

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

	<p>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.</p>		<p>positive findings are included. An increased incidence of early foetal deaths would reflect sperm cell mutations.]</p>	
--	--	--	---	--

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 <i>tk</i> 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
<i>Salmonella typhimurium</i> 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 1 st but not the 2 nd assay. No increase at 7.5 mg/plate.	DeMerlis et al. 2002; HLS, 2000c; Kelly et al. 2003
<i>Salmonella typhimurium</i> 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
<i>Salmonella typhimurium</i> 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	Schweickl et al. 1996
<i>Escherichia coli</i> 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

References

Celvol [undated]. Product data available via <http://www.celanese.com/>.

Chang Chun (2005). Material safety data sheet on polyvinyl alcohols (9002-24-5 & 25213-24-5). Chang Chun Petrochemical Co. Ltd. Available at <http://www.ccp-twn.com/msds.NSF/0/E721C42C6B496E4548256A2900083771?OpenDocument>.

CSTEE (2002). Opinion on risk to human health from chrysotile asbestos and organic substitutes, C2/GF/csteeop/Asbestos 17122002/D(02). Scientific Committee on Toxicity, Ecotoxicity and the Environment (CTSEE). Opinion expressed at the 35th CSTEE plenary meeting, 17 December 2002.

DeMerlis C C et al. (2002). Evaluation of the genotoxic potential of polyvinyl alcohol in a short-term battery of tests. *Toxicological Sciences* 66, 72.

DeMerlis C C & Schoneker D R (2003). Review of the oral toxicity of polyvinyl alcohol (PVA). *Food and Chemical Toxicology* 41, 319.

Dupont (2005). Material safety data sheet on Elvanol polyvinyl alcohol (25213-24-5), revised 30 June 2005, available at http://msds.dupont.com/msds/pdfs/EN/PEN_09004a2f80432be8.pdf.

Hatano Research Institute (1999). Report on the chromosomal aberration test of vinylon fibre using Chinese hamster lung (CHL/IU) cells (cited in CSTEE, 2002).

Hayashi T & Arai F A (2002). A chromosomal aberration study of fibrillated PCA fibre in cultured mammalian cells. *Environmental Mutagen Research* 24, 23-27 (cited in CSTEE, 2002).

HLS (2000a). Polyvinyl alcohol (PVA): mouse micronucleus test. Unpublished report No. 003/994931 from Huntingdon Life Sciences, Huntingdon, Cambs. Submitted to WHO by Colorcon, West Point, PA, USA (cited in DeMerlis & Schoneker, 2003; JECFA, 2004).

HLS (2000b). Polyvinyl alcohol (PVA): mammalian cell mutation assay. Unpublished report No. 002/002105 from Huntingdon Life Sciences, Eye, Suffolk, UK. Submitted to WHO by Colorcon, West Point, PA, USA (cited in DeMerlis & Schoneker, 2003; JECFA, 2004).

HLS (2000c). Polyvinyl alcohol (PVA): bacterial mutation assay. Unpublished report No. 001/994757 from Huntingdon Life Sciences, Eye, Suffolk, UK. Submitted to WHO by Colorcon, West Point, PA, USA (cited in DeMerlis & Schoneker, 2003; JECFA, 2004).

ITW Mark-Tex [undated]. Material safety datasheet on ER017, containing polyvinyl alcohol (25213-24-5). Available at <http://www.dykem.com/Msds/MarkingSystems/GraphicPens/FilmOpaque/08030.pdf>.

JECFA (1996-2000). Compendium of food additive specifications from the 46th through 55th JECFA meetings, 1996 – 2000, updated to include data from the JECFA meeting of 2003. Joint FAO/WHO Expert Committee on Food Additives. Available at http://apps3.fao.org/jecfa/additive_specs/docs/12/additive-0897.pdf.

JECFA (2004). Safety evaluation of certain food additives and contaminants. Polyvinyl alcohol. 61st Meeting of the Joint FAO/WHO Expert Committee on Food Additives. Food Additive Series: 52.

Kelly C M et al. (2003). Subchronic toxicity study in rats and genotoxicity tests with polyvinyl alcohol. *Food and Chemical Toxicology* 41, 719.

Nair B (1998). Final report on the safety assessment of polyvinyl alcohol. *International Journal of Toxicity* 17, 67-92.

Nippon Gohsei (2004a). Material safety data sheet – Gohsenol – generic grades (9002-24-5 & 25213-24-5), prepared 1 March 2004, available at http://www.nippon-gohsei.com/resources/pdf/msds_uk/MSDS_Gohsenol_GradesNAG.pdf.

NTP (1998). Technical report on the toxicology and carcinogenesis studies of polyvinyl alcohol (CAS No. 9002-89-5) in female B6C3F1 mice (intravaginal studies). NTP TR 474. NIH Publication 98-3964.

RTECS (1997). Registry of Toxic Effects of Chemical Substances, available via the Canadian Centre for Occupational Health and safety. Datasheet on polyvinyl alcohol (9002-89-5) 18/11, last updated October 1997, accessed September 2005.

Schweikl H et al. (1996). Mutagenic activity of various dentine bonding agents. *Biomaterials* 17, 1451-1456 (cited in DeMerlis & Schoneker, 2003; JECFA, 2004).

Shibuya T et al. (1985). Mutagenicity testing of ST-film with the Ames test, chromosome test *in vitro* and micronucleus test in female mice. *Journal of Toxicological Sciences* 10, 135-141 (cited in JECFA, 2004; Nair, 1998; NTP, 1998).

Vyshemirskaja L D et al. (1988). Study of chronic toxicity and late effects of polyvinyl alcohol of the 18/11 mark. *Gigiena i Sanitariya* 9, 83-84 (cited in RTECS, 1997). [In Russian.]