

G047
Fluoroalkenes

Results of Testing

Chemical Name	CAS No.	Study Code/Type	Protocol/Guideline	Species	Exposure	Dose/Concentration	No. per Group	Results	Reference
Tetrafluoroethene	116-14-3	HECTOXCARC Carcinogenesis study	National Toxicology Program (NTP)	F344 rats	inhalation, 6 hr/day, 5 d/wk, 103 wk	156, 312, 625 ppm (male); 312, 625, 1250 ppm (female)	60 male and female	Clear evidence of carcinogenic activity of TFE in male rats based on increased incidence of renal tube neoplasms (mainly adenomas) and hepatocellular neoplasms. Clear evidence of carcinogenic activity of TFE in female rats based on increased incidence of renal tube neoplasms, liver hemangiosarcomas, hepatocellular neoplasms, and mononuclear cell leukemia. Increased incidences of renal tubule degeneration and hyperplasia in males and females, increased severity of kidney nephropathy in males, and liver angiectasis and cataracts in females were also noted. There were also slight increased in the incidence of mononuclear cell leukemia and testicular interstitial cell adenomas in males.	NTP TR-450 (Draft), December, 1995
Tetrafluoroethene	116-14-3	HECTOXCARC Carcinogenesis study	National Toxicology Program (NTP)	B6C3F ₁ mice	inhalation, 6 hr/day, 5 d/wk, 95 wk	0, 312, 625, 1250 ppm	58 male and female	Clear evidence of carcinogenic activity of TFE in male and female mice based on increased incidences of liver hemangiomas and hemangiosarcomas, hepatocellular neoplasms, and histiocytic sarcomas. There was also an increased incidence of renal tubule karyomegaly in males and females, renal tubule dilatation in males, liver angiectasis in males and females, hematopoietic cell proliferation of the liver in females and splenic hematopoietic cell proliferation in males and females.	NTP TR-450 (Draft), December, 1995
Tetrafluoroethene	116-14-3	HEGTOXCHRM Mammalian bone marrow micronucleus assay	40 CFR 798.5460 (modified)	mice	inhalation, whole body, 6 hr	0, 5000, 12000, 19000 ppm (males); 0, 7000, 17000, 28000 ppm (females)	5/sex	Treatment did not increase the frequency of micronuclei in females. In males, the frequency was slightly increased at low and mid-treatment levels at the 72-hour sampling time, only.	53 FR 20685; 6/6/88 OTS05228091
Tetrafluoroethene	116-14-3	HEGTOXMUTA Mutagenicity study	40 CFR 798.5300 (modified)	Chinese hamster ovary cells (CHO)	<i>in vitro</i>	0, 20, 40, 60, 80, 100% (atmospheric concentrations)	Not applicable	Treatment at up to cytotoxic levels did not increase the frequency of mutations at the HPRT locus in the presence or absence of Aroclor-induced rat liver homogenate.	53 FR 19334; 5/27/88 OTS0522807
Hexafluoropropene	116-15-4	HEGTOXCHRM Rodent dominant lethal assay	40 CFR 798.5450 (modified)	rat	inhalation, 6 hr/d, 5 d	0, 25, 100, 400 ppm	Not specified	Treatment at up to toxic levels did not increase the frequency of dominant lethal mutations.	53 FR 45385; 11/9/88 OTS0522791
Hexafluoropropene	116-15-4	HEGTOXMUTA Mutagenicity study	40 CFR 798.5300 (modified)	Chinese hamster ovary cells (CHO)	<i>in vitro</i>	0, 0.1, 0.25, 0.50, 1.00, 1.50% (atmospheric concentrations)	Not applicable	Treatment at up to cytotoxic levels did not increase the frequency of mutations at the HPRT locus in the presence or absence of Aroclor-induced rat liver homogenate.	53 FR 37643; 9/27/88 OTS0522811

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Hexafluoropropene	116-15-4	HEGTOXMUTA Mutagenicity study	40 CFR 798.5300 (modified)	Chinese hamster ovary cells (CHO)	<i>in vitro</i>	0, 0.05, 0.15, 0.20, 0.30, 0.35% (atmospheric concentrations)	Not applicable	Treatment at up to cytotoxic levels did not increase the frequency of mutations at the HPRT locus in the presence or absence of Aroclor-induced rat liver homogenate.	53 FR 19334; 5/27/88 OTS0522806
Hexafluoropropene	116-15-4	HEGTOXMUTA Mutagenicity study (voluntary test)	Non-TSCA Protocol/ Guideline (docket OPTS-42002E)	Chinese hamster ovaries (CHO)	<i>in vitro</i>	0, 0.03, 0.08, 0.41, 0.74, 1.13, 2.5% (v/v)	Not applicable	There were no increases in mutagenic activity induced by exposure to the test material either in the presence or absence of metabolic activation.	51 FR 16203; 5/1/86 OTS0512564
Hexafluoropropene	116-15-4	HESTOX Subchronic inhalation toxicity	40 CFR 798.2450 (modified)	mice	whole body, 6 hr/d, 5 d/wk, 13 wks	0, 10, 50, 150 ppm (target)	25/sex	Kidney lesions were seen at 50 and 150 ppm in both sexes, and these could still be seen throughout the 28 day observation period. No other effects were reported.	54 FR 8816; 3/2/89 OTS0522814
Hexafluoropropene	116-15-4	HESTOX Subchronic inhalation toxicity	40 CFR 798.2450 (modified)	rat	whole body, 6 hr/d, 5 d/wk, 13 wks	0, 10, 50, 150 ppm (target)	20/sex	High-dose males showed increased water consumption and decreased lymphocyte count. Urinalysis showed increased fluoride ions in both sexes at 50 ppm and above. These rats also had polyuria and low urine osmolality.	54 FR 8816; 3/2/89 OTS0522814
Vinyl fluoride	75-02-5	HECTOXCARC Oncogenicity study	40 CFR 798.3300 (modified)	mice	inhalation, 6 hr/d, 5 d/wk, 18-months	0, 25, 250, 2500 ppm	95/sex	Survival was decreased in male mice of the 250 and 2500 ppm groups and female mice of all groups. At necropsy, the following observations were made: nodules, masses and discoloration of the lung, and fluid in the plural cavity; masses of the peritoneal cavity and hemorrhage, cysts, masses, discoloration and nodules of the liver; and mammary gland masses. Microscopically, these lesions were correlated with bronchioloalveolar adenoma and hyperplasia; hepatic hemangiosarcoma and hepatocellular hyperplasia with angiectasis and peliosis; and mammary gland adenocarcinoma and hyperplasia. The incidence of these lesions were concentration-related in all exposed groups. The test substance was determined to be carcinogenic in both sexes at concentrations greater than 25 ppm.	57 FR 37541; 8/19/92, Docket OPTS-44590

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Vinyl fluoride	75-02-5	HECTOXCARC Oncogenicity study	40 CFR 798.3300 (modified)	rat	inhalation, 6 hr/d, 5 d/wk, 2 years	0, 25, 250, 2500 ppm	95/sex	Survival was decreased in male rats of the 250 and 2500 ppm groups and female rats of all groups. At necropsy, the following observations were made: masses, nodules, discoloration and hemorrhage of the liver; mass/nodules and discoloration of the lungs, and fluid of the peritoneal cavity; and masses of the head, face and periaural area; and abscesses of the face. Microscopically, these lesions were correlated with hepatic hemangiosarcoma, hepatocellular adenoma and carcinoma, foci of clear cell and basophilic alteration, and sinusoidal dilation, metastatic lung tumors, and Zymbal's gland tumors. The incidence of these lesions were concentration-related in all exposure groups. The test substance was determined to be carcinogenic in both sexes at concentrations greater than 25 ppm.	57 FR 37541; 8/19/92, Docket# OPTS-44590
Vinyl fluoride	75-02-5	HEGTOXCHRM Rodent dominant lethal assay	40 CFR 798.5450 (modified)	rat	inhalation, 6 hr/d, 5 d	0, 200, 2000, 20,000 ppm	Not specified	Treatment did not increase the frequency of dominant lethal mutations, nor were there signs of toxicity.	53 FR 43267; 10/26/88 OTS0522790
Vinyl fluoride	75-02-5	HEGTOXDNAF DNA damage in mammalian cells (voluntary test)	40 CFR 798.5510 (modified)	rat	<i>in vivo</i> inhalation, 6 hr/day, on 1, 2, or 5 consecutive days	0, 20,000 ppm	4 males	Examination of rat testicular DNA using the alkaline elution method of detection showed no increase in single strand breaks, nor increased DNA cross links following exposure.	56 FR 1633; 4/22/91 OTS0532956
Vinyl fluoride	75-02-5	HEGTOXDNAF Unscheduled DNA synthesis (voluntary test)	40 CFR 798.5550 (modified)	rat	<i>in vivo</i> inhalation, 6 hr/d for 1, 2, or 5 consecutive days	20,000 ppm	15 males	Vinyl fluoride did not induce unscheduled DNA synthesis in this assay.	56 FR 2178; 1/22/91 OTS0532955
Vinyl fluoride	75-02-5	HEGTOXMUTA Sex linked recessive lethal study	40 CFR 798.5275 (modified)	<i>Drosophila melanogaster</i>	inhalation, 24 hr	0, 47.6%	Not specified	Statistically increased (p<0.01) sex-lined recessive lethals were noted in the treatment group.	53 FR 33537; 8/31/88 OTS0522809
Vinylidene fluoride	75-38-7	HECTOXCARC Oncogenicity study	40 CFR 798.3300 (modified)	mice	inhalation, 16 months	Not specified	Not specified	Summary information indicates survival had decreased to about 80% among high-exposure males and to about 78% in mid-exposure females.	OTS0532940
Vinylidene fluoride	75-38-7	HEGTOXCHRM Mammalian bone marrow micronucleus assay	40 CFR 798.5395 (modified)	mice	inhalation, 6 hr	0, 5198, 15620, 41550 ppm	5/sex	Treatment did not increase the frequency of micronuclei, nor did it induce signs of toxicity.	53 FR 49227; 12/6/88 OTS0522784

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Vinylidene fluoride	75-38-7	HEGTOXMUTA Sex linked recessive lethal study	40 CFR 798.5275 (modified)	<i>Drosophila melanogaster</i>	inhalation, 24 hr	0, 5.1, 21.8, 42.8% in air	Not specified	Treatment did not affect the percentage of sex-linked recessive lethals.	53 FR 33537; 8/31/88 OTS0522810
Vinylidene fluoride	75-38-7	HESTOX Subchronic inhalation toxicity	40 CFR 798.2450 (modified)	mice	6 hr/day, 5 d/wk, 13 wks	0, 1000, 7000, 40,000 ppm	10/sex	Increased mean corpuscular hemoglobin concentration was noted in high-exposure males, rough coat and sensitivity to touch in high-level males and mid- and high-level females, and increased locomotor activity in both sexes of all groups.	54 FR 12953; 3/29/89 OTS0522815
Vinylidene fluoride	75-38-7	HESTOX Subchronic inhalation toxicity (voluntary test)	Non-TSCA Protocol/ Guideline (docket OPTS-42002E)	rat	whole body, 6 hr/d, 5 d/wk, 13 wks	0, 1000, 7000, 40,000 ppm (target)	30/sex	Vacuolar degeneration of the vomeronasal gland was seen in all treatment groups. Decreased body weight gain, anemia, and decreased white blood cell count were seen at mid- and high-dose levels. Altered relative weights of spleen, testes, heart, and lung were noted in high-dose animals.	51 FR 27598; 8/1/86 OTS0522774