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Fixate™ Freestyle Polymer Toxicology Studies

Toxicity studies were conducted on a Lubrizol Advanced Materials, Inc. experimental polymer that is chemically and structurally similar to Fixate™ Freestyle polymer. It is believed that the following results for the test material represent the toxicity potential for Fixate Freestyle polymer.

Acute Oral Toxicity

The acute oral toxicity of the test material was evaluated according to OECD Guidelines for Testing of Chemicals No. 401 (adopted 24 February 1987) and Method B1 of Commission Directive 92/69/EEC (Annex V of Council Directive 67/548/EEC). A group of ten rats (five males and five females) was given a single oral dose of undiluted test material at a dose level of 2000 mg/kg bodyweight. The animals were observed for fourteen days. There were no deaths. No signs of systemic toxicity were noted during the study. No abnormalities were noted at necropsy.

The acute oral median lethal dose (LD_{50}) the test material was found to be greater than 2000 mg/kg bodyweight.

Eye Irritation

The irritation potential of the test material was evaluated in rabbits according to OECD Guidelines for Testing of Chemicals No. 405 (adopted 24 February 1987) and Method B5 of Commission Directive 92/69/EEC (Annex V of Council Directive 67/548/EEC). A standard amount, 0.1 ml, of the test material was administered to the eye of three albino rabbits. The other eye of the test animals served as a control. The eyes were not washed after instillation.

The test material produced moderate conjunctival irritation in all treated eyes one hour after treatment. Moderate conjunctival irritation was noted in one treated eye with minimal conjunctival redness in one other treated eye at 24 hours. Treated eyes appeared normal at the 24 or 48-hour observations.

The test material produced a maximum group mean score of 8.0 according to a modified Kay and Calandra classification system. It was classified as a minimal irritant to the rabbit eye (class 3 on a 1 to 8 scale).

Skin Irritation

The skin irritation potential of the test material polymer was evaluated in rabbits in accordance with OECD Guidelines for Testing of Chemicals No. 404 (adopted 17 July 1992) and Method B4 of Commission Directive 92/69/EEC (Annex V of Council Directive 67/548/EEC). Each of three rabbits received a 0.5 ml dose of the test material as a dermal application to the intact skin. The dose was held in contact with the skin under a semi-occlusive binder for an exposure period of 4 hours. Following the exposure period, the binder was removed, and the remaining test article was wiped from the skin using cotton wool soaked in 74% Industrial Methylated Spirits. The test sites were subsequently examined and scored for dermal irritation for up to three days following patch removal.

The test material produced a primary irritation index of 0.0 and was classified as non-irritant to rabbit skin. No corrosive effects were noted.

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Skin Sensitization

The skin sensitization potential of the test material was evaluated in the guinea pig using Magnusson & Kligman Maximization Test in accordance with OECD Guidelines for Testing of Chemicals No. 406 (adopted 17 July 1992) and Method B6 of Commission Directive 92/69/EEC (Annex V of Council Directive 67/548/EEC). In the induction phase the test material was administered via intradermal injection (0.1%) and topical application (undiluted). In the subsequent challenge phase the test material was applied topically (undilluted and 75%). No sensitization was observed with the test material, which was classified as a non-sensitizer to guinea pig skin.

Mutagenicity

The Reverse Mutation Assay "Ames Test" using *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100 and *E. Coli* strain WP2uvrA$^-$ was conducted on the test material. A preliminary test was carried out to select appropriate dose levels for use in the main study. The test material was non-toxic to the strains of bacteria used up to the maximum dosage of 5000 μg/plate and therefore was tested up to this maximum dose.

No significant increases in the frequency of revertant colonies were recorded for any of the strains of bacteria, at any dose level either with or without metabolic activation.

The test material was considered to be non-mutagenic under the conditions of this test.

Acute Aquatic Toxicity

The acute aquatic Toxicity of the test material was evaluated using *Daphnia Magna* in accordance with OECD Guidelines for Testing of Chemicals No. 202 (1984) and Method C.2 of Commission Directive 92/69/EEC (Annex V of Council Directive 67/548/ EEC).

The 48-hour EC_{50} of the test material in the fresh water invertebrate *Daphnia Magna* based on nominal concentrations was determined to be greater than 100 mg/l. The no observed effect concentration was greater than or equal to 100 mg/l.

Assessment of Ready Biodegradability

The biodegradability of the test material was evaluated using the CO_2 Evolution Test in an aerobic aqueous media in accordance with OECD Guidelines for Testing of Chemicals No. 301B (1992) and Method C.4-C of Commission Directive 92/69/EEC (Annex V of Council Directive 67/548/EEC) and US EPA Draft Ecological Effects Test Guidelines OPPTS 835.3110 Paragraph (M). The test material was exposed to activated sewage sludge micro-organisms at a concentration of 10 mg C/l in a sealed vessel for 28 days. The degradation of the test material was assessed by the determination of carbon dioxide produced, as compared to a control solution.

The test material attained 92% degradation after 28 days. Although the test material could not be considered ready biodegradable under OECD 301B (failed to satisfy the 10-day window validation criterion), it was considered as ready biodegradable in terms of the classification and labeling requirements under EU Directive for Dangerous Substances, L110A (>70% degradation over a 28-day period).