

Insights

CONSUMER PRODUCTS REGULATIONS ON THE RISE FOR 1,4-DIOXANE

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SUMMARY

In a growing trend to regulate the chemicals contained in consumer products, numerous states are enacting laws and regulations to address the presence of 1,4-dioxane in consumer products. 1,4-dioxane is a synthetic industrial chemical, and it is found in household substances such as in shampoo, soap, household cleaners, dyes, paints, and adhesives. 1,4-dioxane may be created as a byproduct during chemical reactions in manufacturing. For additional background information regarding 1,4-dioxane, refer to [BCLP's Client Alert discussing regulatory re-opener issues](#).

This Client Alert discusses the limited efforts to-date by the federal government and the more substantial efforts by numerous states to regulate 1,4-dioxane in consumer products. The perceived risks are two-fold: (1) downstream disposal in wastewater; and (2) potential health risks to consumers using the product.

I. Federal Landscape

Since 2016, the National Toxicology Program has classified 1,4-dioxane as “[reasonably anticipated to be a human carcinogen](#).” In 2019, the U.S. Environmental Protection Agency (“EPA”) conducted a [risk evaluation](#) for 1,4-dioxane (i.e., an evaluation to determine whether 1,4-dioxane presents an unreasonable risk of injury to health or the environment). In December of 2020, EPA issued its [final risk evaluation report](#), which determined that 1,4-dioxane can present an unreasonable risk in certain manufacturing, processing, industrial, and commercial settings. The report concluded that 1,4-dioxane does not pose an unreasonable risk to consumers using consumer products that contain the chemical.

At this time, there are no federal regulations specifically addressing the presence of 1,4-dioxane in consumer products. The Food and Drug Administration (“FDA”) has investigated [1,4-dioxane in cosmetics](#), but it has yet to issue any enforceable regulations.

II. State Laws and Regulations

New York is leading the charge toward enhanced consumer product regulation.

In two laws ([household cleansing products](#) and [cosmetic and personal care products](#)) that became effective on January 1, 2022, the State Legislature banned 1,4-dioxane in these products other than in “trace concentrations.” The law addresses the risks of 1,4-dioxane to be disposed into wastewater as well as human exposure to the consumer products. The phase-in schedule and statutory definition of “trace concentrations” are as follows:

New York 1,4-Dioxane Requirements

Consumer Product	Concentration*	Date
Cleansing Products	2 ppm	12/31/22
Cleansing Products	1 ppm	12/31/23
Cosmetics	10 ppm	12/31/22
Personal Care Products	2 ppm	12/31/22
Personal Care Products	1 ppm	12/31/23
*The statute requires the New York State Department of Environmental Conservation (“NYSDEC”), in consultation with the State Health Department, to review these trace concentration thresholds and determine whether they should “be lowered to better protect human health and the environment.”		

California has also taken action. California’s Office of Environmental Health Hazard Assessment (“OEHHA”) has identified 1,4-dioxane as a risk to human health, and it lists a “safe harbor” requirement of [30 µg per day](#). Exposures that are below the “safe harbor” level are exempt from the requirements of Proposition 65. Since 1988, OEHHA has designated 1,4-dioxane as a cancer risk under [Proposition 65](#).

In 2017, California’s Cleaning Product Right to Know Act requires manufacturers to list 1,4-dioxane if it appears in finished products in total concentrations at or above 10 ppm. The [bill](#) and a [related summary](#) discuss this requirement.

Numerous states have prohibited 1,4-dioxane from appearing in children's products, usually if 1,4-dioxane is present at a concentration greater than 1 ppm. Typically, these laws and regulations require manufacturers to report to a state agency or department.

- Oregon – Toxic Free Kids Act (requiring manufacturers of children's products containing 1,4-dioxane as a "high priority chemical of concern" to provide notice)
- Vermont (Vermont Department of Health Rule) (regulating the inclusion of 1,4-dioxane in children's products as a chemical of "high concern to children")
- Washington (Washington Department of Ecology information) (requiring manufacturers that produce 1,4-dioxane in children's products as a "chemical of high concern to children" to file a report)

In New York, a law enacted in 2020 requires NYSDEC to consider 1,4-dioxane and a host of other chemicals to promulgate a list of "chemicals of concern." Then, the law requires a manufacturer who offers a children's product for sale or distribution in New York to file a report with NYSDEC identifying any chemical of concern or high-priority chemical present at or above practical quantification limits. The reports are due twelve months after a chemical of concern or high-priority chemical appears on NYSDEC's list. NYSDEC has yet to promulgate regulations implementing this statute.

III. Further Agency Investigation as to Disposal is Likely to Yield Additional Regulations

California's Department of Toxic Substances Control ("DTSC") has identified 1,4-dioxane as a contaminant of concern, particularly citing the disposal risk rather than a direct risk to the consumer. DTSC states the following: "DTSC is concerned about the potential adverse impacts to Californians from exposure to 1,4-dioxane, especially children and environmental justice communities. Many personal care and cleaning products are washed down the drain during or after use, releasing 1,4-dioxane into wastewater." DTSC is currently evaluating additional information to create, in part, regulations pertaining to 1,4-dioxane.

In 2019, DTSC issued a document entitled "1,4-Dioxane in Personal Care and Cleaning Products" which was disseminated at public hearings during that time. The document evaluated consumer products containing 1,4-dioxane for possible designation as Priority Products under California's Safer Consumer Products regulations, and it also addressed multiple potential human exposure pathways to 1,4-dioxane.

It is our understanding that DTSC has taken no formal action to date to designate 1,4-dioxane contained in beauty, personal care, hygiene products, and cleaning products as a Priority Product. DTSC is currently involved in a lengthy process to gather information, evaluate public comments, and assess an alternatives analysis.

IV. Conclusion

We expect the regulation of 1,4-dioxane in consumer products will continue for the foreseeable future. In the absence of federal regulation, State legislatures and agencies continue to focus on the presence of potentially harmful chemicals in consumer products to protect the health of consumers and water resources.

If you have any questions regarding 1,4-dioxane, please contact Phil Karmel (212-541-2311), John Kindschuh (314-259-2313), or Erin Brooks (314-259-2393).

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