

## 8. REGULATIONS AND ADVISORIES

The international and national regulations and guidelines regarding styrene in air, water, and other media are summarized in Table 8-1.

ATSDR has derived an acute-duration inhalation MRL of 2 ppm for styrene. This MRL is based on a NOAEL of 20 ppm for alterations in tests of reaction time and attention in subjects exposed to styrene for 3 hours (Seeber et al. 2004) and an uncertainty factor of 10 to account for human variability.

ATSDR has derived a chronic-duration inhalation MRL of 0.2 ppm for styrene. This MRL is based on a LOAEL of 20 ppm estimated from a meta-analysis of data (Benignus et al. 2005) from occupational exposure studies demonstrating alterations in choice reaction time and color discrimination in styrene workers and an uncertainty factor of 100 (10 for use of a LOAEL and 10 for human variability).

EPA (IRIS 2007) has derived an inhalation reference concentration (RfC) of 1 mg/m<sup>3</sup> (0.2 ppm) based on a NOAEL<sub>HEC</sub> value of 34 mg/m<sup>3</sup> in a cross-sectional study in workers finding central nervous system effects in workers exposed to >22 ppm (Mutti et al. 1984a) and an uncertainty factor of 30 (3 for the use less than chronic study, 3 for human variability, and 3 for database inadequacies).

ATSDR has derived an acute-duration oral MRL of 0.1 mg/kg/day for styrene. This MRL is based on a LOAEL of 100 mg/kg/day for impaired learning in rats exposed to styrene for 14 days (Husain et al. 1985) and an uncertainty factor of 1,000 (10 for use of a LOAEL, 10 for extrapolation from rats to humans, and 10 for human variability).

EPA (IRIS 2007) has established an oral reference dose (RfD) of 0.2 mg/kg/day based on a NOAEL of 200 mg/kg/day from a subchronic oral toxicity study in beagle dogs in which red blood cell and liver effects was observed (Quast et al. 1979). The uncertainty factor used in this assessment was 1,000 (10 for interspecies extrapolation, 10 for human variability variation, and 10 for extrapolation of subchronic effects to chronic effects).

The International Agency for Research on Cancer (IARC) has classified styrene as a Group 2B carcinogen (possibly carcinogenic to humans) (IARC 2006). The Department of Health and Human Services and the EPA has not classified styrene for human carcinogenicity (IRIS 2007; NTP 2005).

**Table 8-1. Regulations and Guidelines Applicable to Styrene**

Agency	Description	Information	Reference
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenicity classification	Group 2B <sup>a</sup>	IARC 2006
WHO	Air quality guidelines		WHO 2000
	TWA based on effects other than cancer or odor/annoyance using an averaging time of 1 week	0.26 mg/m <sup>3</sup>	
	Based on sensory effects or annoyance reactions, using an averaging time of 30 minutes		
	Detection threshold	0.07 mg/m <sup>3</sup>	
	Recognition threshold	0.21–0.28 mg/m <sup>3</sup>	
	Guideline value	0.07 mg/m <sup>3</sup>	
	Drinking water quality guidelines	0.02 mg/L <sup>b</sup>	WHO 2004
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)	85 mg/m <sup>3</sup>	ACGIH 2006
	STEL (15-minute TWA)	170 mg/m <sup>3</sup>	
AIHA	ERPG-1 <sup>c</sup>	213 mg/m <sup>3</sup>	AIHA 1995
	ERPG-2 <sup>c</sup>	1,065 mg/m <sup>3</sup>	
	ERPG-3 <sup>c</sup>	4,260 mg/m <sup>3</sup>	
EPA	AEGL-1 <sup>d</sup>		EPA 2007a
	10 minutes	85 mg/m <sup>3</sup>	
	30 minutes	85 mg/m <sup>3</sup>	
	60 minutes	85 mg/m <sup>3</sup>	
	4 hours	85 mg/m <sup>3</sup>	
	8 hours	85 mg/m <sup>3</sup>	
	AEGL-2 <sup>d</sup>		
	10 minutes	980 mg/m <sup>3</sup>	
	30 minutes	682 mg/m <sup>3</sup>	
	60 minutes	554 mg/m <sup>3</sup>	
4 hours	554 mg/m <sup>3</sup>		
8 hours	554 mg/m <sup>3</sup>		

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Agency	Description	Information	Reference
<b>NATIONAL (cont.)</b>			
EPA	AEGL-3 <sup>d</sup>		EPA 2007a
	10 minutes <sup>e</sup>	8,094 mg/m <sup>3</sup> (1,862 ppm)	
	30 minutes <sup>e</sup>	8,094 mg/m <sup>3</sup> (1,862 ppm)	
	60 minutes <sup>e</sup>	4,686 mg/m <sup>3</sup> (1,078 ppm)	
	4 hours	1,448 mg/m <sup>3</sup> (333 ppm)	
	8 hours	1,448 mg/m <sup>3</sup> (333 ppm)	
	Level of distinct odor awareness	2.3 mg/m <sup>3</sup> (0.5 ppm)	
EPA	Hazardous air pollutant	Yes	EPA 2007c 42 USC 7412
NIOSH	REL (10-hour TWA)	50 ppm	NIOSH 2005
	STEL (15-minute TWA)	100 ppm	
	IDLH	2,982 mg/m <sup>3</sup> (686 ppm)	
OSHA	PEL (8-hour TWA) for general industry	100 ppm	OSHA 2006c 29 CFR 1910.1000, Table Z-2
	Acceptable ceiling concentration	200 ppm	
	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift for a maximum duration of 5 minutes in any 3 hours	600 ppm	
	PEL (8-hour TWA) for shipyard industry	100 ppm	
	PEL (8-hour TWA) for construction industry	100 ppm	
b. Water			
EPA	Designated as hazardous substances in accordance with Section 311(b)(2)(A) of the Clean Water Act	Yes	EPA 2007b 40 CFR 116.4

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Agency	Description	Information	Reference
<b>NATIONAL (cont.)</b>			
EPA	Drinking water standards and health advisories		EPA 2006
	1-day health advisory for a 10-kg child	20 mg/L	
	10-day health advisory for a 10-kg child	2 mg/L	
	DWEL	7 mg/L	
	Lifetime	0.1 mg/L	
	10 <sup>-4</sup> Cancer risk	No data	
	Master Testing List	Yes <sup>f</sup>	EPA 2007d
	National primary drinking water standards		EPA 2003
	MCLG	0.1 mg/L	
	MCL	0.1 mg/L	
	Public health goal	0.1 mg/L	
	Reportable quantities of hazardous substances designated pursuant to Section 311 of the Clean Water Act	1,000 pounds	EPA 2007e 40 CFR 117.3
<b>c. Food</b>			
FDA	Bottled drinking water	0.1 mg/L	FDA 2006a 21 CFR 165.110
	Food additives permitted for direct addition to food for human consumption	Yes	FDA 2007b 21 CFR 172
	Indirect food additives: adhesives and components of coatings	Yes	FDA 2006b 21 CFR 175
	EAFUS	Yes <sup>h</sup>	FDA 2007a
<b>d. Other</b>			
ACGIH	Carcinogenicity classification	A4 <sup>i</sup>	ACGIH 2006
	Biological exposure indices (end of shift at end of workweek)		
	Sum of mandelic acid and phenyl glyoxylic acid in urine	400 mg/g creatinine	
	Styrene in venous blood	0.2 mg/L	
EPA	Carcinogenicity classification	No data	IRIS 2007
	RfC	1 mg/m <sup>3</sup> (0,2 ppm)	
	RfD	0.2 mg/kg/day	
	Superfund, emergency planning, and community right-to-know		
	Designated CERCLA hazardous substance	Yes <sup>j</sup>	EPA 2007f 40 CFR 302.4
	Reportable quantity	1,000 pounds	

**Table 8-1. Regulations and Guidelines Applicable to Styrene**

Agency	Description	Information	Reference
<b>NATIONAL</b> (cont.)			
EPA	Effective date of toxic chemical release reporting	01/01/2000	EPA 2007g 40 CFR 372.65
NTP	Carcinogenicity classification	No data	NTP 2005

<sup>a</sup>Group 2B: possibly carcinogenic to humans

<sup>b</sup>Concentrations of the substance at or below the health-based guideline value may affect the appearance, taste, or odor of the water, leading to consumer complaints (WHO 2004).

<sup>c</sup>ERPG-1 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing other than mild, transient health effects; ERPG-2 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing irreversible or other serious adverse effects; and ERPG-3 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without life-threatening health effects (AIHA 1995).

<sup>d</sup>AEGL-1 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects, however, the effects are not disabling and are transient and reversible upon cessation of exposure; AEGL-2 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape; and AEGL-3 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death (EPA 2007a).

<sup>e</sup>Safety considerations against the hazard of explosion must be taken into account.

<sup>f</sup>Styrene was recommended to the MTL by the U.S. EPA's Office of Pollution Prevention and Toxics on the basis of the SIDS. Styrene was added to the MTL in 1993 and the chemical testing program is currently underway by way of a VTA. The testing needs include health effects, environmental effects, and environmental fate and exposure.

<sup>g</sup>Potential health effects from exposure above the MCL include liver, kidney, or circulatory system problems. Common sources of contaminant in drinking water include discharges from rubber and plastic factories and leaching from landfills (EPA 2003).

<sup>h</sup>The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

<sup>i</sup>A4: not classifiable as a human carcinogen

<sup>j</sup>Designated CERCLA hazardous substance pursuant to Section 311(b)(2) of the Clean Water Act and Section 112 of the Clean Air Act.

ACGIH = American Conference of Governmental Industrial Hygienists; AEGL = acute exposure guideline levels; AIHA = American Industrial Hygiene Association; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; ERPG = emergency response planning guidelines; FDA = Food and Drug Administration; GRAS = Generally Recognized As Safe; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; MTL = Master Testing List; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; SIDS = Screening Information Data Sets; STEL = short-term exposure limit; TLV = threshold limit values; TWA = time-weighted average; USC = United States Code; VTA = Voluntary Testing Agreement; WHO = World Health Organization