TOX-204
Original Date of Issue: January 16, 2015

Avalure™ Flex-6 Polymer
Toxicology Studies

INCI NAME: Polyurethane-62 (and) Trideceth-6

TEST (Test ID: OS337361)	RESULTS	CONCLUSION
***In vitro* Eye Irritation** Eye irritation potential was predicted by measurement of cytotoxicity using the EpiOcular™ reconstructed human cornea epithelia (RhCE) model. The study design[1] measures cell viability following exposure to the test item, a negative and a positive control. A measurement of greater than 60% cell viability is considered negative for eye irritation.	Cell Viability (%) Negative control = 100% (reference) Positive control = 25% Test Item = 63%	**Not an irritant**
***In vitro* Skin Irritation** Skin irritation potential was predicted by measurement of cytotoxicity using the EpiSkin™ reconstructed human epidermis (RhE) model. The study design[2] 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 = 7% Test Item = 95%	**Not an irritant**
***In vitro* Skin Sensitization** Skin sensitization was determined using the Direct Peptide Reactivity Assay (DPRA)[3]. Reactivity (% depletion) of the test item to cysteine and lysine peptides was measured by LC-UV analytical method. A mean of Cys and Lys percent depletion determined to be less than 6.38% will be considered to have “No reactivity / Minimal reactivity” and the DPRA prediction can be considered as “Negative”.	Mean depletion rate (%) Reference Controls = Acceptable Positive Control = 78.04% Test Item = 0.02%	**Not a sensitizer**

[1] OECD Draft Guideline, Reconstructed Human Cornea-like Epithelium (RhCE) Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage (25 Judy 2014).
[2] OECD Guideline No. 439, *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method (26 July 2013).
[3] OECD Draft Proposal for Guideline, *in chemico* skin sensitization: Direct Peptide Reactivity Assay (DPRA) (15 May 2014).

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

TEST	RESULTS	CONCLUSION
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 WPluvrA* 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.	Neither cytotoxicity nor precipitation was observed for TA98, TA100, TA1535, TA1537 and WP2Mvr/4 at any dose level both with and without metabolic activation. 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**

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