

Ethyl cellulose

Toxicological Data on the Unburnt Ingredient

[+ve, positive; -ve, negative; ?, equivocal; with, with metabolic activation; without, without metabolic activation]

In vivo

Species	Test conditions	Endpoint	Results	Reference
Mouse, numbers not disclosed	A pre-publication abstract of a mouse micronucleus test. An aqueous ethyl cellulose dispersion administered by gavage. No further details available (publication awaited).	Chromosome damage	-ve	DeMerlis <i>et al.</i> 2005
The following studies summarise data on chemically related materials.				
Rat	Methyl cellulose Rats administered 4.75, 47.5 and 475 mg/kg bw once or 5 g/kg bw/day for 5 days (presumably by the oral route) and assessed for chromosome aberrations in the bone marrow cells.	Chromosome damage	-ve	Litton Bionetics, Inc. 1974
Rat, males	Methyl cellulose A dominant lethal assay. Rats administered 4.75, 47.5 and 475 mg/kg bw	Germ cell mutations or damage to germ cell chromosomes	-ve	Litton Bionetics, Inc. 1974

	once or 5 g/kg bw/day for 5 days (presumably by the oral route). No further details were available, but treated male rats would have been mated with untreated females (probably for several weeks) and the females assessed for early foetal deaths.			
--	---	--	--	--

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
? Probably <i>Salmonella typhimurium</i>	A pre-publication abstract of a bacterial reverse mutation assay (presumably an Ames test). No further details available (publication awaited).	Mutation	With and without S9	-ve	DeMerlis <i>et al.</i> 2005
? Possibly mouse lymphoma cells	A pre-publication abstract of a cell mutation assay. No further details available (publication awaited).	Mutation	Probably with and without S9	-ve	DeMerlis <i>et al.</i> 2005
The following studies summarise data on chemically related materials.					
<i>Salmonella typhimurium</i> TA1530, G46 and <i>Saccharomyces cerevisiae</i>	Methyl cellulose A host mediated assay. Rats administered 4.75, 47.5 and 475 mg/kg bw once or 5 g/kg bw/day for	Mutation	Not relevant (bacteria were exposed in intact rats)	-ve	Litton Bionetics, Inc. 1974

	5 days (presumably by the oral route) and tested for reverse mutagenesis in <i>Salmonella typhimurium</i> TA1530, G46 or mitotic recombination in <i>Saccharomyces cerevisiae</i> .				
<i>Salmonella typhimurium</i> TA92, TA94, TA98, TA100, TA1535, TA1537, TA1538	Methyl cellulose Tested in Ames tests at concentrations of 50 ug/plate or ≤70 mg/plate.	Mutation	With and without	-ve The Ishidate <i>et al.</i> study was probably a good quality study.	Blevins & Taylor, 1982; Ishidate <i>et al.</i> 1984
<i>Salmonella typhimurium</i> TA92, TA94, TA98, TA100, TA1535, TA1537, TA1538	Sodium carboxymethyl cellulose Tested in Ames tests at concentrations of 5% and up to 5 mg/plate (plate incorporation assays) and at concentrations of up to 10% (suspension assays).	Mutation	With and without rat, mouse or monkey liver, lung or testes S9	-ve The Ishidate <i>et al.</i> study was probably a good quality study.	Ishidate <i>et al.</i> 1984; Litton Bionetics, Inc. 1975 & 1980
<i>Saccharomyces cerevisiae</i> D4	Sodium carboxymethyl cellulose Tested for recombinogenicity at concentrations of 0.25, 0.5 and 1.0%.	Recombination	No data	-ve	Litton Bionetics, Inc. 1975

Chinese hamster fibroblast cells	Methyl cellulose Chromosomal aberration study at concentrations of ≤ 4.0 mg/ml.	Chromosome damage	Without	-ve A limited study, not tested with S9.	Ishidate <i>et al.</i> 1984
Chinese hamster fibroblast cells	Sodium carboxymethyl cellulose Chromosomal aberration study at concentrations of ≤ 2.8 mg/ml.	Chromosome damage	Without	-ve A limited study, not tested with S9.	Ishidate <i>et al.</i> 1984
Human embryonic lung cells (WI-38)	Methyl cellulose Chromosomal aberration study at concentrations of 80, 800 and 8000 ug/ml.	Chromosome damage		-ve	Litton Bionetics, Inc. 1974

References

Blevins R D & Taylor D E (1982). Mutagenicity screening of twenty-five cosmetic ingredients with the Salmonella/microsome test. *Journal of Environmental Science and Health A17*, 217-239 (cited in JECFA, 1990).

DeMerlis C C *et al.* (2005). A subchronic toxicity study in rats and genotoxicity tests with an aqueous ethylcellulose dispersion. *Food and Chemical Toxicology* 43, 1355-1364 (data cited from the Science Direct pre-publication abstract. Full paper not yet published).

Ishidate M Jr *et al.* (1984). Primary mutagenicity screening of food additives currently used in Japan. *Food and Cosmetics Toxicology* 22, 623-638 (cited in JECFA, 1990).

JECFA (1990). Toxicological evaluation of certain food additives and contaminants: thirty-fifth meeting of the Joint FAO/WHO Expert Committee on Food Additives. WHO Food Additive Series 26. World Health Organization, Geneva.

Litton Bionetics, Inc. (1974). Mutagenic evaluation of compound, FDA 71-51, Methocel. Unpublished Report by Litton Bionetics, Kensington, Maryland.

Submitted to WHO by the U.S. Food and Drug Administration (cited in JECFA, 1990).

Litton Bionetics, Inc. (1975). Mutagenic evaluation of compound FDA 73-69. Sodium carboxymethylcellulose gum, low viscosity. Unpublished Report by Litton Bionetics, Kensington, Maryland. Submitted to WHO by the U.S. Food and Drug Administration (cited in JECFA, 1990).

Litton Bionetics, Inc. (1980). Mutagenicity evaluation of sodium-CMC, purified grade, in the Ames Salmonella/microsome plate test. Unpublished Report by Litton Bionetics, Kensington, Maryland. Submitted to WHO by the U.S. Food and Drug Administration (cited in JECFA, 1990).