

Second Annual Report on

Carcinogens

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U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service



RSV 0020096

VINYL CHLORIDE

Vinyl chloride is a human carcinogen. Its target organs are the liver, brain, lung and haemo-lymphopoietic system. Similar carcinogenic effects were first demonstrated in rats and were later confirmed in mice and hamsters. Although evidence of a carcinogenic effect of vinyl chloride in humans has come from groups occupationally exposed to high doses of vinyl chloride, there is no evidence that there is an exposure level below which no increased risk of cancer would occur in humans.

Vinyl chloride was tested in rats by oral, subcutaneous and intraperitoneal administration and in mice, rats and hamsters by inhalation exposure. Following oral and inhalation exposure, vinyl chloride was carcinogenic in all three species, producing tumours at different sites, including angiosarcomas of the liver. Vinyl chloride was carcinogenic in rats following prenatal exposure. A dose-response effect has been demonstrated.¹

¹IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, vol. 19. IARC, Lyon, France, pp. 377-437, 1979.

Vinyl chloride (VC), an industrial chemical, is a colorless gas that is slightly soluble in water.

The principal use of VC is in the production of plastics. It is also used in the synthesis of other chemicals and formerly was used as an aerosol propellant. The vinyl chloride-vinyl acetate copolymers are used extensively in the production of vinyl asbestos floor tiles.

Annual domestic production of VC is approximately 7 billion lb. Domestic production of VC homopolymer is reported as 5 billion lb and imports as 55 million lb, and the VC acetate copolymer has a reported domestic production of 279 million lb.

Human exposure to VC occurs primarily through inhalation and less frequently through skin absorption. More than 3.5 million workers are potentially exposed to this chemical. In addition, 4.6 million people are potentially exposed who live within 5 miles of industrial sites at which environmental emissions could occur. Air emissions near production facilities contained 3.1-12.5 ppb of VC. Very low levels of exposure may occur from leaching into food and beverages (0.05-25 ng/kg) or medical products from unreacted VC remaining in polyvinyl chloride.

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The Consumer Product Safety Commission, EPA, and the FDA each banned the use of VC as an aerosol propellant, eliminating exposure of 1-5 million people annually. Under the Clean Water Act, EPA has published a water quality criteria document for the protection of human health addressing VC. The Clean Air Act, National Emission Standards for Hazardous Pollutants, addresses VC emissions from production and manufacturing facilities. The Resource Conservation and Recovery Act (RCRA) subjects VC waste products, off-specification batches, and spill residues in excess of 2,200 lb to handling and report/recordkeeping requirements. RCRA also designates VC as a hazardous constituent of waste, and subjects wastes known to contain it to the same requirements. FDA has eliminated the use of VC in drug products and has alerted food manufacturers to the need for monitoring packaging materials for the chemical. The Bureau of Foods is presently reevaluating its position on the September 3, 1975 proposal and may withdraw it. The OSHA standard of 1 ppm as an 8-hour time-weighted average, and a 5 ppm ceiling for any 15-minute period, was adopted in October 1974. Medical surveillance, training for workers, use of protective clothing and respirators, warning signs, product labeling, and periodic monitoring are required by OSHA.

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REGULATIONS

Regulations and Other Actions	Effect of Regulations and Other Comments	Citation of Regulation
Ban of self-pressurized household products that contain vinyl chloride monomer as an ingredient or in the propellant. (CPSC)	As a result of bans by CPSC, FDA, EPA, 1-5 million persons no longer exposed. (CPSC)	1600 CFR 1500.17(a)(10) (CPSC)
CAA, 112: NESHAP addressed vinyl chloride emission from vinyl chloride monomer production and polymerization, and certain ethylene dichloride manufacturing facilities. Promulgated 10/21/76, 12/3/76, 6/7/77.	Impose engineering controls that have been shown to reduce emissions by 95 percent over precontrol levels. 4,600,000 people live within 5 miles of facilities subject to these standards.	40 CFR 61.60, 61.71
CWA, 304(a): Water quality criteria document published in final, 11/28/80.	A concentration of 2.0 µg/l is estimated to limit cancer risk to one in a million.	45 FR 231, p. 79318
FIFRA, 3: Cancellation/suspension of all vinyl chloride monomer containing pesticides registered for use in homes, food-handling establishments, hospitals, and enclosed areas, 3/75.	Most VC in pesticides was used as an aerosol in propellants. (EPA)	40 FR 3934
RCRA, 3001-3004: Subjects waste product, off-specification batches, and spill residues in excess of 1000 kg to handling and report/recordkeeping requirements. Also designates vinyl chloride as a hazardous constituent of wastes, and subjects wastes known to contain it to the same requirements. Promulgated 5/19/80.		40 CFR 261.11, 261.33 (EPA)
See Carcinogen Assessment Group statement under 2-acetylaminofluorene. (EPA)		
FDA Bureau of Drugs, Bureau of Medical Devices.	Has eliminated the use of vinyl chloride in drug products and as a propellant vehicle in aerosol products.	39 FR 30830 (1974)
Any drug products containing vinyl chloride must pass through the New Drugs Application Process.	This has alerted manufacturers to the need to monitor their packaging materials for vinyl chloride monomer. Bureau of Alcohol, Tobacco, and Firearms has banned polyvinyl chloride containers for alcoholic beverages based on FDA work.	40 FR 40528 (FDA)
Bureau of Foods published notice to regulate vinyl chloride monomer in packaging material 40 FR 40528 (1975), but rules were not finalized. (FDA)	The Bureau of Foods is presently reevaluating its position on the 9/3/75 proposal and may withdraw it. (FDA)	
PEL: 1 ppm 8-hr TWA, 5 ppm/15 min TWA ceiling; no direct contact with liquid.	Regulatory History: 1952: Walsh-Healy, 500 ppm maximum allowable concentration.	29 CFR 1910.1017 (OSHA)
Protective clothing, respiratory, training, and medical surveillance requirements for workers; monitoring requirements; sign requirements for regulated areas; labeling requirements for containers. (OSHA)	8/27/71: OSHA Takeover Standard-- 500 ppm (1300 mg/m ³) ceiling. 4/5/74: Emergency Temporary Standard-- 50 ppm ceiling. 4/5/75: Final Standard--current limit effective. (OSHA)	RSV 0020099