

Glucamate™ CCO Thickener

Toxicology Studies

INCI NAME: Methyl Glucose Caprate / Caprylate / Oleate AND Propanediol

The following tests were performed on materials with chemical compositions representative of Glucamate CCO. This toxicology data is expected to be predictive of the toxicity of Glucamate™ CCO thickener.

<u>TEST (Test ID: OS300759B)</u>	<u>RESULTS</u>	<u>CONCLUSION</u>
<p>Eye Irritation</p> <p>Eye irritation was investigated according to OECD test guideline no. 405, commission regulation 440/2008/EC, Japanese MAFF (2000) and EPA OPPTS 870.2400 (1998). Scoring of irritation effects was performed approximately 1, 24, 48 and 72 hours after test item instillation.</p>	<p>The test item did not cause any damage to the eye. The individual mean scores for corneal opacity and iris light reflex were 0.00 for all three animals. The individual mean scores for the conjunctivae were 0.00 for reddening and 0.00 for chemosis.</p>	<p>Not an irritant</p>
<p>Skin Irritation</p> <p>The acute dermal irritation potential was investigated according to OECD test guideline No. 404, Commission Regulation (EC) No. 440/2008, B.4, Japanese MAFF 12-Nousan.8187 (2000) and EPA OPPTS 870.2400 (1998). The scoring of skin reactions was performed 1, 24, 48 and 72 hours after removal of the dressing.</p>	<p>The test item did not elicit any skin reactions at the application at any of the observation times (all scores 0).</p>	<p>Not an irritant</p>
<p>Skin Sensitization</p> <p>Skin sensitization was determined using the Direct Peptide Reactivity Assay (DPRA)¹. 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".</p>	<p>Mean depletion rate (%)</p> <p>Reference Controls = Acceptable</p> <p>Positive Control = 74.38%</p> <p>Test Item = 0%</p>	<p>Not a sensitizer</p>

¹ OECD Draft Proposal for Guideline, *in chemico* skin sensitization: Direct Peptide Reactivity Assay (DPRA) (15 May 2014).

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TEST

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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