Allura red

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, CD-1 ICR strain (groups of 4 females)	Comet assay. Animals given a single dose of 2 g/kg bw by gavage on day 11 of pregnancy, and assessed for DNA damage in the brain, lung, liver, kidney, glandular stomach, colon, urinary bladder and embryo cells 3, 6 and 24 hr after treatment.	DNA damage	+ve DNA damage was observed in the colon after 3 hr.	Tsuda et al. 2001
Mouse, CD-1 ICR strain (groups of 4 males)	Comet assay. Animals given a single dose of 0, 1, 10, 100, 1000 or 2000 mg/kg bw by gavage and assessed for DNA damage in the brain, lung, liver, kidney, glandular stomach, colon, urinary bladder and bone marrow	DNA damage	+ve Dose-related DNA damage was observed in the colon and stomach after 3 hr. The colon was the only organ affected after 24 hr.	Tsuda et al. 2001

	3 (all doses), 6 and 24 hr (2000 mg/kg bw only) after treatment.			
Mouse, ddY strain (groups of 4 males)	Comet assay. Animals given a single dose of 0, 1, 10, 100, 1000 or 2000 mg/kg bw by gavage and assessed for DNA damage in the brain, lung, liver, kidney, glandular stomach, colon, urinary bladder and bone marrow 3 (all doses) and 24 hr (2000 mg/kg bw only) after treatment.	DNA damage	+ve Dose-related DNA damage was observed in the colon and stomach after 3 hr. The colon was the only organ affected after 24 hr.	Sasaki et al. 2002a & b; Kawaguchi et al. 2001
Mouse (males, numbers unknown)	Animals given 4000 and 20,000 ppm (up to about 2.6 g/kg bw/day) in the diet for 8 weeks. Each male was then mated with 2 untreated females and the males from the F_1 generation were subsequently mated with untreated females to	Heritable translocation	-ve	Jorgenson et al. 1978

	assess the induction of heritable translocation. No further details of this unpublished study were available from the expert review.			
Drosophila melanogaster	Fed 'at the LD_{50} dose for 24 days' and examined for recessive lethal effects (chromosome loss, mutation at specific loci, and sex-linked recessive lethal damage (SLRL) and chromosomal translocation). No further details of this unpublished study were available from the expert review.	Chromosome damage, mutation and SLRL mutation	-ve SLRL was not increased when compared with the study controls but was higher when compared with controls combined from three studies. Concluded to be negative by the EPA (Lee et al. 1983).	Anon, 1977a & 1978

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Salmonella typhimurium, strains TA97, TA98, TA100, TA1535	Ames test. Tested in a preincubation assay at concentrations of up to 10 mg/plate.	Mutation	With and without rat and hamster liver S9	-ve A good quality study.	NTP

Salmonella typhimurium, strains TA98, TA100, TA1535, TA1537, TA1538	Ames test. Tested at concentrations of up to 1 mg/plate.	Mutation	With and without	-ve	Brown et al. 1978
Salmonella typhimurium, strains TA98, TA100	Ames test. Tested in a preincubation assay. Test concentrations unspecified.	Mutation	With and without	-ve A limited assay. Only 2 strains were tested, however current protocols recommend using at least 4 strains.	Zeiger & Margolin, 2000
Salmonella typhimurium, strains TA98, TA100, TA1535, TA1537, TA1538	Ames test. Tested at concentrations of up to 10 mg/plate.	Mutation	With and without	-ve	Bonin & Baker, 1980
Salmonella typhimurium, various strains including TA98, TA100, TA1535, TA1537, TA1538	3 Ames tests cited in a JECFA review. Limited details available from the expert review.	Mutation	With and without	-ve	Brusick, 1976; Muzzall & Cook, 1979; Viola & Nosotti, 1978
Salmonella typhimurium, various strains	Various other Ames tests. The full papers for these studies were not obtained as the results are in line with the other Ames test	Mutation	With and without	-ve	Brown & Dietrich, 1983; Chung et al. 1981; Ozaki et al. 1998; Prival et al. 1988; Rafii et

	reports consulted, which include high quality studies.				al. 1997
Salmonella typhimurium, strains TA1535, TA1537 and/or TA98, TA100	The effect of azo-reduction on the mutagenic potential of allura red was examined. Allura red was preincubated (aerobically and anaerobically), or treated with Clostridium bacteria (which have azoreductase activity), or flavin mononucleotide (a facilitator of azo reduction), before being tested in the Ames assay.	Mutation	With and without	-ve	Brown & Dietrich, 1983; Brown et al. 1978; Prival et al. 1988; Rafii et al. 1997
Salmonella typhmurium, strain TA1538	Liquid fluctuation test. Cells were treated with a concentration of 10 mg/ml for 72-96 hr and the increase in turbidity was assessed.	Mutation	With and without	-ve A limited assay as only tested in one strain.	Haveland-Smith & Combes, 1980
Escherichia coli, strain WP2uvrA	Liquid fluctuation test. Cells were treated with a concentration of 10 mg/ml for 72-96 hr and the increase in	Mutation	With and without	-ve	Haveland-Smith & Combes, 1980

	turbidity assessed.				
Escherichia coli, wild-type strain (WP2trp uvr A), and two strains deficient in DNA repair capability (WP67 trp uvr A pol A and WP100 trp uvr A rec A)	Differential killing assays (rec and pol assays). Cells treated with a concentration of 10 mg/ml for 3.5 hr (repair-proficient cells (WP2); both rec and pol assays), 5.5 hr (repair-deficient cells (WP100); rec assay) and 4.5 hr (repair-deficient cells (WP67); pol assay). DNA damage is indicated by a higher toxicity in the DNA repair deficient strains compared with the wild-type strains.	DNA damage (indicative test)	With and without	-ve	Haveland-Smith & Combes, 1980
Escherichia coli, two wild-type strains (AB1157, CSH7) and three strains deficient in DNA repair capability (TN1005, RPC501, UM1)	Differential killing assays. Treated with allura red and illuminated with visible light for 18 hr. Concentrations not specified. DNA damage is indicated by a difference in toxicity between the wild and DNA repair	DNA damage (indicative test)	Without	-ve A limited study as no activation was used.	Kuraoka et al. 1991

	deficient strains.				
Human, MCF-7 breast cancer cells	Cells treated with allura red and assayed for p53-DNA binding. No further details available.	DNA damage	Not specified	-ve	Dees et al. 1997
Saccharomyces cerevisiae, 3 strains	Genetic tests. No further details of this unpublished study were available from the expert review.	Chromosome damage	With and without	-ve	Anon, 1977b
Saccharomyces cerevisiae, 1 strain	Mutation assay. No further details of this unpublished study were available from the expert review.	Mutation	Probably with and without	-ve	Brusick, 1976

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