Brilliant blue FCF aluminium lake

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
Rat (Wistar Hanlbm: Wist (SPF)), group of 4	Oral treatment with 10 ml/kg [presumably around 10 g/kg bw via stomach tube] of Blue 1 (84% purity), with examination for the induction of unscheduled DNA synthesis in the liver.	DNA damage (indicative test)	-ve	RCC, 2002
Rat	Acid Blue 9 (83% purity) was given at 500 mg/kg bw by stomach tube. The investigators suggested that the observed activity might have been due to impurities present. [The CAS given in this paper was 2650-18-2 (the ammonium salt) however the synonyms listed suggest that the sodium salt (3844-45-9) may have been tested.]	DNA damage	Weak +ve [The effect may possibly have been due to impurities.]	Kornbrust & Barfknecht, 1985
Mouse (ddY), groups of 6 males	C.I. Acid Blue 9 (3844-45-9) was administered by single intraperitoneal (i.p.) injection (up	Chromosome damage	-ve	Hayashi et al. 1988

	to 2000 mg/kg bw) and with 4 daily s.c. injections (1010 mg/kg bw). Bone marrow samples were taken at 24 or 26 hr to examine the induction of micronuclei.			
Mouse (ddY), groups of 4	Mice were given Brilliant Blue FCF (3844-45-9), 2 g/kg bw orally, in the Comet assay, with examinations of eight tissues at 3 and 24 hr for the migration of nuclear DNA.	DNA damage (indicative)	-ve	Sasaki et al. 2002

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Mouse lymphoma cells, L5178Y (tk+/tk-)	FD&C Blue 1 (3844-45-9; 88% purity) was tested at up to 5000 [no units are given in the citation; possibly μg/ml] for 4 hr (+/- S9) and 24 hr (-S9).	Mutation	With and without S9	-ve	RCC, 2000
Mouse lymphoma cells, L5178Y (tk+/tk-)	C.I. Acid Blue 9 was tested in a good quality study at up to 0.49 and 1.9 mg/ml (-S9 and +S9, respectively). [Cameron et	Mutation	With and without S9	+ve (+S9)	Cameron et al. 1987; NCI

	al. gives the CAS number of the ammonium salt (2650-18-2) but the structure of the sodium salt (3844-45-9).]				
Hamster, CHL cells	Pigment FD&C Blue 1 was tested in various tests for chromosome aberrations. Two papers (Ishidate 1984 & 1988) indicate the ammonium salt (2650-18-2) was tested. The earlier Ishidate paper and that of Kawachi et al. simply describe the test material as Brilliant Blue FCF, although Ishidate et al. 1981 is included in a data compilation on 3844-45-9.	Chromosome damage	With and without S9	+ve	Ishidate et al. 1981, 1984 & 1988; Kawachi et al. 1980
Rat liver cells	Acid Blue 9 was used in a test to detect the induction of DNA repair. [The	DNA damage (indicative test)	Not appropriate	+ve	Kornbrust & Barfknecht, 1985

	citation indicates that CAS number corresponds to the ammonium salt (2650-18-2) while the synonyms indicate the sodium salt (3844-45-9) may have been used.]				
Hamster and rat cells	Cell transformation assays attempt to determine whether exposed cells may be made to more closely resemble a cancerous state. In various tests (a) the sodium salt (3844-45-9) or (b) the ammonium salt (2650-18-2) were tested.	Cell transformation	With and without S9	-ve	(a) Longstaff et al. 1984; Price et al. 1978 (b) Ishidate et al. 1984
Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 *Escherichia coli* WP2uvrA	FD&C Blue 1, C.I. 42090 (88% purity) was tested at up to 5 mg/plate in well conducted, unpublished studies. [The citation notes that C.I.	Mutation	With and without S9	-ve	RCC, 1999

	42090 has the CAS 3844-45-9, but may include also the ammonium salt and aluminium lake (2650-18-2; 68921-42-6). The precise identity of the tested material is not specified.]				
Salmonella typhimurium strains TA98, TA100, TA102, TA1535, TA1537	In another well conducted study, FD&C Blue 1 (presumably 3844-45-9; 93% purity) was tested at up to 5 mg/plate.	Mutation	With and without S9	-ve	Cosmital, 2002
Salmonella typhimurium strains TA98, TA100, TA1535, TA1337, TA1538	C.I. Acid Blue 9 was tested in a good quality Ames test at up to 10 mg/plate. Pre-incubation was used in some tests with TA98 and TA100. [Cameron et al. gives the CAS number of the ammonium salt (2650-18-2) but the structure of	Mutation	With S9 derived from rat and hamster liver	+ve (+S9 derived from hamster liver)	Cameron et al. 1987; NCI

	the sodium salt (3844-45-9).]				
Salmonella typhimurium strains including TA92, TA94, TA98, TA100, TA1535, TA1537, TA1538; TA2637	The sodium and ammonium salts, or Brilliant Blue FCF not further specified were tested in various Ames tests.	Mutation	With and without S9	-ve	BIBRA, 1999; CCRIS, 2001; Gene-Tox, 1995 (citing Auletta et al. 1977; Bonin et al. 1981; Bonin & Baker, 1980; Brown et al. 1978; Fujita & Sasaki, 1993; Haveland-Smith & Combes, 1980; Ishidate et al. 1981 & 1984; Kawachi et al. 1980; Kier et al. 1986; Longstaff et al. 1984; Ozaki et al. 1998
Salmonella typhimurium	Brilliant Blue FCF (not further specified) was tested in an Ames test with Trp-P-1 (a powerful mutagenic dietary component).	Mutation	With S9	+ve Increased mutagenicity of Trp-P-1.	Yamada et al. 1988
Escherichia coli *Bacillus subtilis* H17 v M45	Brilliant Blue FCF (the sodium salt (3844-45-9), the ammonium salt (2650-18-2) or unspecified) were tested in	DNA damage (indicative test)	With and without S9	-ve	BIBRA, 1999, Gene-Tox, 1995 (citing Haveland-Smith & Combes, 1980; Kawachi et al. 1980; Leifer et al. 1981; Mizuta & Umisa, 1979)

	various rec assays.				

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