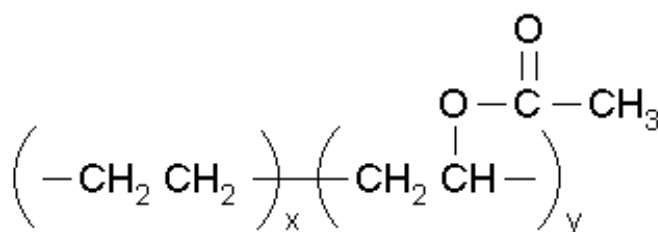


ETHYLENE VINYL ACETATE COPOLYMER

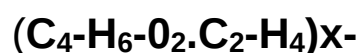
SYNONYMS

Acetic acid ethenyl ester, polymer with ethane
 Ethylene-vinyl acetate latex
 Ethylene-vinyl acetate molding resin
 Ethylene-vinyl acetate copolymer resin

CHEMICAL STRUCTURE



CHEMICAL FORMULA



IDENTIFIER DETAILS

CAS Number : 24937-78-8
 CoE Number : -
 FEMA : -
 EINECS Number : -
 E Number : -

CLP CLASSIFICATION

Ingredient CLP Classification: No

Endpoint	Classification	Category
Acute Oral Toxicity	-	-
Acute Dermal Toxicity	-	-
Acute Inhalation Toxicity	-	-
Skin Corrosive/irritant	-	-
Eye Damage/Irritation	-	-
Respiratory Sensitisation	-	-
Skin Sensitisation	-	-
Mutagenicity/Genotoxicity	-	-
Carcinogenicity	-	-
Reproductive Toxicity	-	-
Specific Target Organ Toxicity	-	-
Aspiration Toxicity	-	-

SPECIFICATIONS

Melting Point: Dependant upon polymer structure.

Boiling point: Dependant upon polymer structure.

PURPOSE

Flavouring substance.

STATUS IN FOOD AND DRUG LAWS

CoE limits:

Beverages (mg/kg)	Food (mg/kg)	Exceptions (mg/kg)
-	-	-

Acceptable Daily Intake:

ADI (mg/kg)	ADI Set by	Date Set	Comments
-	-	-	-

FDA Status:

Section Number	Comments
177.1350 Substances for use as basic components of single and repeated use food contact surfaces. CFR 21: 177.1350 Ethylene-vinyl acetate copolymers	May be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with conditions outlined in the report.

HUMAN EXPOSURE

Reported Uses: Biomaterial for artificial hearts and as an antithrombogenic material and as a drug delivery system [quoted in Shin *et al.*,1996].

TOXICITY DATA

***In Vivo* Toxicity Status**

Dermal toxicity

20 rabbits given corneal implants of ethylene-co-vinyl acetate copolymer did not show any signs of local irritation, similarly mice and rats given ethylene-

co-vinyl acetate implants were reported to show no signs of inflammation [quoted in Nieme *et al.*,1985].

Intracutaneous irritation studies and intramuscular studies were conducted on new Zealand white rabbits. The 2.0 ml saline and cotton seed oil extracts of EH40 and EH50 did not induce any oedema or erythema. For the implantation studies there were no effects of implantation (10mm x1 mm x1mm, size of the implant), with both leading to an acceptable healing pattern for biocompatible materials. The healing pattern around EH50 was found to be better than EH40 and the control material (ultra high molecular weight polyethylene). It was concluded that both of the composites were biologically compatible [Velayudhan *et al.*, 2005].

Other relevant studies

Poly (ethylene-co-vinyl acetate) is regarded as stable *in vivo* and is one of the many biocompatible polymers being developed for the controlled release of many substances. There are many examples of devices have been produced, one such device being an implantable opioid delivery system which is capable of releasing pain relief subcutaneously at a continuous rate for a four week period. This has been developed in order to deliver pain relief to patients in countries where there are limited pumps, catheters or where outpatient support services are expensive. In this study ethylene vinyl acetate copolymer discs containing opioids were implanted into New Zealand white rabbits and were observed to continuously deliver opioids for a four-week period, [Lesser *et al.*,1996]. It should be noted however that Lesser *et al.*,(1996) reported the FDA approved usage of ethylene vinyl acetate in a pilocarpine release system for the management of glaucoma [Ocuser[®]] and an intrauterine hormone release system termed Progestasert[®] [Lesser *et al.*,1996].

Poly [ethylene-co-vinyl acetate] has also been used as a delivery system to administer recombinant human nerve growth factor intracranially in rats [up to 4 weeks], [Saltzman *et al.*,1999], and has been implicated for *in vivo* gene delivery in DNA vaccination and gene therapy [Luo *et al.*,1999].

The two main types of synthetic, nondegradable polymers used in the delivery of female contraceptives are reported to be silicone elastomers and ethylene co vinyl acetate (EVA; ELVAX). To date the toxicological studies on EVA are reported to be sparse however, Shastri (2002) concluded that EVA elicited no adverse local or systemic response over extended periods of time *in vivo* [Shastri, 2002].

Steroid releasing vaginal rings made of ethylene vinyl acetate copolymer or polysiloxane rubber have/are being developed. A few such devices are reported to have 'reached the market' in some countries. However the acceptability of these devices are 'yet to be established' [Sarkar, 2003].

EVA is one of the most common materials used in the construction of mouth guards for playing sports [Westerman *et al.*, 2002].

Behavioural data:

No data identified

***In Vitro* Toxicity Status**

Carcinogenicity and mutagenicity

Additional information concerning the *in vitro* mutagenicity of this material may be found in "An Interim report on data originating from Imperial Tobacco Limited's Genotoxicity testing programme September 2003" or "An updated report on data originating from Imperial Tobacco Limited's external Genotoxicity testing Programme – Round 2, August 2007".

Primary polypropylene modified with ethylene vinyl acetate copolymer was not toxic towards mouse 3T3 fibroblasts and isolated mouse peritoneal macrophages. The viability of the cells cultivated in the presence of primary polypropylene modified with ethylene vinyl acetate copolymer was unaffected after radiation treatment [used as a mode of sterilisation], [the exact details of the study were unclear as the original paper was in Polish therefore, these conclusions have been taken from an English translated abstract], [Lewandowska-Szumiel Malgorzata *et al.*, 1997].

Biocompatibility studies have been conducted with a composite material containing hydroxyapatite and ethylene vinyl acetate copolymer to be used to repair defective bone tissue, containing 40%(EH40) and 50% hydroxyapatite (EH50). Both EH50 and EH40 were not cytotoxic to L929 (mouse fibroblast subcutaneous connective tissue), when incubated at $37 \pm 2^{\circ}\text{C}$ for 24 hours [Velayudhan *et al.*, 2005]

A toxicological evaluation by Coggins *et al.*, (2013) of ethylene vinyl acetate, polyvinyl acetate and starch tested varying levels of the different side-seam adhesives and the transfer of adhesives from packaging materials using experimental cigarettes. Levels were determined by the number of lines of adhesive applied to the cigarette paper; high application levels (three lines of adhesive) were compared with low application levels (one line of adhesive). There were differences in some mainstream cigarette smoke constituents as a function of the level of adhesive added to experimental cigarettes and between the tested adhesives. None of these differences translated into statistically significant differences in the *in vitro* or *in vivo* assays. Newer "high-speed-manufacture" vinyl acetate-based adhesives can therefore replace the older "low-speed-manufacture" adhesives in cigarettes.

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