

Avalure™ Flex-6 Polymer

Toxicology Studies

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

TEST (Test ID: OS337361)

***In vitro* Eye Irritation**

Eye irritation potential was predicted by measurement of cytotoxicity using the EpiOcular™ reconstructed human cornea epithelia (RhCE) model. The study design¹ 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.

***In vitro* Skin Irritation**

Skin irritation potential was predicted by measurement of cytotoxicity using the EpiSkin™ reconstructed human epidermis (RhE) model. The study design² 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.

***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”.

RESULTS

Cell Viability (%)
 Negative control = 100% (reference)
 Positive control = 25%
 Test Item = 63%

Cell Viability (%)
 Negative control = 100% (reference)
 Positive control = 7%
 Test Item = 95%

Mean depletion rate (%)
 Reference Controls = Acceptable
 Positive Control = 78.04%
 Test Item = 0.02%

CONCLUSION

Not an irritant

Not an irritant

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 July 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).

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TEST

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.

RESULTS

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.

CONCLUSION

Non-mutagenic

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