

## CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding creosote 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. Note that no MRLs have been derived for creosote (see Section 1.3 and Appendix A for detailed information).

**Table 7-1. Regulations and Guidelines Applicable to Coal Tar Creosote, Coal Tar, Coal Tar Pitch, and Coal Tar Pitch Volatiles**

Agency	Description	Information	Reference
<b>Air</b>			
EPA	RfC	Not assessed	<a href="#">IRIS 1988</a>
WHO	Air quality guidelines	No data	<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 2009b</a>
	RfD	Not assessed	<a href="#">IRIS 1988</a>
WHO	Drinking water quality guidelines	Not listed <sup>a</sup>	<a href="#">WHO 2022</a>
FDA	Food and drugs regulations		
	Beechwood creosote	Allowed under synthetic flavoring substances and adjuvants regulation	<a href="#">FDA 2021a</a>
	Coal tar 0.5–5%	Allowed as active ingredient for the control of dandruff, seborrheic dermatitis, and psoriasis	<a href="#">FDA 2021d</a>
	Any over-the-counter drug product introduced after the dates specified that is labeled, represented, or promoted for the uses specified is regarded as a new drug for which an approved new drug application is required for marketing		<a href="#">FDA 2021b</a>
	Beechwood creosote (1990)	Expectorant drug products	
	Beechwood creosote and creosote (1993)	Poison ivy, oak, and sumac drug products	

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Agency	Description	Information	Reference
	Beechwood creosote, oral (1991) and topical (1995) Coal tar (1991)	Nasal decongestant drug products Topical acne drug products and diaper rash drug products	
	Drugs, recommended warning and caution statements		<a href="#">FDA 2021c</a>
	Creosote in preparations for external use	Caution: do not apply to large areas of the body	
	Creosote in douche preparations	The use of solutions stronger than those recommended may result in severe local irritation, burns, or serious poisoning. Do not use more often than twice weekly unless directed by physician	
<b>Cancer</b>			
HHS	Carcinogenicity classification Coal tars and coal-tar pitches	Known to be human carcinogens	<a href="#">NTP 2021</a>
EPA	Carcinogenicity classification Creosote	B1 <sup>b</sup>	<a href="#">IRIS 1988</a>
IARC	Carcinogenicity classification Creosotes	Group 2A <sup>c</sup>	<a href="#">IARC 2010</a>
	Occupational exposures during coal tar distillation	Group 1 <sup>d</sup>	<a href="#">IARC 2012a</a>
	Coal tar pitch	Group 1 <sup>d</sup>	<a href="#">IARC 2012b</a>
<b>Occupational</b>			
OSHA	PEL (8-hour TWA) for general industry, shipyards, and construction Coal-tar pitch volatiles (benzene-soluble fraction)	0.2 mg/m <sup>3</sup>	OSHA <a href="#">2021a</a> , <a href="#">2021b</a> , <a href="#">2021c</a>
NIOSH	REL (up to 10-hour TWA) Coal-tar pitch volatiles (cyclohexane-extractable fraction)	0.1 mg/m <sup>3 e</sup>	<a href="#">NIOSH 1977</a>
	IDLH	80 mg/m <sup>3 e</sup>	<a href="#">NIOSH 1994</a>
<b>Emergency Criteria</b>			
EPA	AEGLs-air	No data	<a href="#">EPA 2018b</a>
DOE	PACs-air Creosote (coal tar)		<a href="#">DOE 2018a</a>
	PAC-1 <sup>f</sup>	0.6 mg/m <sup>3</sup>	
	PAC-2 <sup>f</sup>	120 mg/m <sup>3</sup>	
	PAC-3 <sup>f</sup>	700 mg/m <sup>3</sup>	

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Agency	Description	Information	Reference
	Coal tar pitch volatiles		
	PAC-1 <sup>f</sup>	0.6 mg/m <sup>3</sup>	
	PAC-2 <sup>f</sup>	120 mg/m <sup>3</sup>	
	PAC-3 <sup>f</sup>	700 mg/m <sup>3</sup>	
	Coal tar, aerosol		
	PAC-1 <sup>f</sup>	2.8 mg/m <sup>3</sup>	
	PAC-2 <sup>f</sup>	31 mg/m <sup>3</sup>	
	PAC-3 <sup>f</sup>	190 mg/m <sup>3</sup>	

<sup>a</sup>In relation to benzo[a]pyrene drinking-water contamination, it is recommended that coal tar-based pipe linings and coatings on storage tanks be discontinued.

<sup>b</sup>B1: probable human carcinogen (limited evidence of carcinogenicity from epidemiological studies) based on EPA's 1986 cancer guidelines.

<sup>c</sup>Group 2A: probably carcinogenic to humans.

<sup>d</sup>Group 1: carcinogenic to humans.

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

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

AEGL = acute exposure guideline levels; DOE = Department of Energy; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; HHS = Department of Health and Human Services; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; NIOSH = National Institute for Occupational Safety and Health; 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; WHO = World Health Organization