TOX-232
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Fixate™ Renew Polymer
Toxicology Studies

INCI NAME: Mixture (see Regulatory Summary)

TEST (Test ID: OS399607)	RESULTS	CONCLUSION
***In vitro* Eye Irritation** Eye irritation potential was predicted by measurement of corneal opacity and permeability using the corneas of eyes isolated from cattle. The study design[1] measures decreased light transmission through the cornea (opacity) and increased passage of sodium fluorescein dye through the cornea (permeability) were combined in an empirically derived formula to generate an *In Vitro* Irritancy Score (IVIS). An IVIS score of ≤ 3 is considered negative for eye irritation.	IVIS Irritancy Score Negative control = 0.4 Positive control = 41.6 Test Item = 1.8	**Not an irritant**
***In vitro* Skin Corrosion** Skin corrosion potential was predicted by measurement of cytotoxicity using the EpiDerm™ reconstructed human epidermis 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 corrosion.	Cell Viability (%) Negative control = 100% (reference) Positive control = 3.4% Test Item = 90.1%	**Non-corrosive**
***In vitro* Skin Irritation** Skin irritation potential was predicted by measurement of cytotoxicity using the EpiSkin™ reconstructed human epidermis (RhE) model. The study design[3] 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 = 4.2% Test Item = 101.8%	**Not an irritant**

[1] OECD Guideline for the Testing of Chemicals No. 437 (updated 09 October 2017) "Bovine Corneal Opacity and Permeability Assay"

[2] OECD Guideline for the Testing of Chemicals No. 431 *In Vitro* Skin Corrosion: Reconstructed Human EpiDermis (RHE) Test Method (29 July 2016)

[3]OECD Guideline No. 439, *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method (28 July 2015).

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