive of the toxicity of the commercial grades of Avalure UR 450 waterborne polymer.

Oral Toxicity

The acute oral toxicity of the test material was evaluated undiluted in rabbits according to international OECD Guidelines No. 401, 1987; Method B1 of Commission Directive 92/69/EEC. A group of 10 animals (5 male and 5 females) were given a single, oral dose of undiluted test material at a dose of 2000 mg/kg body weight and then were observed for 14 days. No deaths or signs of systemic toxicity were noted. The oral LD_{50} was determined to be greater than 2000 mg/kg.

Dermal Toxicity

The dermal toxicity of the test material was evaluated undiluted in rabbits according to international OECD Guidelines No. 402, 1987; Method B3 of Commission Directive 92/69/EEC. A group of 10 animals (5 male and 5 females) were given a single, 24-hour, semi-occluded application of 2000 gm/kg to the intact skin and then were observed for 14 days. No deaths or signs of systemic toxicity were noted. The dermal LD_{50} was determined to be greater than 2000 mg/kg.

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 at I, 24, 48, and 72 hours following patch removal.

Under the test conditions, the test material caused no skin irritation (Primary Irritation Index 0.0).

Eye Irritation

The eye irritation potential of the test material was evaluated undiluted according to international OECD Guidelines No. 405, 1987; Method B5 of Commission Directive 92/69/EEC. A standard amount of the test material (0.1ml) 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.

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Under the test conditions, the test material (undiluted) produced minimal conjunctival irritation (maximum mean score 4.0 out of 110; class 3 on a 1 to 8 scale) which cleared by 48 hours.

Skin Sensitization

The skin sensitization potential of the test material was evaluated in the guinea pig (20 test animals and 10 controls) using the Magnusson and Kligman test according to OECD Guidelines No. 406, 1992; Method B6 of Commission Directive 92/69/EEC. Based on dose rangefinding tests animals were shaved and injected intradermally with Freund's Complete Adjuvant (1:1 in distilled water), a 25 % w/v solution of the test material in distilled water, and a 25% emulsion of the test material in the Freund's solution. The sites were evaluated at 24 and 48 hours after exposure and were treated with a topical application of the undiluted material on day 7 and covered with an occlusive dressing. The dressing was kept in place for 48 hours and the was removed. The site was evaluated 24 hours later. Following the induction phase the animals were shaved again and challenged with 50% and 25% w/v in distilled water and covered again with an occlusive dressing. The dressings and test material were removed after 24 hours. The skin was again clipped and the site was read at 24 and 48 hours. No signs of erythema or edema were noted following the challenge phase. The test material was determined to produce a 0% (0/20) sensitization rate and was classified as a non-sensitizer to guinea pig skin.