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Amended Final Safety Assessment of Polyvinyl Acetate[1]

Abstract: The polymer Polyvinyl Acetate (PVAc) is used in cosmetics as a binder, emulsion stabilizer, and hair fixative. Current reported uses are limited to a few eye makeup formulations. As used in cosmetic formulations, PVAc is an emulsion containing 55 to 60% resin. The Cosmetic Ingredient Review (CIR) Expert Panel had previously published a review of the safety of this ingredient in *J Am Coll Toxicol* (1992;11:465–74) concluding that the available data were not sufficient to support safety. The report included mutagenesis and carcinogenesis studies with negative findings. Data from pregnant rabbits indicated that PVAc was not transferred to the fetus, even when administered by the i.v. route, suggesting that present cosmetic use practices preclude any reproduction or developmental toxicity hazard to humans. Composition and impurities data and human skin irritation and sensitization data, however, were not available. Data received since that assessment include the nature of the ingredient as used in cosmetics, the identity of many of the impurities, and the test results of human exposure to aqueous emulsions containing ≤50% PVAc. Less than 2 ppm of arsenic and <20 ppm of heavy metals reportedly will be in a typical emulsion. The clinical testing of an aqueous emulsion with 50% PVAc produced no irritation or sensitization. Based on the recent information, this ingredient is found to be safe for use as a cosmetic ingredient in the present practices of use. **Key Words:** Polyvinyl Acetate—Cosmetic use—Impurity—Human.

In an earlier evaluation (Elder, 1992), the Cosmetic Ingredient Review (CIR) Expert Panel found that there were insufficient data to support the safety of Polyvinyl Acetate (PVAc) and cited three missing pieces of data: (a) composition of the PVAc as used in cosmetic formulations, including impurities and additives; (b) skin irritation (human); and (c) skin sensitization (human). Data received since that evaluation have been reviewed, incorporated into the original report, and used as the basis for an amended conclusion.

PVAc as used in cosmetic products and reviewed in this report is the emulsion rather than the solid form. All available safety test data on PVAc are included in this report. Some safety test data on films and polymers of vinyl acetate in an earlier report (Elder, 1983) are also included.

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[1] Reviewed by the Cosmetic Ingredient Review Expert Panel.

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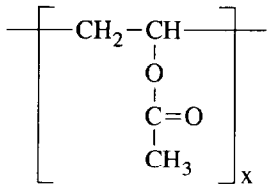
CHEMISTRY

Definition and Structure

PVAc (CAS No. 9003-20-7) is the homopolymer of vinyl acetate (Wenninger and McEwen, 1993). It conforms to the general formula:



PVAc is also known as the homopolymer of ethenyl acetate (Wenninger and McEwen, 1993), vinyl acetate homopolymer, vinyl acetate polymer, and vinyl acetate resin (IARC, 1979).

Properties

PVAc is a clear white to pale yellow solid (Food Chemicals Codex, 1981). The melting range (softening range) of PVAc is between 30° and 50°C (Lindemann, 1971); the softening point of various PVAc resins ranged from 43 to 141°C, depending on molecular weight (Union Carbide Corporation, 1989*a*). The refractive index of PVAc has been reported as 1.4669 (Lindemann, 1971) and 1.4665 at 20°C (Union Carbide Corporation, 1989*a*). PVAc has reported specific gravities of 1.19 at 15°C (Hawley, 1971), 1.177 (temperature unspecified) (Matharu and Lalla, 1985), and 1.18 (temperature unspecified) (Union Carbide Corporation, 1989*a*). A saponification value of 260 to 270 has been recorded for PVAc (Matharu and Lalla, 1985). PVAc is insoluble in water (Hawley, 1971; Grant, 1972), gasoline, oils, fats (Hawley, 1971), mineral oil (Grant, 1972), high-molecular-weight alcohols, aliphatic hydrocarbons, carbon disulfide, and cyclohexane. It is soluble in low-molecular-weight alcohols, esters, chlorinated hydrocarbons, and benzene and in acetone, chloroform, carbon tetrachloride, trichloroethylene, and methylene chloride (Hawley, 1971; Lindemann, 1971). PVAc is tasteless and odorless (Hawley, 1971) or may have a slight characteristic odor (Union Carbide Corporation, 1989*b*). It is not known if PVAc, used as a cosmetic ingredient, contains plasticizers or emulsifiers.

Method of Manufacture

PVAc is manufactured by the polymerization of vinyl acetate using peroxide catalysts (Hawley, 1971) or other initiators (Lindemann, 1971). Most commercial production of PVAc is made by an emulsion polymerization reaction carried out in aqueous solution, in the presence of emulsifiers or protective colloids and an initiator as well as a neutralizer (Lindemann, 1971). Chemicals identified from

patents and the trade literature to be used as emulsifiers, protective colloids, neutralizers, and initiators are shown below in Table 1.

Another process, suspension polymerization, is conducted in the same manner as emulsion polymerization, with the use of more water and the addition of a suspending agent such as partially hydrolyzed polyvinyl alcohol. That process results in the solid resin as small pearls (IARC, 1979; Lindemann, 1971). After completion of polymerization, the resin is purified by the removal of residual catalyst, vinyl acetate, and solvent by vacuum drying, steam sparging, and/or washing (Food Chemicals Codex, 1981); as noted previously, commercial forms of PVAc contain small amounts of residual monomer (Union Carbide Corporation, 1989*b*). PVAc may be produced as a co-polymer and referred to as PVAc if it contains ≥60% vinyl acetate (IARC, 1979), but PVAc as defined for cosmetic use is a homopolymer (CTFA, 1994). If the PVAc is supplied as an emulsion, it generally contains 55% resin (IARC, 1979).

Impurities

PVAc intended for use as a food chemical may contain not more than 3 ppm arsenic, not more than 0.05% free acetic acid, not more than 0.004% heavy metals, and not more than 3 ppm lead (Food Chemicals Codex, 1981). PVAc contains residual vinyl acetate, usually <0.02% of the total polymer (Union Carbide Corporation, 1989*a*). Depending on whether the PVAc is supplied as a solid or as an emulsion, it may contain hardeners, plasticizers (typically, dialkyl-phthalate), emulsifiers, thickeners, biocides, pigments, and other additives used to impart desired characteristics in the final product (IARC, 1979; Union Carbide Corporation, 1989*a;* CTFA, 1994). Purification steps are taken to remove residual plasticizers, emulsifiers, and antifreezing agents for PVAc intended for cosmetic use (CTFA, 1994). One typical PVAc composition included (a) no plasticizer; (b) 0.2% dihydroxy acetic acid as a preservative; (c) arsenic <2 ppm; and (d) heavy metals

TABLE 1. *Components used in commercially produced Polyvinyl Acetate*

Component function	Specific component
Emulsifiers	Sodium lauryl sulfate
	Alkylarenesulfonates
	Ethylene oxide adducts of alkylphenols
	Ethylene oxide-propylene oxide copolymers
	Poly(ethylene oxide)-fatty acid esters and ethers
Protective colloids	Polyvinyl alcohol
	Hydroxyethylcellulose
	Maleic anhydride-alkyl vinyl ether copolymers
	Gum arabic
Initiators	Alkali peroxysulfites
	Hydrogen peroxide
	t-Butyl hydroperoxide
	Cumene hydroperoxide

Data adapted from Lindemann (1971).

<20 ppm (CTFA, 1994). Another formulation was identical except for the use of 2% ethanol as a preservative (CTFA, 1994).

Chemical Reactivity

PVAc is a stable compound (Union Carbide Corporation, 1989*b*) resistant to weathering (Hawley, 1971). PVAc is resistant to heat and light, and will swell and soften on continuous immersion in water (Union Carbide Corporation, 1989*a*). Vinyl acetate in liquid form polymerizes on exposure to light (Sax, 1979; Windholz, 1983).

Analytical Methods

PVAc may be identified through its infrared absorption spectrum (Food Chemicals Codex, 1981). Pyrolysis gas chromatography may also be used to identify PVAc in various plastics, rubbers, and adhesives (IARC, 1979). PVAc may also be identified by liquid chromatography, ultraviolet-visible spectrophotometry, and by hydrolysis followed by potentiometric titration or gas chromatographic analysis of the acid. Colorimetry of the iodine complex of PVAc may also be used to identify the compound. The method of determination used depends on the form in which the PVAc is present (i.e., adhesive, paint, paper coating).

USE

Cosmetic

United States

PVAc is used in cosmetics as a binder, emulsion stabilizer, film former, and hair fixative (Wenninger and McEwen, 1992). The PVAc used in cosmetics is an emulsion containing 55 to 60% resin rather than the solid form of PVAc (Eiermann, personal communication)[2].

Data submitted to the Food and Drug Administration (FDA) indicate that PVAc is used in a total of seven eye makeup formulations (FDA, 1994). As reported to the FDA in 1989 and confirmed in 1994, PVAc is used in cosmetics at concentrations <25% (FDA, 1989; CTFA, 1994).

International

PVAc is listed in the Japanese Cosmetic Ingredient Dictionary, a compilation of cosmetic ingredients previously approved for products marketed in Japan (Rempe and Santucci, 1992).

Noncosmetic

PVAc has a variety of noncosmetic uses. In veterinary medicine, it is used as an adhesive film former in antibiotic aerosol sprays for teat treatments in cattle (Rossoff, 1974). It is also used as a diluent for inks used to mark gum, confections, and food supplements in tablet form (Furia, 1977), and as a base for chewing gums

[2]Available for review from: Director, Cosmetic Ingredient Review, 1101 17th Street NW, Suite 310, Washington, D.C. 20036, U.S.A.

(Food Chemicals Codex, 1981). PVAc is used as an adhesive for paper, wood, glass, metal, and porcelain (Hawley, 1971). It is also approved as an adjuvant for pesticide chemicals; as a substance in the manufacture of paper and paperboard products that come in contact with aqueous, fatty, and dry foods, and in resinous and polymeric coatings, in closures with sealing gaskets for foods, in cellophane, and in water-insoluble hydroxyethyl cellulose film (Food Chemical News Guide, 1988). Other noncosmetic uses of PVAc include sealants, latex paints, shatterproof photographic bulbs, bookbinding, and textile finishing; as a component of lacquers, inks, and plastic wood; and as a strengthening agent for cement (Hawley, 1971). PVAc may also be used as an intermediate for the conversion into polyvinyl alcohol and acetals (Hawley, 1971). PVAc is also used for binding bag seams, laminations, tube winding, remoistenable labels, and in smoothing plasterboard tape joints, in spackling paste, and in secondary furniture gluing (IARC, 1979). Mixtures containing 18 to 24% PVAc have been reported suitable for mouth protection during sports activities (Bishop et al., 1985). Mixtures of polyethylene glycols and PVAc may be used as tissue-embedding media, with the PVAc adding tensile strength and ease of handling of sections on water (Reid and Sarantakos, 1966). PVAc has also been used as a component of chemical protective clothing (Coletta, 1985).

GENERAL BIOLOGY

Effects on Blood

To assess blood compatibility of artificial materials, the blood of human donors was passed through columns containing various materials, including PVAc beads (Lindon et al., 1978). The PVAc was observed for signs of platelet retention and release of platelet constituents due to lysis. Platelet aggregation and adhesion to the PVAc resulted in retention of platelets in the test column. When various blood sample parameters of the donors were examined to assess the causes of donor-to-donor variability, it was reported that the amount of platelet retention by PVAc increased as the sedimentation rate increased. The use of birth control pills by female blood donors increased platelet retention by PVAc. PVAc did not adsorb serotonin from platelet-free plasma, and did not cause lysis of erythrocytes.

Absorption, Distribution, and Excretion

An aqueous emulsion of PVAc was administered to rabbits by the following routes: subcutaneous (s.c.) in 2 rabbits, intratracheally in 3 rabbits, and intravenously (i.v.) in 131 rabbits (Miyasaki, 1975). In the s.c. study, 2 rabbits were injected with 0.3 ml of 30% PVAc. The PVAc remained localized at the site of injection with little absorption. When 1 ml/kg of a 3% solution of PVAc was injected intratracheally in 3 rabbits every fourth day for a total of four injections, the PVAc was phagocytized by alveolar phagocytes. Six groups of rabbits received i.v. injections. The first group of 41 rabbits received 1 ml/kg injections of 5% PVAc daily for 1, 2, 4, 8, 12, 16, or 24 weeks; a second group of 60 rabbits received daily injections of 2 ml/kg of 5% PVAc for 3 days, or 1, 2, 3, 6, 12, or 24

weeks; a third group of 5 rabbits received daily injections of 3 ml/kg of 5% PVAc for 26 weeks; a fourth group of 2 rabbits received injections for 26 weeks as did the third group, followed by a 12-week nontreatment period; a fifth group of 18 rabbits received daily injections of 4 ml/kg of 5% PVAc for 1, 2, 4, or 6 weeks; and a sixth group of 5 pregnant rabbits each received a 5 ml/kg-injection of 5% PVAc.

A small amount of the i.v. injected PVAc was excreted in the urine; the remainder was retained in the body. The PVAc injected daily over a long period of time caused enlargement of the spleen, lymph nodes, and liver. The monocyte-macrophage system of the liver, spleen, bone marrow, lymph nodes, adrenal glands, and lungs phagocytosed the injected PVAc, forming foam cells. The cellular storage of PVAc remained unchanged 3 months after treatment. In the treated group of the pregnant rabbits, PVAc was not transferred to the fetus in appreciable amounts.

ANIMAL TOXICOLOGY

Acute Toxicity

PVAc, 25 g/kg as a single dose, was administered orally to rats and mice (strain unspecified) (IARC, 1979). Effects due to oral administration of PVAc included lymphoid infiltration of the liver, depigmented epithelial cells of the renal tubules, and a slight increase in the number of polynucleated cells in the spleen.

Short-term Toxicity

Extracts of a commercial hair spray containing polyvinyl pyrrolidine (PVP)/polyvinyl acetate (PVAc) were dissolved in isotonic saline and injected s.c. in the scapular area of adult mice, rats, and guinea pigs (Gebbers et al., 1979); polymer concentrates were not stated. PVP and PVAc alone in saline were also injected s.c. in the scapular area of mice, rats, and guinea pigs. Control animals received injections of saline. The animals were killed 4, 10, or 30 days after injection and the injection site was biopsied; samples from the liver, spleen, and kidneys were obtained for electron microscopic evaluation. A strong s.c. foreign body reaction with granulomas was seen in the animals injected with hair spray extracts and with PVP/PVAc 4 and 10 days postinjection. No reaction was noted at 30 days. The foreign body reaction consisted of many monocytes, large macrophages, multinucleated giant cells with periodic acid-Schiff (PAS)–positive inclusions, and many foam cells. Lamellar lysosomal inclusions were observed in the macrophages and giant cells. The Kupffer's cells of the liver and macrophages of the spleen contained PAS-positive cytoplasmic inclusions 4 weeks after injection of hair spray extract and PVP/PVAc.

Chronic Toxicity

When PVAc, 250 mg/kg, was administered orally for 12 months to rats and mice, fluctuations in weight, changes in blood composition, changes in liver-to-body weight ratios, and changes in cholinesterase and catalase activities were observed (IARC, 1979). No other details were given.

Dermal Irritation

A dose of 0.1 ml of a solution of 1.25% PVAc in ethanol saline was injected s.c. into the shaved posterior dorsal skin of 24 adult albino rats to determine the irritation potential of the PVAc (Carpenter et al., 1976). Twelve negative vehicle controls and 24 positive controls (carrageenan) were included in the study program. Two rats from the negative control group and four rats from the positive control group and four from the test group were killed on days 3, 7, 14, 21, 28, and 42. The injection sites were removed and preserved for microscopic examination. Tissue samples obtained from the test rats killed on day 3 had a moderate subacute inflammatory infiltrate of lymphocytes and plasma cells. Ulceration, accompanied by edema and tissue destruction, was frequently observed. Tissue samples from the rats killed on day 7 had retained PVAc surrounded by a severe inflammatory response. Ulceration, accompanied by abscesses and necrosis, was present in almost all the rats. In addition to lymphocytes and plasma cells, neutrophils were also present in abundance. The inflammatory response had reduced in severity by day 14, although many plasma cells and lymphocytes were still present. Many areas of granulation tissue were evident, as well as foci of necrosis with ulceration and an accompanying acute response. The tissue samples from the rats killed on day 21 had a moderate inflammatory response, with inflammatory cells and granulation tissue in abundance. By day 28, a minimal inflammatory response was evident, with cicatrization and early maturation of collagen fibrils. By day 42, inflammatory response was minimal, with the epithelium intact and cicatrization of the dermis. The PVAc response was similar to that of the positive control through day 14, at which time the PVAc response was much reduced compared to the positive control. PVAc was considered very irritating when injected s.c., with an initial response similar to that of the positive control except for granuloma formation, which did not occur in the PVAc-treated animals. The adverse irritation reactions to the i.v. injection of PVAc cited in this section are similar to that previously reported as a foreign body reaction by Gebbers et al. (1979) in their short-term toxicity i.v. studies of PVAc using mice, rats, and guinea pigs.

Reproduction and Developmental Toxicity

No studies have reported effects of PVAc on reproduction, teratology, or other developmental toxicity. However, data from pregnant rabbits (Miyasaki, 1975) indicate that PVAc was not transferred to the fetus in appreciable amounts, even when administered by the i.v. route, thus suggesting that no developmental effects could be produced by the usual dermal application of cosmetic ingredients.

GENOTOXICITY

PVAc was tested for mutagenic potential in the Ames test using *Salmonella typhimurium* strains TA92, TA1535, TA100, TA1537, TA94, and TA98, with metabolic activation (Ishidate et al., 1984). PVAc, 98.6% pure and dissolved in ace-

tone, at a maximum dose of 5.0 mg/plate, was not mutagenic under the conditions of the study.

PVAc was also tested for mutagenic potential in the chromosomal aberration test using a Chinese hamster fibroblast cell line (Ishidate et al., 1984). No metabolic activation system was used. The test cells were exposed to three concentrations of the test substance; the maximum concentration was 200 mg/ml. Polyploid cells, as well as cells with chromosomal structural aberrations, were recorded. A result was considered positive if >10% aberrations were found, equivocal if 5.0 to 9.9% aberrations were detected, and negative if there were <4.9% aberrations. The negative controls, consisting of untreated and solvent-treated cells, contained <3.0% aberrations. The maximum incidence of polyploid cells in the treated groups was 2.0%; no chromosomal aberrations were observed at 24 and 48 h. PVAc was negative for mutagenicity under the conditions of the study.

CARCINOGENICITY

In a single inhalation study, 96 rats were exposed 6 h/day, 5 days/week, to vinyl acetate at a concentration of 8,750 mg/m^3 for 1 year and observed until death. There was no evidence that vinyl acetate influenced the incidence of neoplasms (Maltoni, 1976).

Vinyl chloride-vinyl acetate (VC/VA) polymer was tested for strain response differences to s.c. implantation of the polymer in 18 strains of mice (Brand et al., 1977). There was a 90 to 100% incidence of neoplasms in female mice of the CBA/H, CBA/H-T6, BALB/cJ, BALB/cWAT, C57BL/10ScSn strains, in males of the AKR/J strain, and in both sexes of the (C57BL/10ScSnxCBA/H)F_1 strain mice. All other strains had intermediate responses, with incidence of neoplasms in males lower than that in females, with the exception of male AKR mice.

VC/VA powder, equivalent to two films 15 × 22 × 0.2 mm (as in the previous study), was injected s.c. in 30 male and 46 female 6-week-old CBA mice; the mice were observed until death (Brand et al., 1975). One female mouse developed a sarcoma possibly due to the clumping of the powder after administration. No other treatment-related neoplasms were observed. Clayson (1962) concluded that the induction of local sarcomas after the s.c. injection of a substance cannot be regarded as sufficient to state that the substance is a chemical carcinogen.

CLINICAL ASSESSMENT OF SAFETY

Irritation

The available results of occupational exposure to vinyl acetate have been well documented (NIOSH, 1978). Some minor skin and eye irritations to airborne vinyl acetate were noted.

An occlusive skin irritation test (CTFA, 1994) was conducted using 54 female volunteers and an aqueous PVAc solution (50% concentration). Approximately 0.05 ml was placed on a patch test plaster that was applied to the intact forearm area for 24 h. On removal of the plaster, the skin response was immediately scored

on a six-point scale: 0(−), no reaction; 1(+/−), faint or minimal erythema; 2(+), distinct erythema; 3(++), distinct erythema with infiltration, edema, or papules; 4(+++), edema or papules, with vesicles; and 5(++++), crust or necrosis. All 54 subjects had no reaction.

Sensitization

A repeat insult patch test (CTFA, 1994) was conducted using 159 volunteers (26 males and 133 females; aged 16–65 years). Aqueous PVAc emulsions at 50% concentration were used for induction and challenge. Induction was done using ~0.2 ml of the PVAc solution placed onto an occlusive patch and then applied to the back of each subject. Patches were left on for 24 h, removed for 24 h, and a new patch applied after examination of the induction site. This sequence was continued through nine applications and varied only by allowing 48 h between applications of the patch on weekends. Two weeks after the last patch was removed, a challenge patch was applied to a previously unexposed site. All challenge sites were evaluated at 24 and 72 h after application, and subjects were instructed to report any delayed skin reactivity occurring at a later time. Thirteen subjects discontinued the study for reasons unrelated to the conduct of the study. Of the 146 subjects completing the study, none had any skin irritation or allergic contact sensitization at any time.

SUMMARY

PVAc as used in cosmetic products is a latex emulsion known as the homopolymer of ethenyl acetate. It is used in cosmetics as a binder, emulsion stabilizer, and hair fixative at concentrations <25%. It is approved for use in cosmetic products in Japan and as a direct and indirect food additive in the United States.

In animal studies, injected PVAc was stored in the body. Enlargement of the lymph nodes, spleen, and liver was apparent. The irritation potential of a hair spray containing PVAc was evaluated by s.c. injection into adult rats. The test compound produced a severe inflammatory reaction. Although no studies have reported effects of PVAc on reproduction or developmental toxicity, other data indicate that PVAc was not transferred to the fetus in any appreciable amounts, even when administered by the i.v. route. This suggests that no developmental effects could be produced by the usual dermal application of cosmetic ingredients.

PVAc was nonmutagenic in the Ames assay, with and without activation, and in the Chinese hamster fibroblast cell assay. Several carcinogenic implantation studies using mice gave negative results. Inhalation studies of VC/VA using rats did not affect the tumor incidence.

No significant skin or eye irritation due to occupational exposure has been reported. PVAc at a concentration of 50% in a cosmetic product showed no irritation reaction in 54 female volunteers tested with occlusive patches and no irritation or allergic contact sensitization in 146 volunteers in a repeat insult patch test.

DISCUSSION

Available data do not completely identify all possible contaminants that may be found in PVAc. The concentrations of arsenic and heavy metals, however, is sufficiently low such that they present no safety concern. In clinical tests, 50% PVAc aqueous emulsions produced no reactions, suggesting that any unidentified impurities are both nonirritating and nonsensitizing. Neither mutagenicity nor carcinogenicity data suggest any biological activity of any concern for cosmetic use.

CONCLUSION

On the basis of the data presented in this report, the CIR Expert Panel concludes that PVAc is safe as a cosmetic ingredient in the present practice of use.

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