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201-14972A

OVERALL SUMMARY FOR FLUOROETHYLENE

Summary

Vinyl fluoride (VF) is a clear, colorless liquefied gas with a faint ethereal odor. VF has a water solubility value of 0.94 g/100 g water @ 3.4 Mpa and 80°C, has a melting point of -160.5°C, and boils at -72°C. VF has a vapor pressure of 1.98×10^4 mm Hg @ 25°C and is flammable in air (2.6-21.7%).

Vinyl fluoride's production and use as a monomer in the synthesis of poly(vinyl fluoride) could result in its release to the environment through various waste streams. When released to the atmosphere, it will degrade by reaction with photochemically produced hydroxyl radicals (estimated half-life of about 1.5 days). Reaction with atmospheric ozone will contribute to its atmospheric degradation (estimated half-life of about 16 days). The resulting estimated atmospheric half-life due to both indirect photochemical reactions is 1.37 days. Vinyl fluoride exists as a gas under normal ambient conditions. If released to soil or water, vinyl fluoride is expected to partition to the atmosphere. Since vinyl fluoride is slightly water soluble, in the unlikely event that a significant release to water occurred, vinyl fluoride is predicted to have a half-life due to volatile losses of 2 hours in rivers and 23.5 hours in ponds (WVOLNT model in EPISUITE 3.11). Estimated biodegradation rates suggest that biodegradation in water will be slow ((BIOWIN (v.4.01) Ultimate Survey Model, SRC, n.d.) and (CATABOL, Jawarska et al., 2002)). However, results from biodegradation models are somewhat inconsistent. In three out of four cases the SRC BIOWIN Probability and MITI models predict vinyl fluoride to be readily biodegradable, while the BIOWIN (v.4.01) Ultimate Survey and CATABOL models predict that the test compound to be slow to biodegrade. Therefore, a closed bottle test, following OECD guideline 301, is recommended.

Modeling of physical/chemical parameters (i.e., Kow) and aquatic toxicity was conducted to help provide insight into the behavior in the environment and the aquatic toxicity of vinyl fluoride. Syracuse Research Corporation models for estimating physical/chemical properties were used to estimate \log_{10} Kow (Meylan and Howard, 1995) for subsequent use in the ECOSAR program (Table 1). ECOSAR (Meylan and Howard, 1999) was used to estimate the aquatic toxicity of vinyl fluoride and the related chemical, vinyl chloride (CAS#75-01-4), to green algae, daphnids (planktonic freshwater crustaceans), and fish. ECOSAR predictions are based on actual toxicity test data for classes of compounds with similar modes of action.

The existing aquatic toxicity test data, coupled with ECOSAR predictions, indicate that vinyl fluoride is likely to be of low concern for acute toxicity to algae, invertebrates, or fish at environmentally relevant concentrations. The existence of vinyl fluoride as a gas under normal ambient conditions also limits potential exposure to aquatic organisms.

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Table 1: Ecotoxicology

	Vinyl Fluoride CAS# 75-02-5	Vinyl Chloride CAS# 75-01-4
Log Kow	1.19	1.62
Toxicity to Fish (LC₅₀ value)	96-hr LC ₅₀ = 197.1 mg/L (E)	96-hr LC ₅₀ = 210 mg/L (M) 96-hr TL ₅₀ = 1220 mg/L (M) 96-hr TL ₅₀ = 1060 mg/L (M) 96-hr LC ₅₀ = 2.3 mg/L (E)
Toxicity to Invertebrates (EC₅₀ value)	48-hr EC ₅₀ = 199.7 mg/L (E)	24-hr LC ₅₀ = 12 mg/L (M) 48-hr EC ₅₀ = 141.5 mg/L (E)
Toxicity to Algae (EC₅₀ value for growth inhibition)	96-hr EC ₅₀ = 119.1 mg/L (E)	72-hr EC ₅₀ = 224 mg/L (M) 7-day EC ₃ ≥ 710 mg/L (NR) 96-hr EC ₅₀ = 25.1 mg/L (E)
E = estimated value, M = value based on measured concentrations, NR = not reported		

VF exhibits very low acute toxicity by the inhalation route with a 4-hour LC₅₀ in mice of 690,000 ppm. In a 90-day study in rats and mice, VF had no effects on the standard endpoints of toxicity (body weights, food consumption, clinical observations, clinical chemistry, and histopathology) up to 20,000 ppm. However, VF induced cell proliferation changes indicative of toxicity at concentrations of 200, 2000, and 20,000 ppm. A no-observable-effect-level (NOEL) was not established for rats and mice in this study. In a lifetime inhalation study in rats and mice, VF was carcinogenic in male and female rats and mice at concentrations greater than or equal to 25 ppm. VF produced hemangiosarcomas in the liver and alveolar-bronchiolar adenomas in mice of each sex, mammary tumors in females, and Harderian gland adenomas in males. In rats, it produced hemangiosarcomas of the liver and Zymbal gland tumors in animals of each sex and an increased incidence of hepatocellular adenomas and carcinomas in females. Survival was decreased in male rats and mice of the 250 and 2500 ppm groups, and female rats and mice of the 25, 250, and 2500 ppm groups. A NOEL for this life-time inhalation study was not determined.

No information was available on the developmental toxicity of VF; however, developmental data were available on the analog, vinyl chloride. A combined reproductive-developmental inhalation study in rats following OECD guidelines produced NOAELs for reproductive and developmental endpoints of ≥ 1100 ppm. Other developmental studies indicate that vinyl chloride produces fetal toxicity only at exposures that produce maternal toxicity.

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Reproductive organs were evaluated histopathologically in the 90-day inhalation and lifetime inhalation studies in both rats and mice. No compound-related effects on the reproductive organs of either male or female rats or mice were observed in the 90-day or lifetime inhalation studies.

VF was not mutagenic in *Salmonella* strains TA1535, TA1537, TA1538, TA98, and TA100 in 2 mutagenicity studies. VF did induce a statistically significant increase in the amount of bacterial revertants in *Salmonella* strain TA1535 in a 3rd study. However, based on the low magnitude of the response it was not considered biologically significant. Similarly, VF was reported to be mutagenic to *E. coli*, but review of the data did not support this conclusion. In the presence of metabolic activation, VF produced HPRT point mutations, and chromosome aberrations, in assays conducted with Chinese hamster ovary (CHO) cells. Without metabolic activation, VF was negative in the CHO/HPRT assay, and equivocal in the chromosome aberration assay. VF was positive in a mouse micronucleus study, and induced sex-linked recessive lethal mutations in *Drosophila*. VF exposure did not increase the frequency of dominant lethal mutations, indicating the VF was not mutagenic to germ cells in the male rat. VF did not induce unscheduled DNA synthesis in spermatocytes of male rats and did not induce DNA single strand breaks or DNA cross links in rat testicular DNA.

Human Exposure

VF is manufactured at the DuPont facility at Louisville, KY. The site utilizes 3 operators/shift year round in the VF operation. During shutdowns and construction activity, personnel in the area could number up to 50. The potential for exposure is greatest during loading of the final product, dumping or removing catalyst, or during unscheduled maintenance. The site has effective safety, health, and environmental practices and procedures in addition to engineering controls and personal protective equipment to control exposure. Adequate safety equipment such as safety showers, eye wash fountains, and washing facilities are available in the event of occupational exposure. Individuals handling VF should avoid contact with eyes, skin, or clothing, should not breath vapor or mist, and should wash thoroughly after handling.

Air monitoring has been regularly conducted and results are in the table below. The DuPont Acceptable Exposure Limit (AEL) for VF is 1 ppm as an 8-hour TWA (time weighted average) and 0.5 ppm for a 12-hour TWA. None of the samples taken suggest the probability of exposure in excess of the current recommended AEL.

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Louisville Exposure Data – 2000 - 2002

People	# of Results	Average of TWA (PPM)	Minimum of Results (PPM)	Max of Results (PPM)
Operation	4	None Detected	None Detected	None Detected
	5	None Detected	None Detected	None Detected
	4	None Detected	None Detected	.14
	4	None Detected	None Detected	None Detected
Detection Limit = 100 ppb.				

References for the Summary

Jawarska, J. S. et al. (2002). SAR QSAR Environ. Res., 13(2):307-323.

Meylan, W. M. and P. H. Howard (1995). J. Pharm. Sci., 84:83-92.

Meylan, W. M. and P. H. Howard (1999). User's Guide for the ECOSAR Class Program, Version 0.993 (Mar 99), prepared for J. Vincent Nabholz and Gordon Cas, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington, DC, prepared by Syracuse Research Corp., Environmental Science Center, Syracuse, NY 13210.

SRC (Syracuse Research Corporation) (n.d.). (HSDB/801).

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TEST PLAN FOR FLUOROETHYLENE

Fluoroethylene CAS No. 75-02-5	Data Available	Data Acceptable	Testing Required
Study	Y/N	Y/N	Y/N
PHYSICAL/CHEMICAL CHARACTERISTICS			
Melting Point	Y	Y	N
Boiling Point	Y	Y	N
Vapor Pressure	Y	Y	N
Partition Coefficient	Y	Y	N
Water Solubility	Y	Y	N
ENVIRONMENTAL FATE			
Photodegradation	Y	Y	N
Stability in Water	Y	Y	N
Transport (Fugacity)	Y	Y	N
Biodegradation	Y	N	Y
ECOTOXICITY			
Acute Toxicity to Fish	Y*	Y	N
Acute Toxicity to Invertebrates	Y*	Y	N
Acute Toxicity to Aquatic Plants	Y*	Y	N
MAMMALIAN TOXICITY			
Acute Toxicity	Y	Y	N
Repeated Dose Toxicity	Y	Y	N
Developmental Toxicity	Y*	Y	N
Reproductive Toxicity	Y	Y	N
Genetic Toxicity Gene Mutations	Y	Y	N
Genetic Toxicity Chromosomal Aberrations	Y	Y	N
* Data were available on an analog chemical.			