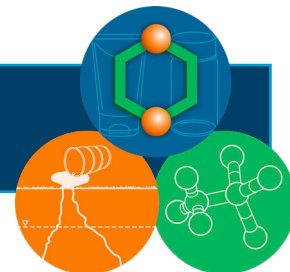




Regulatory Framework 1,4-Dioxane



1 Introduction

Several federal government agencies have identified or regulated 1,4-dioxane (Chemical Abstracts Service [CAS] Registry Number #123-91-1) as a hazardous substance since the early 1980s. However, 1,4-dioxane did not become an environmental contaminant of emerging concern until the early 2000s, after the U.S. Environmental Protection Agency (USEPA) initiated a reassessment of the toxicity of 1,4-dioxane and began developing cleanup guidelines for various media. In 2008, the USEPA included 1,4-dioxane in the Safe Drinking Water Act Candidate Contaminant List (Hatzinger et al. 2017) (USEPA 2008); (USEPA 2010); (USEPA 2017a)). At the same time, in the early 2000s, analytical methods with lower detection and reporting limits for soil and water samples became more readily available at commercial laboratories. Subsequently, investigators have detected 1,4-dioxane as a contaminant in air, soil, and water at numerous sites throughout the world. The USEPA has found that 1,4-dioxane is likely to be carcinogenic to humans (USEPA 2013).

The Interstate Technology and Regulatory Council (ITRC) has developed a series of six fact sheets to summarize the latest science and emerging technologies regarding 1,4-dioxane. The purpose of this fact sheet is to:

- review the history of 1,4-dioxane manufacturing and usage
- provide an overview of the potential sources of releases of 1,4-dioxane to the environment

Note: ITRC is developing a 1,4-dioxane guidance document for publication in late 2020. The guidance document will provide additional details on 1,4-dioxane history of use and potential sources.

2 Federal Regulation of 1,4-Dioxane

At least 17 regulations from the USEPA, the Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and the U.S. Department of Transportation (DOT) impose various requirements for 1,4-dioxane, ranging from general surveillance and screening to formal risk management. A comprehensive summary of federal regulations pertaining to 1,4-dioxane can be found in Appendix A of the 2018 USEPA report Problem Formulation of the Risk Evaluation for 1,4-Dioxane (USEPA 2018b).

Drinking Water

The USEPA does not use a single numeric value to address 1,4-dioxane in drinking water. In 1987, the agency established an unenforceable and nonregulatory health advisory for 1,4-dioxane of 4,120 micrograms per liter ($\mu\text{g}/\text{L}$) and 412 $\mu\text{g}/\text{L}$ for 1 day and 10 days of exposure, respectively, to 1,4-dioxane in drinking water. Based on the data available at the time, the health advisory did not provide values for lifetime exposure but stated that a concentration of 7 $\mu\text{g}/\text{L}$ to 700 $\mu\text{g}/\text{L}$ corresponded to a cancer risk of 1 in 1,000,000 and 1 in 10,000, respectively, assuming a person consumes the water with 1,4-dioxane for 70 years.

In its 2012 Edition of the Drinking Water Standards and Health Advisories, the USEPA listed a health advisory of 35 $\mu\text{g}/\text{L}$ for 1,4-dioxane based on a lifetime cancer risk of 1 in 10,000. This assumes that a person consumes the water with 1,4-dioxane for 70 years. Most commonly, the USEPA uses a concentration range of 0.35 to 35 $\mu\text{g}/\text{L}$, which corresponds to a cancer risk of 1 in 1,000,000 and 1 in 10,000, respectively, when communicating exposure risks associated with 1,4-dioxane in drinking water (USEPA 2017d). The values also assume that a person consumes water with 1,4-dioxane for 70 years (USEPA 2018a); (USEPA 2017d). Health advisories provide information on drinking water contaminants that can cause human health effects that are known or are anticipated to occur. The USEPA issues health advisories for some contaminants when it does not establish enforceable drinking water standards. USEPA programs cite health advisories as a partial basis to require potentially responsible parties to implement response actions when drinking water sources are being threatened or contaminated. Additionally, the USEPA has used its authority under Section 1431 of the federal Safe Drinking Water Act (SDWA) to direct responsible parties to implement response actions to abate 1,4-dioxane contamination at sites in Arizona and Florida (USEPA 2007); (USEPA 2003). The USEPA's most recent guidance for using its emergency authority under Section 1431 of the SDWA specifically references exceedances

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of health advisories under certain conditions as a basis for issuing enforcement orders to responsible parties (USEPA 2018d).

The SDWA establishes the requirements that the USEPA must follow in adopting standards for drinking water quality and monitoring requirements for public water systems. The USEPA has not adopted a maximum contaminant level (MCL) for 1,4-dioxane, but under the SDWA's [third \(2009\)](#) and [fourth \(2016\)](#) CCL, the agency identified 1,4-dioxane as a chemical that is expected to occur in public drinking water systems and that may require regulation (USEPA 2009); (USEPA 2017a). As part of the [Third Unregulated Contaminant Monitoring Rule \(UCMR3\)](#), the USEPA in 2013–2015 required all drinking water systems serving more than 10,000 people to sample for 1,4-dioxane (USEPA 2012). UCMR3 also included a representative number of public water systems serving less than 10,000 people. [Sampling under this program identified that 22% of the public water systems tested had detectable levels of 1,4-dioxane above the reporting limit of 0.07 µg/L and 7% had 1,4-dioxane levels above the lower end of the USEPA's reference concentration range of 0.35 µg/L \(USEPA 2017d\). None of the public water systems tested had 1,4-dioxane in their drinking water above the upper end of the USEPA's reference concentration range of 35 µg/L \(USEPA 2017d\). Currently, there are no federal requirements for public water systems to continue monitoring, and there are no water quality standards under the SDWA.](#)

Surface Water

The USEPA has not developed recommended surface water quality criteria under Section 304(a) of the Clean Water Act for 1,4-dioxane that protect aquatic life or human health. However, the [USEPA's Enforcement and Compliance History Online Database \(ECHO\)](#) lists numerous National Pollutant Discharge Elimination System (NPDES) permits with monitoring requirements for 1,4-dioxane and a limited number of permits containing effluent limits for the 2018 reporting period (USEPA 2019e). The USEPA may also include effluent limitations in NPDES general permits. One example of this is the [general permit issued in 2016 for discharges of remediation and dewatering wastewater \(WW\) in New Hampshire and Massachusetts](#) (USEPA 2017b). This general permit includes a water quality– and technology-based effluent limitation of 200 µg/L (USEPA 2017b).

Regional Screening Levels for Soil, Groundwater, and Air

The USEPA has established [regional screening levels \(RSLs\)](#) for soil, groundwater, and air using risk assessment guidance from the USEPA Superfund program (USEPA 2019d). Risk assessors, remediation project managers, and others use screening levels for site screening and as initial cleanup goals. Screening levels are not de facto cleanup standards; rather, they are levels that, when exceeded, warrant further action or study. The USEPA has established oral, dermal, and inhalation screening levels for 1,4-dioxane. The agency has also developed a risk-based site screening level for soil to protect groundwater. The [RSL for 1,4-dioxane in tap water, 0.46 µg/L, includes exposure via ingestion, dermal contact, and inhalation](#) and corresponds to a 1 in 1,000,000 cancer risk (USEPA 2018c).

Other Federal Regulations

1,4-Dioxane is a [Hazardous Air Pollutant \(HAP\)](#) under the Clean Air Act and is [considered a hazardous substance](#) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (USEPA 2019c); (USEPA 2004). It is also a [U-listed hazardous waste under Section 3001 of the Resource Conservation and Recovery Act](#) if it is a “discarded commercial product” (for example, an expired and discarded bottle of technical-grade 1,4-dioxane), and based on flash point, it could be classified as a D001 characteristic flammable waste if present in an aqueous solution with as little as 3%–4% by weight (Astbury 2004, USEPA 1980). Further, 1,4-dioxane's use is subject to Toxic Substances Control Act (TSCA) regulations. In a draft risk evaluation for 1,4-dioxane under TSCA, the USEPA is evaluating the risk associated with [14 conditions](#) of use associated with the manufacturing (including import), processing, distribution, use, and disposal of 1,4-dioxane (USEPA 2019b). The storage, use, and release of 1,4-dioxane is also subject to the [reporting requirements](#) of the Toxics Release Inventory (TRI) under the Emergency Planning and Community Right-to-Know Act, which can be accessed at <https://www.epa.gov/epcra> (USEPA 2015a). According to the most recent data submitted to the USEPA under the TRI, 50 facilities released a total of [614,514 pounds of 1,4-dioxane in 2017](#), down from a total of over [1.7 million pounds in 2014](#) (USEPA 2019a); (USEPA 2015b). Of the 2017 total, about 58,000 pounds (9%) were released to water.

The FDA is the federal agency responsible for protecting public health through ensuring the safety, efficacy, and security

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of human and veterinary drugs, biological products, medical devices, and the nation's food supply, cosmetics, and radiation-emitting products. Since the 1980s, the FDA (2019) has recommended that manufacturers remove 1,4-dioxane from their products and limit the concentration in cosmetics to no more than 10 parts per million (ppm). OSHA established a permissible exposure limit (PEL) for 1,4-dioxane of 100 ppm or 360 milligrams per cubic meter (mg/m³) as an eight-hour time-weighted average (TWA). Although OSHA established a PEL for 1,4-dioxane, OSHA has recognized that many of its PELs are outdated and inadequate for ensuring the protection of workers' health. OSHA recommends that employers follow California's OSHA limit of 0.28 ppm, the National Institute for Occupational Safety and Health–recommended exposure limit of 1 ppm as a 30-minute ceiling, or the American Conference of Governmental Industrial Hygienists' threshold limit value of 20 ppm (USEPA 2017c).

3 State Regulations of 1,4-Dioxane

Several states have developed standards and guidance values for 1,4-dioxane in water, soil, and air across multiple regulatory programs. Figure 1 summarizes the regulatory and guidance concentrations established by some states for drinking water and groundwater. It provides a detailed summary of federal and state values. At this time, no state has adopted an MCL for 1,4-dioxane.

States that have not adopted standards or guidance values for 1,4-dioxane often reference the USEPA's RSLs for water, soil, and air. The examples below describe key state programs for water, soil, remediation, hazardous substances, or consumer products.

Figure 1: 1,4-Dioxane State Regulatory Values for Drinking Water and Groundwater (µg/L)

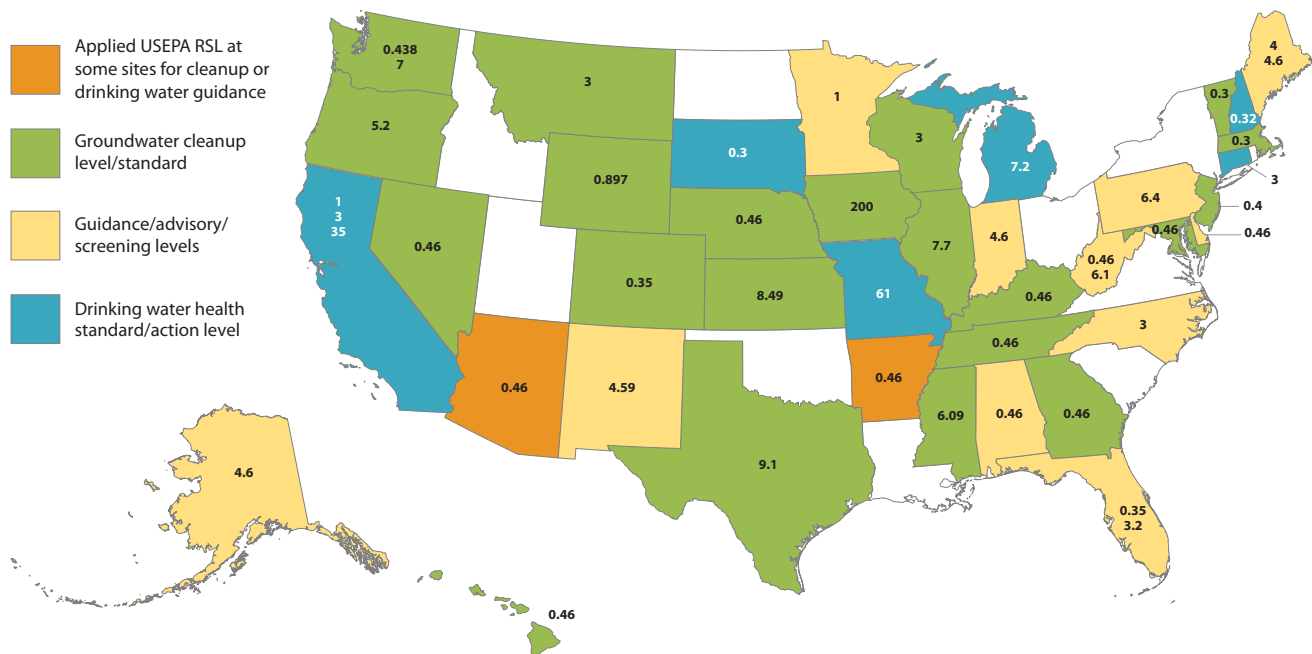


Figure 1. 1,4-Dioxane state regulatory values for drinking water and groundwater in micrograms per liter (µg/L). (RSL: regional screening level; USEPA: U.S. Environmental Protection Agency.)

Regulatory Framework: 1,4-Dioxane *continued*

The California State Water Resources Control Board (Water Board) adopted a “[Water Quality Control Policy for Recycled Water](#)” on December 11, 2018. The policy includes sampling for 1,4-dioxane in treated WW that will be reused (i.e., effluent water reuse) and includes a monitoring trigger level (MTL) of 1 µg/L. An MTL is the concentration above which response actions may be required. The Water Board’s Science Advisory Panel established MTLs for constituents of emerging concern in recycled water in their [final report](#) (Drewes et al. 2018). Recent [permits](#) issued by the Water Board have required 0.5 Log removal (68.4% reduction) of 1,4-dioxane in WW that is treated for reuse.

A number of consumer products contain 1,4-dioxane as an unwanted byproduct of various chemical reactions that occur during the manufacturing processes. In the United States, only two states have established labeling requirements. California listed 1,4-dioxane as a chemical known to cause cancer under the state’s [Safe Drinking Water and Toxic Enforcement Act of 1986](#) (commonly referred to as Proposition 65; see <https://oehha.ca.gov/proposition-65>). Proposition 65 requires manufacturers, distributors, and retailers to provide warning labels on products containing 1,4-dioxane at concentrations expected to result in human exposures above the [Safe Harbor Level of 30 µg per day](#) (CAOEHHA 2013). Proposition 65 also prohibits companies from discharging 1,4-dioxane to sources of drinking water. [California’s Cleaning Products Right to Know Act](#) requires that manufacturers disclose all ingredients, including 1,4-dioxane, in cleaning products beginning in 2020 (online disclosure) and 2021 (on-label disclosure) if the chemical is present in the final product at or above a concentration of 0.001% or 10,000 µg/L (California 2017). New York enacted a law that prohibits the sale of personal care and cleaning products with 1,4-dioxane concentrations above 2 ppm after December 31, 2022, and above 1 ppm after December 31, 2023. The law also prohibits the sale of cosmetics with concentrations above 10 ppm after December 31, 2022. Every two years, starting no later than 2025, the New York State Department of Environmental Conservation will evaluate if it should lower these thresholds.

4 International Regulation of 1,4-Dioxane

The World Health Organization (WHO 2017) and several other countries have proposed guidelines for 1,4-dioxane in drinking water and/or groundwater. Table 1 summarizes the guidelines.

Table 1. Comparison of federal and international regulatory values

Country/Organization	Concentration (µg/L)	Description of value referenced
United States - USEPA	35/0.46	Health advisory level/RSL
World Health Organization (WHO)	50	Suggested drinking water threshold
Japan - Ministry of Health, Labour, and Welfare	50	Adopted WHO threshold
Canada - Health Canada	50	Proposed maximum acceptable concentration for drinking water

Definitions: µg/L: micrograms per liter; RSL: regional screening level; WHO: World Health Organization.

5 References

The references cited in this fact sheet, and the other ITRC 1,4-Dioxane fact sheets, are included in one combined list that is available on the ITRC web site.

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