Tartrazine

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
Groups of four male ddY mice	Groups of animals were treated orally with 0, 1, 10, 100 or 2000 mg/kg bw in the comet assay. The glandular stomach, colon, liver, kidney, urinary bladder, lung, brain and bone marrow was assayed.	DNA damage	+ve (Dose-related DNA damage in the glandular stomach and colon)	Sasaki et al. 2002
Male Sprague-Dawley rats	A 94% colour at a dose of 500 mg/kg bw was given by gavage in an unscheduled DNA synthesis test. [No further details given in review]	DNA damage (indicative test)	-ve	Korncrust and Barfknecht, 1985.
5 male mice per group	Animals were given 5, 10, 25, 50, 100 and 200 mg/kg bw by peritoneal injection.	Chromosome effects	+ve	Giri et al. 1990

	Animals were sacrificed 24 hours after treatment and bone marrow was examined for sister chromatid exchange.			
15 male rats per group	Diets containing 0, 100, 200, 500 and 1000 ppm were administered for 3, 6 and 9 months. 5 animals from each group were sacrificed at 3-monthly intervals and bone marrow examined for chromosome aberrations.	Chromosome damage	+ve	Giri et al. 1990
Chinese hamster. Groups of 4 (SCE test) or 6 (CA or micronucleus tests)	Assays for sister chromatid exchanges (SCE), micronuclei (MN) or chromosomal aberrations (CA) in the bone marrow cells (examined at 24, 30 or 26 hrs following treatment) in animals given single oral doses of 50	Chromosome damage or effects	-ve	Renner, 1984

	mg/kg bw (SCE assay) or 200 mg/kg bw (CA and MN assays).			
Male mice [numbers not specified]	Animals were treated orally with 0.5 or 5 mg/kg bw/day for 5 days. [No further details in abstract]	Chromosome damage	-ve	Durnev et al. 1995 [English abstract on Russian language report]
Drosophila melanogaster	Fruit flies given 600 ppm tartrazine orally. Specific locus test. [No further details given]	Mutation	+ve	Tripathy et al. 1989

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Salmonella typhimurium TA98, TA100 and YG1024	In a limited study, up to 3.65 mg/plate was tested using the pre-incubation method.	Mutation	With and without S9	+ve (in strain YG1024 in the presence of S9)	Varella et al. 2004
Salmonella typhimurium TA98 and TA100	After oral administration of tartrazine, bile and faeces of treated rats were investigated in the Ames test.	Mutation	With and without S9	Faecal extracts were positive in TA100 in the presence of S9	Munzner and Wever, 1987.
Salmonella typhimurium TA98 and TA100	Tartrazine was administered to rats by gavage and	Mutation	With and without S9	Urine was positive in TA98 in the	Henschler et al. 1985

	their urine was used in the Ames test.			presence of S9	
Salmonella typhimurium TA1535, TA1537, TA98 and TA100 *Escherichia coli* wP2uvrA	Rigorous study tested 33, 100, 333, 1000, 2500 and 5000 ug/plate. Tests conducted in accordance with OECD Guideline 471 (1997) in compliance with GLP.	Mutation	With and without S9	-ve	N.N. June 2000
Salmonella typhimurium TA97 and TA102	Five concentrations tested, up to 10 mg/plate.	Mutation	with and without S9	-ve	Fujita & Sasaki, 1993
Salmonella typhimurium strains TA97, TA98, TA100, TA1535 and TA1537	Pigment yellow 100 (26% purity) tested at up to 10 mg/plate or to limit of toxicity	Mutation	With and without S9	-ve a good quality protocol, though a low purity material was tested	Zeiger et al. 1988
Salmonella typhimurium TA1535, TA100, TA1537, TA98 and TA1538	Five concentrations tested, up to 10 mg/plate	Mutation	with and without S9	-ve	Cameron et al. 1987
Salmonella typhimurium TA92, TA1535, TA100, TA1537, TA94 and TA98	Six concentrations were tested, up to 5 mg/plate.	Mutation	with and without S9	-ve	Ishidate et al. 1984
Salmonella	Test	Mutation	With and	-ve	Brown and

typhimurium TA1535, TA100, TA1537, TA1538 and TA98	conditions not fully described in review.		without S9		Dietrich, 1983; Longstaff et al. 1984; and Prival et al. 1988 reviewed in SCCNFP, 2004.
Salmonella typhimurium TA1535, TA100, TA1537, TA1538 and TA98	Test conditions not described. One or more of five standard strains used.	Mutation	Not stated	-ve	Brown et al. 1978; Anon, 1986
Salmonella typhimurium TA100 and TA98	50-300 ug tartrazine/plate	Mutation	With and without S9	-ve	Raffi et al. 1997
Mouse Lymphoma L51878Y cells	Tests conducted in accordance with OECD Guideline 476 (1997) in compliance with GLP. Cells were treated for 4 hours with up to 5000 ug/ml.	Mutation	With and without S9	-ve	N.N. August 2000
Mouse lymphoma cells	Test conditions not described in review	Mutation	Without S9	-ve	Cameron et al. 1987
Cultured Chinese hamster fibroblasts (CHL)	Cultures were exposed to three different concentrations up to a maximum of 2.5 mg/ml, for 24 and 48 hours.	Chromosome damage	Without	+ve	Ishidate et al. 1984
Cultured hamster	2100 mg/l [no further details	Chromosome damage	Not stated	+ve	Anon, 1981

fibroblast	given in RTECs; possibly same study as Ishidate et al. 1984)				
Muntiacus muntjac fibroblast cells	Conditions not described in review	Chromosome damage	Not stated	+ve	Patterson and Butler, 1982
Cultured human lymphocytes	Test conditions are not described in the brief published abstract.	Chromosome damage	Without	+ve	Fischer et al. 1992
Cultured human lymphocytes	100 mg/L [no further details given in RTECS on this Russian study]	Chromosome damage	Not stated	+ve	Anon, 1975
Cultured rat hepatocytes	A 94% colour at a dose of 2 x 10^{-3} to 2 x 10^{-6} M was reportedly tested.	DNA damage	Not applicable	-ve	Korncrust and Barfknecht, 1985.
Bacillus subtilis H17, M45T	Rec assay. Not further described.	DNA damage	Not stated	No conclusion	Anon, 1981
Saccharomyces cerevisiae	Test conditions not described in review.	Mitotic recombination	Without S9	-ve	Sankaranarayanan et al. 1979.
Saccharomyces cerevisiae	Test conditions not described	Mitotic recombination	Not stated	-ve	Zimmermann et al, 1984
Baby Syrian hamster kidney fibroblasts (BHK21, C13) cells	Test conditions not described in review	Cell transformation	Not stated	-ve	Longstaff et al. 1984

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