Brilliant blue FCF

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),	C.I. Acid Blue 9 (3844-45-9) was	Chromosome damage	-ve	Hayashi et al. 1988

groups of 6 males	administered by single intraperitoneal (i.p.) injection (up 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	C.I. Acid Blue	Mutation	With and	+ve (+S9)	Cameron et al.

lymphoma cells, L5178Y (tk+/tk-)	9 was tested in a good quality study at up to 0.49 and 1.9 mg/ml (-S9 and +S9, respectively). [Cameron et al. gives the CAS number of the ammonium salt (2650-18-2) but the structure of the sodium salt (3844-45-9).]		without S9		1987; NCI
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.	Chromosome damage	With and without S9	+ve	Ishidate et al. 1981, 1984 & 1988; Kawachi et al. 1980

	1981 is included in a data compilation on 3844-45-9.				
Rat liver cells	Acid Blue 9 was used in a test to detect the induction of DNA repair. [The 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.]	DNA damage (indicative test)	Not appropriate	+ve	Kornbrust & Barfknecht, 1985
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	Cell transformation	With and without S9	-ve	(a) Longstaff et al. 1984; Price et al. 1978 (b) Ishidate et al. 1984

	salt (2650-18-2) were tested.				
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. 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.]	Mutation	With and without S9	-ve	RCC, 1999
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 the sodium salt (3844-45-9).]	Mutation	With S9 derived from rat and hamster liver	+ve (+S9 derived from hamster liver)	Cameron et al. 1987; NCI
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 various rec assays.	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)

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