TOX-224
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OILKEMIA 5S *Polymer*
Toxicology Studies

INCI NAME: Caprylic/Capric Triglyceride (and) Polyurethane-79

TEST	***RESULTS***	***CONCLUSION***
Caprylic/Capric Triglyceride	**See CIR reports** Final Report 12/05/2017 IJT 22(Suppl. 1):1-35, 2003 JEPT 4(4):105-120, 1980	**Safe as used**

Polyurethane-79: *The remainder of this document reflect data on the Polyurethane-79 portion of this product.*

***In vitro* Eye Irritation** The objective of this study was to evaluate the potential irritant and corrosive properties of the test item to the eye. The Bovine Corneal Opacity and Permeability (BCOP) test method can identify chemicals inducing serious eye damage and chemicals not requiring classification for eye irritation or serious eye damage. Study was based on the OECD Guideline 437.	**Macroscopic examination** No notable opaque spots or irregularities were observed on the item-treated corneas. ***In vitro* Irritancy Score** The mean *In Vitro* Irritancy Score (IVIS) of the test item-treated corneas was: 0.	**Not an irritant**
***In vitro* Skin Corrosion** An *in vitro* skin corrosivity test was performed in a reconstructed human epidermis model. EPISKIN™ is designed to predict and classify the corrosive potential of chemicals. The corrosivity of the test item was evaluated according to the OECD Guideline 431. This study measures cell viability following exposure to the test item, a negative and a positive control. A measurement of greater than 35% cell viability is considered negative for skin corrosion.	**Cell Viability (%)** Negative control = 100% (reference) Positive control = 0.3% Test Item = 106.2%	**Non-Corrosive**

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TOXICOLOGY STUDIES

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***In vitro* Skin Irritation** Skin irritation potential was predicted by measurement of cytotoxicity using the EpiSkin™ reconstructed human epidermis (RhE) model (OECD Guideline 439). The study design measures cell viability following exposure to the test item, a negative and a positive control. A measurement of greater than 50% cell viability is considered negative for skin irritation.	**Cell Viability (%)** Negative control = 100% (reference) Positive control = 6% Test Item = 97%	**Not an irritant**
Skin Sensitization A skin sensitization study was conducted on a polymer with chemical compositions representative of the polymer in OILKEMIA 5S Polymer. The data is expected to be predictive of the skin sensitizing potential of this polymer. Skin sensitization was evaluated using the globally accepted Buehler test method (OECD Guideline 406). Testing was conducted on the polymer at 100% (undiluted) in both induction and challenge phase. During the induction phase, occluded patches were applied for 6 hours once per week for 3 weeks on 10 test subjects. After patch removal, the sites were evaluated at 24 hrs post removal for dermal reactions. Two weeks after the last induction exposure a challenge dose was applied (occluded patch, 6 hrs exposure). Skin reactions were measured at 24 and 48 hours after patch removal.	No signs of irritation or contact sensitization were detected in test subjects during the study.	**Not a sensitizer**
In vitro Mutagenicity The mutagenic potential of this polymer was assessed using a bacterial/microsome test system (AMES). *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli WP2uvrA* were treated with the test material both with and without metabolic activation. 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 bacterial strains, at any dose level either with or without metabolic activation.	**Non-mutagenic**

Reference: OS374382/EX-1611

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