8. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding coal tars, coal tar pitch, and creosote in air, water, and other media are summarized in Table 8-1. ATSDR has derived no MRLs for any of the creosotes, in part because creosote is a mixture that can vary in chemical components and concentrations. No EPA reference concentration or reference dose exists for the compound.

The EPA has determined that creosote is a class B1 carcinogen (probable human carcinogen) (IRIS 2001). A potency factor was not provided in IRIS. IARC classifies creosote as Group 2A (probably carcinogenic to humans) and coal tars as Group 1 (carcinogenic to humans) (IARC 2001). The National Toxicology Program classifies coal tar (coke oven emissions, coal tar, coal tar pitch, and creosotes) as a known human carcinogen (NTP 1998).

Coal tar creosote is on the list of chemicals appearing in "The Emergency Planning and Community Right-to-Know Act of 1986" (EPCRA) (EPA 1987b). Section 313 of Title III of EPCRA requires owners and operators of certain facilities that manufacture, import, process, or otherwise use the chemicals on this list to report annually their release of those chemicals to any environmental media.

OSHA requires employers of workers who are occupationally exposed to coal tar pitch volatiles to institute engineering controls and work practices to reduce employee exposure to, and maintain employee exposure at or below permissible exposure limits (PEL). The employer must use engineering and work practice controls, if feasible, to reduce exposure to or below an 8-hour time-weighted average (TWA) of 0.2 mg/m³. Respirators must be provided and used during the time period necessary to install or implement feasible engineering and work practice controls (OSHA 1999a).

Agency	Description	Information	Reference
INTERNATIONAL Guidelines:			
IARC	Carcinogenicity classification Creosotes Coal-tars	Group 2Aª Group 1 ^b	IARC 2001
<u>NATIONAL</u> Regulations and Guidelines:			
a. Air:			
ACGIH	TWA—coal tar pitch volatiles ^c	0.2 mg/m ³	ACGIH 2001
NIOSH	REL—coal tar pitch volatiles ^d IDLH	0.1 mg/m³ 80 mg/m³	NIOSH 2001
OSHA	8-Hour TWA for general industry—coal tar pitch volatiles ^e	0.2 mg/m ³	OSHA 2001b 29CFR1910.1000 Table Z-1
	8-Hour TWA for construction industry—coal tar pitch volatiles ^e	0.2 mg/m ³	OSHA 2001a 29CFR1926.55
	8-Hour TWA for shipyard industry—coal tar pitch volatiles ^e	0.2 mg/m ³	OSHA 2001c 29CFR1915.1000
b. Water		No data	
c. Food			
ATF	Denaturant authorized for denatured spirits—coal tar		ATF 2001 27CFR21.151
FDA	Active ingredient for the control of dandruff, seborrheic dermatitis, and psoriasis—coal tar	0.5–5%	FDA 2001a 21CFR358.710
	Synthetic flavoring substance and adjuvants—beechwood creosote	Used in the minimum quantity required to produce their intended effect, and in accordance with all principles of good manufacturing practice	FDA 2001d 21CFR172.515

Table 8-1. Regulations and Guidelines Applicable to Coal Tar Creosote,Coal Tar, Coal Tar Pitch, and Coal Tar Pitch Volatiles

Agency	Description	Information	Reference
NATIONAL (cont.)			
FDA	Based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses		FDA 2001b 21CFR310.545
	Coal tar	Topical acne drug products and diaper rash drug products	
	Beechwood creosote	Expectorant drug products	
	Creosote (beechwood) and creosote	Poison ivy, oak, and sumac drug products	
	Creosote (beechwood), oral and topical	Nasal decongestant drug products	
	Drugs, recommended warning and caution statements—creosote		FDA 2001c 21CFR369.20
	External use	Caution—do not apply to large areas of the body	
	Douche preparations	Warning—use of solutions stronger than recommended may result in severe local irritation, burns, or serious poisoning; do not use more than twice weekly	
d. Other			
ACGIH	Carcinogenicity classification—coal tar pitch volatiles ^c	A1 ^f	ACGIH 2001
EPA	RfC RfD Carcinogenicity classification—creosote	No data No data B1 ^g	IRIS 2001

Table 8-1. Regulations and Guidelines Applicable to Coal Tar Creosote,
Coal Tar, Coal Tar Pitch, and Coal Tar Pitch Volatiles (continued)

Agency	Description	Information	Reference
NATIONAL (cont.)			
EPA	CERCLA Section 102 and RCRA Section 3001 reportable quantity—creosote and coal tar	1 pound	EPA 2001b 40CFR302.4
	Identification and listing of hazardous waste—creosote identified as a toxic waste	U051	EPA 2001c 40CFR261.33
	Toxic chemical release reporting: Community right-to-know; effective date—creosote	01/01/90	EPA 2001d 40CFR372.65
	TSD facilities; Henry's law constant less than 0.1 atm m ³ /mol—creosote		EPA 2001a 40CFR265 Appendix VI
NTP	Carcinogenicity classification—coal tar and coal tar aerosols	Known to be a human carcinogen	NTP 1998
<u>STATE</u> Regulations and Guidelines:		No data	

Table 8-1. Regulations and Guidelines Applicable to Coal Tar Creosote,Coal Tar, Coal Tar Pitch, and Coal Tar Pitch Volatiles (continued)

^aGroup 2A: Probably carcinogenic to humans

^bGroup 1: Carcinogenic to humans

°Coal tar pitch volatiles: benzene soluble aerosol

^dCoal tar pitch volatiles: cyclohexane-extractable fraction

^eCoal tar pitch volatiles: benzene soluble fraction, anthracene, benzo[a]pyrene, phenanthrene, acridine, chrysene, pyrene

^fA1: Confirmed human carcinogen

⁹B1: Probable human carcinogen

ACGIH = American Conference of Governmental Industrial Hygienists; ATF = Alcohol, Tobacco, and Firearms; CERCLA = Comprehensive Environmental Response Compensation and Liability Act; CFR = Code of Federal Regulations; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; IRIS = Integrated Risk Information System; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicological Program; OSHA = Occupational Safety and Health Administration; RCRA = Resource Conservation and Recovery Act; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TSD = transport, storage, and disposal; TWA = time-weighted average