Pigment red 57

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
Mice, strain NMRI (6 per sex per group)	Unclear if the calcium or sodium salt was tested. Single oral dose of 0, 0.5, 1 or 2 g/kg bw, killed after 24 hr; a further group on the top dose only, killed after 48 hr. Peripheral red blood cells examined for micronuclei. Study carried out to OECD Guidelines. No evidence of toxicity.	Chromosome damage	-ve	Honavar, 2002

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Chinese hamster lung cells (CHL/IU cells)	Treated with up to 5 mg/ml of the calcium salt for 48 hr. Examined for chromosome aberrations and polyploidy.	Chromosome damage	With and without S9	-ve (good quality study)	JETOC, 1997; Kusakabe et al. 2002
Mouse lymphoma L5178Y cells	Up to 0.32 mg/ml of calcium salt and incubated for 4 or 24 hr (toxic at highest dose).	Mutation	With and without S9	-ve	Wollny, 2002

	Carried out according to OECD Guidelines.				
Salmonella typhimurium, strains TA1535, TA1537, TA98, TA100, and TA102	Ames test, sodium salt tested at up to 5 mg/plate. Carried out to OECD Guidelines.	Mutation	With and without S9	-ve	Aeby & Bracher, 2002
Salmonella typhimurium, strains TA1535, TA1537, TA98, TA100, and *Escherichia coli*, strain WP2 uvrA	Ames test, calcium salt tested up to 5 mg/plate	Mutation	With and without rat and hamster S9	-ve (good quality study)	JETOC, 1997
Salmonella typhimurium, strains TA1535, TA1537, TA1538, TA98, and TA100	Ames assay, disodium salt tested at up to 2.5 mg/plate. Revertant data not presented in citing source.	Mutation	With and without metabolic activation (probably S9)	-ve	BASF, 1981
Salmonella typhimurium, strains TA1535, TA1537, TA1538, TA98, and TA100	Ames assay, disodium salt tested up to 0.5 mg/plate.	Mutation	With and without S9	-ve (slight effect in TA98 with S9, but no doubling of the untreated control frequency of revertants)	Brown et al. 1979
Salmonella typhimurium, strains TA1535, TA1537,	Ames assay. Doses not explicitly stated, but disodium and	Mutation	With and without S9	-ve	Muzzall & Cook, 1979

TA98, and TA100	calcium salts presumably tested up to 0.4 mg/plate. Data on revertant numbers not given.				
Salmonella typhimurium, strains TA98, TA100	Ames assay, calcium salt tested up to 1 mg/plate. Paper in Japanese, with some data in English. Ten commercial brands of the dye seem to have been tested.	Mutation	With and without S9	? (some brands gave weak responses in TA98 [only without S9] which the investigators believed were due to impurities)	Miyagoshi et al. 1983
Salmonella typhimurium, strains TA98, TA100 Limited study as only two strains used	Ames assays. Disodium salt synthesized under various reaction conditions, calcium salt synthesized using a single method, and these and ethyl acetate extracts of them were tested along with those of 3 commercial dyes (selected from Miyagoshi et al. 1983, above; it was not clear whether these were calcium or disodium salts).	Mutation	With and without S9	Synthesized calcium salt: -ve Extract of synthesized calcium salt: +ve (but mutagenic activity was eliminated by rinsing lake with water before extraction) Synthesized sodium salts: ratio of reactants used in synthesis appeared to affect mutagenic activity of dyes and extracts.	Miyagoshi et al. 1987

	Commercial dyes, their extracts and the corresponding residues were tested up to 1 mg/plate, 0.1mg/plate and 1 mg/plate, respectively.			Commercial dyes and corresponding extracts were +ve in TA98 without S9.	
Salmonella typhimurium, strains TA98, TA100	Ames assay. Disodium salt tested at 50 and 200 µg/plate.	Mutation	With and without S9	-ve Limited study as only two strains and low doses used	Rafii et al. 1997
Salmonella typhimurium, strain TA98	Ames assay. Disodium salt tested up to 0.5 mg/plate.	Mutation	With S9	-ve Limited study as only one strain used	Green & Pastewka, 1979 & 1980
Salmonella typhimurium, strains TA1535, TA1538	Ames assay. Disodium salt tested at 0.01 mg. Data poorly presented, revertant data not presented individually for this substance.	Mutation	With and without S9	-ve Limited study as only two strains and one, low dose used	Milvy & Kay, 1978
Salmonella typhimurium, strains not specified	Ames assay. Calcium salt apparently tested. No further details available in citing source.	Mutation	Not known	-ve	Office of Environmental Chemicals Safety Environmental Health Bureau, 1995 (possibly the same data as JETOC, 1997

					above)
Rat liver cells (hepatocytes)	DNA repair test. Unspecified salt tested at up to 60 µg/ml.	DNA damage	Not applicable	-ve	Ciba-Geigy, 1995a
Mammalian fibroblasts (not further specified)	Cell transformation assay. Unspecified salt tested at up to 200 µg/ml.	Transformation	With and without metabolic activation (probably S9)	-ve	Ciba-Geigy, 1995b

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