

## CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding silica in air, water, and other media are summarized in Table 7-1. This table is not an exhaustive list, and current regulations should be verified by the appropriate regulatory agency.

ATSDR develops MRLs, which are substance-specific guidelines intended to serve as screening levels by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. See Section 1.3 and Appendix A for detailed information on the MRLs for silica.

**Table 7-1. Regulations and Guidelines Applicable to Silica**

Agency	Description	Information	Reference
<b>Air</b>			
EPA	RfC	No data	<a href="#">IRIS 2018</a>
WHO	Air quality guidelines	Not listed	<a href="#">WHO 2010</a>
<b>Water &amp; Food</b>			
EPA	Drinking water standards and health advisories	Not listed	<a href="#">EPA 2018a</a>
	National primary drinking water regulations	Not listed	<a href="#">EPA 2009</a>
	RfD	No data	<a href="#">IRIS 2018</a>
	Tolerance exemptions for minimal risk active and inert ingredients in pesticides		<a href="#">EPA 2018b</a>
	Silica, amorphous, fumed (crystalline free)	Yes	
	Silica gel	Yes	
	Silica, vitreous	Yes	
WHO	Drinking water quality guidelines	Not listed	<a href="#">WHO 2017</a>
FDA	Substances added to food <sup>a</sup>		
	Silicon dioxide	Approved under food additive, GRAS, and color additive regulations	<a href="#">FDA 2018a</a>
	Diatomaceous earth	Approved under food additive and GRAS regulations	<a href="#">FDA 2018b</a>

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Agency	Description	Information	Reference
USDA	Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"		<a href="#">USDA 2018</a>
	Silicon dioxide	Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available	
	Diatomaceous earth	Food filtering aid only	
<b>Cancer</b>			
HHS	Carcinogenicity classification Silica, crystalline (respirable size)	Known to be a human carcinogen	<a href="#">NTP 2016</a>
EPA	Carcinogenicity classification	No data	<a href="#">IRIS 2018</a>
IARC	Carcinogenicity classification Silica, amorphous	Group 3 <sup>b</sup>	<a href="#">IARC 1997</a>
	Silica dust, crystalline, in the form of quartz or cristobalite	Group 1 <sup>c</sup>	<a href="#">IARC 2012</a>
<b>Occupational</b>			
OSHA	PEL (8-hour TWA) for general industry, construction or shipyard employment Respirable crystalline silica (quartz, cristobalite, and/or tridymite) <sup>d</sup>	0.05 mg/m <sup>3</sup>	<a href="#">OSHA 2018a</a> , <a href="#">OSHA 2018b</a> , <a href="#">OSHA 2018c</a> , <a href="#">OSHA 2018d</a>
	Amorphous silica, including natural diatomaceous earth	80 mg/m <sup>3</sup> /%SiO <sub>2</sub>	<a href="#">OSHA 2018c</a>
	PEL (8-hour TWA) for any operations or sectors where the exposure limit in 29 CFR 1910.1053 is stayed or is otherwise not in effect Quartz (respirable) Cristobalite, tridymite	10 mg/m <sup>3</sup> /(%SiO <sub>2</sub> +2) Use 1/2 the value calculated from the formula for quartz	<a href="#">OSHA 2018c</a>
NIOSH	REL (up to 10-hour TWA) Silica, amorphous	6 mg/m <sup>3</sup>	<a href="#">NIOSH 2016a</a>
	Silica, crystalline (as respirable dust)	0.05 mg/m <sup>3e</sup>	<a href="#">NIOSH 2016b</a>
	<b>IDLH</b> Silica, amorphous	3,000 mg/m <sup>3</sup>	<a href="#">NIOSH 1994a</a>
	Silica, crystalline (as respirable dust; cristobalite, tridymite)	25 mg/m <sup>3</sup>	<a href="#">NIOSH 1994b</a>
	Silica, crystalline (as respirable dust; quartz, tripoli)	50 mg/m <sup>3</sup>	

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Agency	Description	Information	Reference
<b>Emergency Criteria</b>			
EPA	AEGLs-air	Not listed	<a href="#">EPA 2016</a>
DOE	PACs-air		<a href="#">DOE 2018b</a>
	<b>PAC-1<sup>f</sup></b>		
	Silica amorphous hydrated	18 mg/m <sup>3</sup>	
	Silica, crystalline-quartz (silicon dioxide)	0.075 mg/m <sup>3</sup>	
	Cristobalite	0.075 mg/m <sup>3</sup>	
	Silica, amorphous fumed	18 mg/m <sup>3</sup>	
	Silica gel, amorphous synthetic	18 mg/m <sup>3</sup>	
	Silica gel	18 mg/m <sup>3</sup>	
	<b>PAC-2<sup>f</sup></b>		
	Silica amorphous hydrated	740 mg/m <sup>3</sup>	
	Silica, crystalline-quartz (silicon dioxide)	33 mg/m <sup>3</sup>	
	Cristobalite	33 mg/m <sup>3</sup>	
	Silica, amorphous fumed	100 mg/m <sup>3</sup>	
	Silica gel, amorphous synthetic	200 mg/m <sup>3</sup>	
	Silica gel	200 mg/m <sup>3</sup>	
	<b>PAC-3<sup>f</sup></b>		
	Silica amorphous hydrated	4,500 mg/m <sup>3</sup>	
	Silica, crystalline-quartz (silicon dioxide)	200 mg/m <sup>3</sup>	
	Cristobalite	200 mg/m <sup>3</sup>	
	Silica, amorphous fumed	630 mg/m <sup>3</sup>	
	Silica gel, amorphous synthetic	1,200 mg/m <sup>3</sup>	
	Silica gel	1,200 mg/m <sup>3</sup>	

<sup>a</sup>The Substances Added to Food inventory replaces EAFUS and contains the following types of ingredients: food and color additives listed in FDA regulations, flavoring substances evaluated by FEMA or JECFA, GRAS substances listed in FDA regulations, substances approved for specific uses in food prior to September 6, 1958, substances that are listed in FDA regulations as prohibited in food, delisted color additives, and some substances "no longer FEMA GRAS."

<sup>b</sup>Group 3: Not classifiable as to its carcinogenicity to humans.

<sup>c</sup>Group 1: Carcinogenic to humans.

<sup>d</sup>In addition to limiting exposures, employers must take other steps to protect workers. The construction standard includes specific exposure control methods.

<sup>e</sup>Potential occupational carcinogen.

<sup>f</sup>Definitions of PAC terminology are available from U.S. Department of Energy (DOE 2018a).

AEGL = acute exposure guideline level; CFR = Code of Federal Regulations; DOE = Department of Energy; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FEMA = Flavor and Extract Manufacturers Association; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; JECFA = Joint FAO/WHO Expert Committee on Food Additives; mppcf = millions of particles per cubic foot; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = protective action criteria; PEL = permissible exposure limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TWA = time-weighted average; USDA = U.S. Department of Agriculture; WHO = World Health Organization