Acetyl tri-butyl citrate

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	Animals given oral doses of up to 10 g/kg bw and hepatocytes assessed for unscheduled DNA synthesis.	DNA damage	-ve	CSTEE, 1999; US EPA, 2001
Rat, Han Wistar, 5/group	Animals given a single dose of 0, 800 or 2000 mg/kg bw/day, by stomach tube, and the liver assessed for unscheduled DNA synthesis approximately 2-4 or 12-14 hosur later.	DNA damage	-ve	EC, 2007; Fellows, 1999

In vitro

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Test system	Test	Endpoint	Activation	Results	Reference
	conditions		status		
Mouse	Mouse	Mutation	With and	-ve	Bigger &
lymphoma	lymphoma		without		Harbell,
L5178Y	assay in cells		S9		1991; NCI
(TK+/-) cells	treated with				Report
	concentrations				_
	of 10-230				
	μg/ml in the				
	absence of S9				
	and 200-480				
	μg/ml in its				
	presence.				
Mouse	No further	Mutation	With S9	Weak +ve	DoH, 1998
lymphoma	details, but				
cells	cited in a				
	report by the				
	UK				
	Committee on				
	Mutagenicity.				

Mouse lymphoma	Two separate experiments;	Mutation	No data	+ve	EC, 2007
cells	mutations at the HK locus examined			Concentration- dependent increase in mutations	
Chinese hamster ovary (CHO) cells	An HGPRT forward mutation assay in which cells were treated with 25- 400 µg/ml according to EC, US EPA and OECD guidelines.	Mutation	With and without S9	-ve	Dow Chemical Company, 1991
Rat lymphocytes	Two chromosomal aberration studies. No further details available.	Chromosome damage	With an without metabolic activation	-ve	EC, 2007
Rat lymphocytes	Cells treated with 0, 4, 13.3, 40, 133 and 400 µg/ml, in DMSO, for 4 hours, according to OECD guideline 473, and examined 24 hours later for chromosome aberrations	Chromosome damage	With and without S9	-ve	Dow Chemical Company, 1988
Salmonella typhimurium strains TA98, TA100, TA1535 and TA1537	Ames test at concentrations of 50-5000 µg/plate in DMSO, according to OECD guideline 471.	Mutation	With and without S9	-ve	Gollapudi & Linscombe, 1988

Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 and TA1538	Ames test at concentrations of 0.3-10 mg/plate in DMSO	Mutation	With and without S9	-ve	San & Wagner, 1991
Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 and TA1538	Ames test at concentrations of 333-10,000 µg/plate in DMSO.	Mutation	With and without S9	-ve	NCI Report
Salmonella typhimurium, strains TA98, TA100, TA1535, TA1537 and TA1538	Ames test at 9-495 µg/plate in DMSO.	Mutation	Without S9	-ve	Heath & Reilly, 1982; US EPA, 2001

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