Polymer of vinyl acetate and hydroxyethylene

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 (Swiss), treated and vehicle control groups of 5/sex	In a good quality study PVA (9002-89-5; pharmaceutical grade) was given on a single occasion by stomach tube at up to 2000 /mg/kg bw. Bone marrow cells were examined for micronuclei 24 or 48 hr following treatment.	Chromosome damage	-ve	DeMerlis et al. 2002; HLS, 2000a; Kelly et al. 2003
Mouse (SLC-BDF_1), groups of 6 females	Single intraperitoneal injection of 622 mg PVA with examination for micronuclei in bone marrow cells after 24 hr.	Chromosome damage	-ve	Shibuya et al. 1985
Rat	A very brief citation of a paper in Russian notes that PVA (described as 18/11; 9002-89-5), was given orally 35 wk	Mutation	+ve [Although no details are reported, the format of the data summary citing this paper is such that only	Vyshemirskaia et al. 1988

	prior to mating, with examination for dominant lethal effects. The dose is described as 14700 mg/kg [presumably mg/kg bw; possibly a total dose given on a number of occasions]. Generally, in dominant lethal studies, treated males are mated with untreated females.		positive findings are included. An increased incidence of early foetal deaths would reflect sperm cell mutations.]	

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Mouse lymphoma cells (L5178Y)	PVA (9002-89-5; pharmaceutical grade) was tested in a good quality study at up to 5 mg/ml, with assessment of mutagenicity at *tk* locus.	Somatic cell mutation	With and without S9	-ve	DeMerlis et al. 2002; HLS, 2000b; Kelly et al. 2003
Chinese hamster V79 lung cells	PVA present in a contraceptive product was tested at up to 0.03 mg product/ml, with examinations for chromosome aberration. PVA was also tested alone at 0.03 mg/ml.	Chromosome damage	Without S9	-ve	Shibuya et al. 1985
Chinese	Cells were	Chromosome	Not stated	-ve	Hatano

hamster lung cells	exposed to PVA fibres, with examinations for chromosome aberration. [No further data were provided in the brief citations of these studies.]	damage	in citation		Research Institute, 1999; Hayashi & Arai, 2002
Salmonella typhimurium TA98, TA100, TA1535, TA1537	PVA (9002-89-5; pharmaceutical grade) was tested in a good quality Ames test at up to 5 mg/plate. TA1537 was subsequently tested at up to 7.5 mg/plate.	Mutation	With and without S9	-ve Increase in revertants with TA1537 at 5 mg/plate (+S9) in the 1st but not the 2nd assay. No increase at 7.5 mg/plate.	DeMerlis et al. 2002; HLS, 2000c; Kelly et al. 2003
Salmonella typhimurium TA98, TA100, TA1537	PVA was tested in an Ames test at up to 1 mg/plate.	Mutation	With and without S9	-ve	Shibuya et al. 1985
Salmonella typhimurium TA97a, TA98, TA100, TA102	A dental adhesive containing an unspecified amount of PVA was tested in an Ames test.	Mutation	With and without S9	-ve	Schweikl et al. 1996
Escherichia coli WP2 uvrA/pKM101	PVA (9002-89-5; pharmaceutical grade) was tested in a good quality study at up to 5 mg/plate.	Mutation	With and without S9	-ve	DeMerlis et al. 2002; HLS, 2000c

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