

G058
Isophorone [78-59-1]

Results of Testing

Chemical Name	CAS No.	Study Code/Type	Protocol/Guideline	Species	Exposure	Dose/Concentration	No. per Group	Results	Reference
Isophorone	78-59-1	HECTOXCARC Carcinogenicity study	National Toxicology Program (NTP)	F344/N rats	gavage, 5 d/wk, 103 weeks	0, 250, 500 mg/kg body wt/day	50 male, 50 female	Some evidence of carcinogenicity in male rats as shown by the occurrence of renal tubular cell adenomas and adenocarcinomas. No evidence of carcinogenicity in female rats.	NTP TR-291, January 1986, NTIS PB86-181823
Isophorone	78-59-1	HECTOXCARC Carcinogenicity study	National Toxicology Program (NTP)	B63F ₁ mice	gavage, 5 d/wk, 103 weeks	0, 250, 500 mg/kg body wt/day	50 male, 50 female	Equivocal evidence of carcinogenicity in male mice as shown by an increased occurrence of hepatocellular adenomas and carcinomas (combined) and of mesenchymal tumors in the integumentary system in animals given 500 mg/kg/d and an increase in malignant lymphomas in animals given 250 mg/kg/d.. No evidence of carcinogenicity in female mice.	NTP TR-291, January 1986, NTIS PB86-181823
Isophorone	78-59-1	HEGTOXCHRM Cytogenetic assay	Non-TSCA Protocol/Guideline (docket OPTS-42029)	mice	intraperitoneal, single injection	0.54 mL/kg	10 (5 male, 5 female)	The incidence of micronucleated polychromatic erythrocytes and the ratio of normochromatic to polychromatic erythrocytes were not significantly different in the treatment groups compared with the vehicle controls.	50 FR 5421; 3/6/85 OTS0507222
Isophorone	78-59-1	HEGTOXDNAF Unscheduled DNA synthesis	Non-TSCA Protocol/Guideline (docket OPTS-42029)	rats	<i>in vitro</i>	0.40, 0.20, 0.10, 0.50, 0.01, 0.0005 µL/mL	Not applicable	None of the tested concentrations caused a significant increase in unscheduled DNA synthesis in primary hepatocytes over the solvent (ethanol) control.	50 FR 5421; 3/6/85 OTS0507222
Isophorone	78-59-1	HEGTOXMUTA Mutagenicity study	Non-TSCA Protocol/Guideline (docket OPTS-42029)	mouse	<i>in vitro</i>	0.067-1.3 µL/mL	Not applicable	L5178YTK cell viability ranged from 12-111% in the non-activated and 9-86% of control in the S9-activated cultures. None of the cultures produced mutation frequencies which were significantly greater than the controls.	50 FR 5421; 3/6/85 OTS0507222
Isophorone	78-59-1	HERTOXTERA Developmental toxicity	Non-TSCA Protocol/Guideline (docket OPTS-42029)	rats and mice	inhalation, 6 hr/d; days 6-15 of gestation	0, 25, 50, 115 ppm	22 rats; 22 mice (pregnant)	Maternal toxicity was evident by differences found between dosed groups and controls for mean body weight and food consumption (115 ppm group of rats and mice). No statistically significant differences among the control and treated groups were found for any of the fetal external, visceral, or skeletal parameters.	49 FR 5187; 2/10/84 OTS0507224
Isophorone	78-59-1	HEDIRR Permeability coefficient (Kp)	69 FR 22402		<i>in vitro</i>			TEST DATA IN REVIEW PROCESS	71 FR 43763 8/2/06 OPPT-2003-0006
Isophorone	78-59-1	HEDIRR Dermal absorption	69 FR 22402		<i>in vitro</i>	10 minutes		TEST DATA IN REVIEW PROCESS	71 FR 43763 8/2/06 OPPT-2003-0006

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Isophorone	78-59-1	HEDIRR Dermal absorption	69 FR 22402		in vitro	60 minutes		TEST DATA IN REVIEW PROCESS	71 FR 43763 8/2/06 OPPT-2003-0006