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Final Report on the Safety Assessment of Polyvinyl Acetate

ABSTRACT

Polyvinyl Acetate, as used in cosmetic products, is a latex emulsion known as the homopolymer of ethenyl acetate. It is used as a binder, emulsion stabilizer, and hair fixative at concentrations less than 25%. Polyvinyl Acetate was nonmutagenic in the Ames assay, with and without activation, and in the Chinese Hamster fibroblast cell assay. Carcinogenic implantation studies using mice gave negative results. It is concluded that the data available are insufficient to support the safety of Polyvinyl Acetate as currently used in cosmetic products. The types of data needed to complete the safety evaluation are listed in the report.

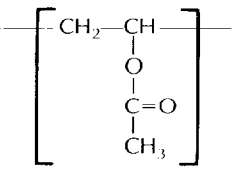
INTRODUCTION

POLYVINYL ACETATE, AS USED in cosmetic products and reviewed in this report, is the latex emulsion rather than the solid form. All available safety test data on Polyvinyl Acetate is included in this report. Some safety test data on films and polymers of vinyl acetate are also included.

CHEMISTRY

Definition and Structure

Polyvinyl Acetate (CAS No. 9003-20-7) is the homopolymer of vinyl acetate (Estrin et al., 1982). It conforms to the general formula:



Polyvinyl Acetate (PVAc) is also known as the homopolymer of ethenyl acetate (Estrin et al., 1982), vinyl acetate homopolymer, vinyl acetate polymer, and vinyl acetate resin (International Agency for Research on Cancer [IARC], 1979).

Properties

PVAc is a clear white to pale yellow solid (Food Chemicals Codex [FCC], 1981). The melting range (softening range) of PVAc is between 30 and 50°C (Lindemann, 1971, in IARC, in 1979); the softening point range of various PVAc resins 43–141°C, depending on molecular weight (Union Carbide Corporation [UCC], 1989a). The refractive index of PVAc has been reported as 1.4669 (Lindemann, 1971, in IARC, 1979) and 1.4665 at 20°C (UCC, 1989a). 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) (UCC, 1989a). A saponification value of 260–270 has been recorded for PVAc (Matharu and Lalla, 1985). PVAc is insoluble in water (Grant, 1972; Hawley, 1971), gasoline, oils, fats (Hawley, 1971), mineral oil (Grant, 1972), high-molecular weight alcohols, aliphatic hydrocarbons, carbon disulfide, and cyclohexane; and 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, in IARC, 1979). PVAc is tasteless and odorless (Hawley, 1971), or may have a slight characteristic odor (UCC, 1989b). It is not known if PVAc, as used as a cosmetic ingredient, contains plasticizers or emulsifiers.

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 (FCC, 1981). PVAc contains residual vinyl acetate, usually less than 0.02% of the total polymer (UCC, 1989a).

Method of Manufacture

PVAc is manufactured by the polymerization of vinyl acetate using peroxide catalysts (Hawley, 1971). The emulsion polymerization reaction is carried out in aqueous solution, and in the presence of surfactants (IARC, 1979). Another process, suspension polymerization, is conducted in the same manner as emulsion polymerization, with the addition of a suspending agent such as partially hydrolysed polyvinyl alcohol, resulting in the solid form of the polymer (IARC, 1979). 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 (FCC, 1981); as noted previously, commercial forms of PVAc contain small amounts of residual monomer (UCC, 1989b). PVAc most often is a copolymer rather than homopolyer; the resin is referred to as PVAc as long as it contains at least 60% vinyl acetate (IARC, 1979). When supplied as an emulsion, PVAc generally contains 55% resin (IARC, 1979). Depending upon whether the PVAc is supplied as a solid or as an emulsion, it may contain hardeners, plasticizers, emulsifiers, thickeners, biocides, pigments, and other additives used to impart desired characteristics in the final product (IARC, 1979; UCC, 1989a).

Chemical Reactivity

PVAc is a stable compound (UCC, 1989b) and is resistant to weathering (Hawley, 1971), heat and light, and will swell and soften upon continuous immersion in water

(UCC, 1989a). Vinyl acetate in liquid form polymerizes upon exposure to light (Sax, 1979; Windholz, 1983).

Analytical Methods

PVAc may be identified through its infrared absorption spectrum (FCC, 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 (Nikitakis, 1988). The PVAc used in cosmetics is an emulsion containing 55–60% resin rather than the solid form of PVAc (Eiermann, 1989).

Data submitted to the Food and Drug Administration (FDA) in 1989 indicated that PVAc was used in a total of two mascaras. The concentration of PVAc used was less than 25% (FDA, 1989).

The FDA cosmetic product formulation computer printout (FDA, 1989) is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations (1982). Ingredients are listed in preset concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentation, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product; the actual concentration would be a fraction of that reported to the FDA. Data submitted within the framework of present concentration ranges provides the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a two- to tenfold error in the assumed ingredient concentration.

International. PVAc is listed in the Japanese Cosmetic Ingredient Dictionary, a compilation of cosmetic ingredients previously approved for products marketed in Japan (Cosmetic, Toiletry, and Fragrance Association [CTFA], 1984).

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 (FCC, 1981). PVAc is used as an adhesive for paper, wood, glass, metal, and porcelain (Hawley, 1971). It is also approved for use as an adjuvant for pesticide chemicals, as a substance

used in the manufacture of paper and paperboard products which would come in contact with aqueous, fatty, and dry foods, 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, 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 18–24% PVAc have been reported to be 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

In order to assess blood compatibility of artificial materials, the blood of human donor was passed through columns containing various materials, including PVAc beads (Lindon et al., 1978). PVAc was observed for signs of platelet retention and release of platelet constitutents 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 absorb 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: subcutaneously (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 the 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 which 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 phagocytized 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

Oral. PVAc, 25 g/kg in a single dose, was administered orally to rats and mice (strain unspecified) (Scherbak et al., 1975, in IARC, 1979). Effects due to oral administration of PVAC induced 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 commerical hair spray containing polyvinyl pyrrolidine (PVP)/ Polyvinyl Acetate (PVAc) were dissolved in isotonic saline and injected subcutaneously 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 sacrificed 4, 10, or 30 days after injection and the injection site was biopsied, and samples from the liver, spleen, and kidneys were obtained for electron microscopic evaluation. A strong subcutaneous 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 d. The foreign body reaction consisted of many monocytes, large macrophages, multinucleated giant cells with periodic acid-Schift (PAS) positive inclusions, and many foam cells. Lamellar lysosomal inclusions were observed in the macrophages and giant cells. The Kupffer 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

Oral. 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 (Scherbak et al., 1975, in IARC, in 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 subcutaneously 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 (carrageenin) were included in the study program. Two rats from the negative control group and 4 rats from the positive control group and 4 rats from the test group were sacrificed 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 who were killed on day 3 had a moderate chronic inflammatory infiltrate with lymphocytes and plasma cells present. Ulceration, accompanied by edema and tissue destruction, was frequently observed. Tissue samples from the rats that were killed on day 7 had retained PVAc surrounded by a severe inflammatory response. Ulceration, accompanied by abscess formation and necrosis, was present in almost all of the tissue samples. In addition to lymphocytes and plasma cells, neutrophils were also present in abundance. The inflammatory response had reduced in severity by day 14, though 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 with normal 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 in comparison to the positive control. PVAc was considered very irritating when injected subcutaneously, with an initial response similar to that of the positive control except for granuloma formation, which did not occur in the PVAc-treated tissues. The adverse irritation reactions to the 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 studies of PVAc using mice, rats, and guinea pigs.

MUTAGENICITY AND CARCINOGENICITY

Mutagenicity

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 acetone, 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 doses of the test substance; the maximum dose was 200 mg/ml. Polyploid cells, as well as cells with chromosomal structural aberrations, were recorded. A result was considered positive if more than 10% aberrations were found, equivocal when 5.0–9.95 aberrations were detected, and negative if there were less than 4.9% aberrations. The negative controls, consisting of untreated and solvent-treated cells, contained less than 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 8750 mg/m^3 for one 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 subcutaneous implantation of the polymer in 18 strains of mice (Brand et al., 1977, in IARC, 1979). There was a 90–100% 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 the 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 subcutaneously in 30 male and 46 female 6-week-old CBA mice; the mice were observed until death (Brand et al., 1975, in IARC, 1979). 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 subcutaneous injection of a substance cannot be regarded as sufficient to state that the substance is a chemical carcinogen.

CLINICAL ASSESSMENT OF SAFETY

Dermal Irritation and Sensitization

The available results of occupational exposure to vinyl acetate have been well documented (NIOSH, 1978). Some minor skin and eye irritation to air borne vinyl acetate was noted. No clinical irritation or sensitization studies have been reported.

SUMMARY

Polyvinyl Acetate 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 less than 25%. It is approved for use in cosmetic products in Japan and as a direct and indirect food additive in the United States.

In animals studies, injected Polyvinyl Acetate 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 subcutaneous injection into adult rats. The test compound produced a severe inflammatory reaction. No significant skin or eye irritation, due to occupational exposure, has been reported.

Polyvinyl Acetate 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 vinyl chloride/vinyl acetate using rats did not affect the tumor incidence.

DISCUSSION

Section 1, paragraph (p) of the CIR Procedures states that "A lack of information about an ingredient shall not be sufficient to justify a determination of safety." In accordance with Section 30(j)(2)(A) of the CIR Procedures, the Panel informed the

public of its decision that the data on Polyvinyl Acetate are insufficient to determine whether this ingredient, under each relevant condition of use, is either safe or unsafe. The Panel released a Notice of Insufficient Data Announcement on February 8, 1991 outlining the data needed to assess the safety of Polyvinyl Acetate as used in cosmetic products. The data needed were: (a) Composition of the Polyvinyl Acetate as it is used in cosmetic formulations, including impurities and additives; (b) skin irritation (human); and (c) skin sensitization (human).

No offer to supply these data was received. In accordance with Section 45 of CIR Procedures, the Expert Panel will issue a Final Safety Evaluation Report—Insufficient Data. When the requested new data are available, the Panel will reconsider the Final Report in accordance with Section 46 of the CIR Procedures, Amendment of a Final Report.

CONCLUSION

The CIR Expert Panel concludes that the data available are insufficient to support the safety of Polyvinyl Acetate as used in cosmetic products.

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