TOX-240
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PemuPur™ START Polymer Toxicology Studies

INGREDIENTS: Microcrystalline cellulose (and) Sphingomonas ferment extract (and) Cellulose gum

The toxicology studies summarized below were performed on materials with chemical compositions representative of PemuPur™ START Polymer. Therefore, this toxicology data is expected to be predictive of the toxicity of the commercial grades of PemuPur™ START Polymer.

INGREDIENT	***TOXICOLOGY RESULTS***	***CONCLUSION***
Microcrystalline cellulose	**See CIR[1] report:** Final Report March 23, 2009	**Safe as used**
Cellulose gum	**See CIR[1] reports:** Final Report March 23, 2009 JACT 5(3):1-59, 1986	**Safe as used**

[1]CIR reports are available at www.cir-safety.org

SPHINGOMONAS FERMENT EXTRACT: The remainder of this document reflect data on the Sphingomonas ferment extract of this product. The toxicology studies summarized below were performed on materials with chemical compositions representative of Sphingomonas ferment extract. Tests conducted prior to 2005.

TEST	***RESULTS***	***CONCLUSION***
Acute oral toxicity	A feeding study of test material up to 5000 mg/kg resulted in no deaths.	Oral LD50 >5000 mg/kg (rat)
Acute Inhalation	A 4-hour exposure of test material at nominal concentration resulted in no deaths.	LC50 >5 mg/l 4-hour (rat)

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TEST	***RESULTS***	***CONCLUSION***
Chronic Oral Toxicity	Repeated oral administration of the test material to rats by gavage for a period of twenty-eight consecutive days at dose levels of up to 1000 mg/kg/day did not result in any toxicologically significant changes in the parameters measured.	No adverse effects observed in long-term feeding studies with rats (NOEL) was 1,000 mg/kg/day. (OECD 407)
Eye Irritation	Single ocular administration with observation period at 24-, 48- and 72-hours post-treatment. Only transient and minor reaction to treatment.	Non-Irritating to eye (rabbit) (OECD 405)
Skin irritation	Topical applications (guinea pig) of test material at 50% concentration in arachis oil with an occluded dressing for 24hr did not result in irritation.	Non-irritating (guinea pig)
Skin sensitization	Skin sensitization testing (OECD 406) was conducted. The test material produced a 0% (0/10) sensitization rate at 25% concentration of test material in arachis oil. This was the maximum tested concentration.	Non-sensitizing (guinea pig) (OECD 406)
Chromosomal Aberrations	Chromosome Aberration Test (*in vitro*) in Human Lymphocytes mammalian cells with the test material did not induce any statistically significant increases in the frequency of cells with aberrations as compared to control materials.	Non-clastogenic. (OECD 473)
Mutagenicity	Reverse Mutation Assay “AMES TEST” of the test material using Salmonella typhimurium and Escherichia coli, was tested up to the maximum recommended dose level of 5000 µg/plate. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.	Non-mutagenic. (OECD 471)