CREOSOTE 213

## **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).

Agency	Description	Information	Reference
<i>.</i> .g ,	•	Air	
EPA	RfC	Not assessed	IRIS 1988
WHO	Air quality guidelines	No data	WHO 2010
	Water	& Food	
EPA	Drinking water standards and health advisories	Not listed	EPA 2018a
	National primary drinking water regulations	Not listed	EPA 2009b
	RfD	Not assessed	<u>IRIS 1988</u>
WHO	Drinking water quality guidelines	Not listed <sup>a</sup>	WHO 2022
FDA	Food and drugs regulations		
	Beechwood creosote	Allowed under synthetic flavoring substances and adjuvants regulation	FDA 2023a
	Coal tar 0.5–5%	Allowed as active ingredient for the control of dandruff, seborrheic dermatitis, and psoriasis	FDA 2023d
	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 ar approved new drug application is required for marketing	1	FDA 2023b
	Beechwood creosote (1990)	Expectorant drug products	
	Beechwood creosote and creosote (1993)	Poison ivy, oak, and sumac drug products	
	Beechwood creosote,	Nasal decongestant drug	

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

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Agency	Description	Information	Reference
	oral (1991) and topical (1995)	products	
	Coal tar (1991)	Topical acne drug products and diaper rash drug products	
	Drugs, recommended warning and caution statements		FDA 2023c
	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	
	Ca	ncer	
HHS	Carcinogenicity classification		NTP 2021
	Coal tars and coal-tar pitches	Known to be human carcinogens	
EPA	Carcinogenicity classification		IRIS 1988
	Creosote	B1 <sup>b</sup>	
IARC	Carcinogenicity classification		
	Creosotes	Group 2A <sup>c</sup>	IARC 2010
	Occupational exposures during coal tar distillation	Group 1 <sup>d</sup>	IARC 2012a
	Coal tar pitch	Group 1 <sup>d</sup>	IARC 2012b
	Оссир	oational	
OSHA	PEL (8-hour TWA) for general industry, shipyards, and construction		OSHA <u>2021a,</u> <u>2021b, 2021c</u>
	Coal-tar pitch volatiles (benzene-soluble fraction)	0.2 mg/m³	
NIOSH	REL (up to 10-hour TWA)		
	Coal-tar pitch volatiles (cyclohexane-extractable fraction)	0.1 mg/m³ <sup>e</sup>	NIOSH <u>1977</u> , <u>2018</u>
	IDLH	80 mg/m³ <sup>e</sup>	NIOSH 1994
	Emergen	cy Criteria	
EPA	AEGLs-air	No data	EPA 2018b
DOE	PACs-air		DOE 2018a
	Creosote (coal tar)		
	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/m³	
	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>&</sup>lt;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.

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

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

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

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

<sup>&</sup>lt;sup>e</sup>Potential occupational carcinogen.

<sup>&</sup>lt;sup>f</sup>Definitions of PAC terminology are available from DOE (2018b).