FOR DISCUSSION ONLY

1,4-Dioxane in Personal Care and Cleaning Products: Seeking Input on Alternatives Analysis Threshold

This draft Alternatives Analysis Threshold (AAT) and rationale lays out the results of the California Department of Toxic Substances Control's (DTSC) research findings. It has been provided for discussion at a public meeting on August 21st. During this meeting, we hope to gain insight regarding the feasibility of meeting this draft AAT and the challenges associated with doing so, as outlined by questions described in our background document. DTSC will take this information into consideration to propose an AAT if a Priority Product(s) containing 1,4-dioxane as the Chemical of Concern is proposed. More information on DTSC's work on 1,4-dioxane can be found at https://dtsc.ca.gov/scp/1-4-dioxane/.

INTRODUCTION

The DTSC's Safer Consumer Products regulations require DTSC to set an Alternatives Analysis Threshold (AAT) for contaminants such as 1,4-dioxane in proposed Priority Products [§69503.5(c)].[1] When a contaminant is present in the product at concentrations below the AAT, manufacturers are required to submit a Priority Product Notification as well as an AAT Notification. Manufacturers whose products contain 1,4-dioxane at or above the AAT would be required to submit the Priority Product Notification and either a Preliminary and then Final Alternatives Analysis, or a notification indicating that they will remove the product from the market place or reformulate the product. Per the regulatory framework, an AAT is to be set at the practical quantitation limit (PQL) by default, although it may be set higher if warranted based on different factors that DTSC may consider in setting the AAT.[2]

DTSC has researched the following areas to date to inform this draft AAT for 1,4-dioxane in personal care and cleaning products:

- Available laboratory procedures
- Regulations at the federal and state level
- The estimated current impacts on the California water supply

Based upon our research findings detailed below, we are seeking input on an AAT of 1 ppm in personal care and cleaning products.

AVAILABLE LABORATORY PROCEDURES

DTSC has identified several analytical methods for measuring 1,4-dioxane in various sample matrices. EPA has a well-established method for quantifying 1,4-dioxane in water at parts per trillion (ppt) levels (EPA Method 522),[3] but it cannot accommodate the complex matrices associated with viscous and foaming products like detergents and gels. Other standard methods to measure 1,4-dioxane include

FDA-USP methods 228 and 467[4,5] and EPA Method 8260 and 8270.[6] These methods use gas chromatography with either flame ionization detection (FDA methods) or mass spectrometry detection (EPA methods). Without modification, none of these standard methods can quantify 1,4-dioxane at the single-digit parts per million (ppm) level. Poor detection limits are due to the solubility and volatility of 1,4-dioxane relative to the separation techniques used as well as challenges associated with the complex matrix of personal care and cleaning products mentioned above. However, modifications to both 8260 and 8270 EPA methods for the specific detection of 1,4-dioxane are well established. These methods employ additional extraction techniques, the use of a deuterated 1,4-dioxane isotope internal standard, and/or isotope dilution. With these modifications we anticipate that laboratories will be capable of reaching reporting limits below 1 ppm for 1,4-dioxane in personal care and cleaning products.[7–9]

REGULATIONS AT THE FEDERAL AND STATE LEVEL

In the United States, the presence of 1,4-dioxane in personal care or cleaning products is not regulated at the federal level. However, the New York State Legislature has recently passed legislation to restrict the levels of 1,4-dioxane in household cleansing products, personal care products, and cosmetics based on concerns for water contamination.[10] If this legislation is signed by the New York governor, 1,4-dioxane concentrations in household cleansing products and personal care products would have to be below 1 ppm and below 10 ppm in cosmetics by the end of 2023. Speakers at the August 21, 2019 workshop will provide additional insight in to the selection of these thresholds.

IMPACTS TO CALIFORNIA WATER SUPPLY

To evaluate the impacts of personal care and cleaning products containing 1,4-dioxane on the California water supply, we estimated the amount of 1,4-dioxane going down the drain for two residential activities: laundering and showering. This calculation requires an estimate of the frequency of the activity (running a load of laundry or taking a shower), the estimated volume of water used for that activity, the 1,4-dioxane concentration in the product used, and the amount of product typically used during that activity. Only three of the product types considered had sufficient data available to perform the analysis: laundry detergent, shampoo, and body wash.

1,4-Dioxane Concentration in Products

Figure 1 shows 1,4-dioxane concentrations in a variety of personal care and cleaning products based on publicly available studies conducted within the last 10 years.[11,12] A product type was excluded from the figure if fewer than 4 data points were available. Recent data from the FDA[7] was not available at the time of these calculations.

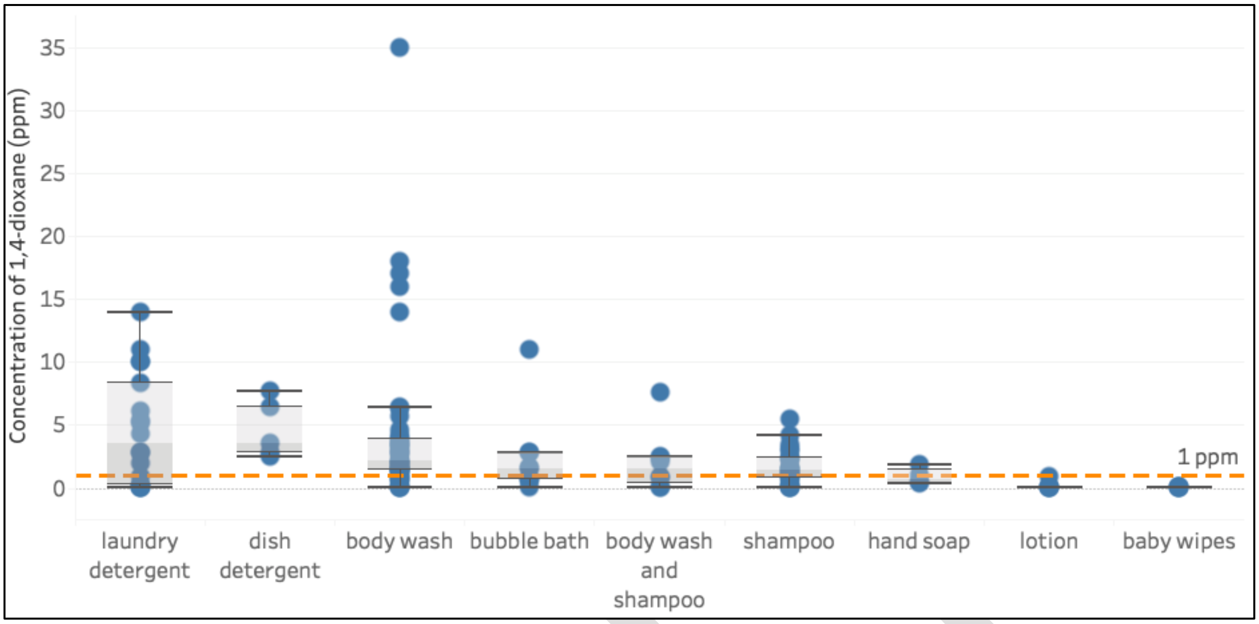

Figure 1. 1,4-Dioxane in products from studies conducted within the last 10 years. Yellow dotted line represents the proposed AAT value of 1 ppm. Detailed data available in Table 1.

While 1,4-dioxane concentrations in products have decreased since product testing was conducted in the 1980's and 1990's,[13] 1,4-dioxane is still prevalent in many personal care and cleaning products, as is shown in Figure 1 and Table 1. While DTSC plans to augment this dataset with its own study of 1,4-dioxane in personal care and cleaning products, this dataset serves as the basis for the calculations outlined below.

Table 1. Summary of 1,4-dioxane concentrations found in personal care and cleaning products in the last 10 years.[11,12]

			1,4-dioxane in product, C_p (µg/g)*	
Product Type	**n**	**< 1 ppm**	**Max**	**Mean**
Dish detergent	5	0%	7.7	4.60
Body wash	42	19%	35	4.43
Laundry detergent	18	33%	14	4.61
Shampoo	23	39%	5.5	1.66
Bubble bath	9	44%	11	2.43
Body wash and shampoo	8	50%	7.6	2.04
Hand soap	4	75%	1.9	0.93
Lotion	6	100%	0.92	0.16
Baby wipes	5	100%	0.01	0.01

* 1 µg/g = 1 ppm

This dataset does not contain data from industrial and institutional (I&I) products, which may have different concentrations of 1,4-dioxane than those used in non-I&I settings. Representative I&I samples will be collected as part of DTSC's independent product testing study.

Product Use Estimates

Data on the frequency of each activity (running a load of laundry or taking a shower), the estimated volume of water used for that activity, and the amount of product typically used during that activity is required to conduct this analysis. Laundry detergent, shampoo, and body wash were the only three product types with sufficient data available, outlined in Table 2.[14–19]

Table 2. Volume and frequency estimates for product use and activity.

Product type (Activity)	Product use per activity m_{pa} (g)	Water use per activity V_a (L)	Number of times performed per person per year
Laundry detergent (load of residential laundry)	98.5[14]	189[15]	100[16]
Shampoo (shower)	13.1[18]	65[19]	312[17]
Body wash (shower)	15.5[18]	65[19]	312[17]

Estimates of Influent 1,4-Dioxane Contribution from Personal Care and Cleaning Products

The diluted down-the-drain concentration of 1,4-dioxane in the water used for an activity in µg/L (C_a) can be calculated using the following equation and information outlined in Tables 1 and 2:

$$C_{\mathrm{a}} = \frac{C_{\mathrm{p}} \times m_{\mathrm{pa}}}{V_{\mathrm{a}}}$$

where C_p is the concentration (µg/g) of 1,4-dioxane in the product (Table 1), m_{pa} is the mass (g) of product used during a given activity (Table 2), and V_a is the total volume (L) of water used for a given activity (Table 2). Table 3 shows the results of this calculation using the maximum and mean values from Table 1 and forcing a hypothetical 1 ppm value.

Table 3. Down-the-drain concentrations of 1,4-dioxane per activity resulting from the use of different products. Each column shows the results for scenarios in which the product concentration is the dataset max, mean, or is set at 1 ppm.

		Down-drain concentration of 1,4-dioxane in water for a given activity (C_a, µg/L)		
Product type (Activity)	**Symbol**	**Cp = Max**	**Cp = Mean**	**Cp = 1 ppm**
Shampoo only (Shower)		1.10	0.33	0.20
Body wash only (Shower)		8.34	1.06	0.24
Laundry detergent (Load of residential laundry)	C_{lw}	7.30	2.40	0.52
Shampoo + Body wash (Shower)	C_{sw}	9.44	1.39	0.44

To understand the overall contribution of the use of these products to 1,4-dioxane concentrations in wastewater influent, we need to know what percentage of wastewater influent is due to each of these activities. To do this, we used available data on population served and volume of residential water processed per day (millions of gallons per day) for three water reclamation plants (WRP) in southern California that are used to generate recycled water: Whittier Narrows Water Reclamation Plant (WN WRP), Orange County Sanitation District (OCSD), and San Jose Creek Water Reclamation Plant (SJC WRP), as shown in Table 4.[20–26] Using the population served (Table 4), the frequency of activity per person per year (Table 2), and the water use per activity (Table 2), we can estimate the percentage of the total wastewater influent volume due to showering and laundering. These estimates are reasonably aligned with residential water use estimates for showering and laundering generated by the US EPA.[15]

Table 4. Data and estimates for three water reclamation plants in Southern California.

Parameter	WN WRP	OCSD	SJC WRP	Weighted average	EPA estimate[15]
Population served	150,000	2,600,000	1,000,000		
Million gallons of residential water processed per day	7.8	176	58.4		
Million gallons of residential water processed per year	2859	64240	21301		
Estimated % influent water from laundering	26.2%	20.2%	23.4%	21.3%	21.7%
Estimated % influent water from showering	28.1%	21.7%	25.2%	22.7%	16.8%

Using these percent composition estimates, the total 1,4-dioxane concentration of influent water (C_{wwtp}) can be characterized by the sum of laundry, shower, and other water inputs:

$$C_{\text{wwtp}} = f_{\text{lw}}(C_{\text{lw}}) + f_{\text{sw}}(C_{\text{sw}}) + f_{\text{ow}}(C_{\text{ow}})$$

where the fractions of influent from laundering (f_{lw}, 0.213) and showering (f_{sw}, 0.227) combine with the remaining influent water from other residential water use (f_{ow}, 0.56) to make up the total residential wastewater processed by the water reclamation plant. Multiplying the fractions by their respective concentration estimates (C_{lw}, C_{sw}, Table 3), we can estimate the contribution of 1,4-dioxane from laundry detergent, body wash, and shampoo to the overall influent water from each activity (Table 5). This is almost certainly an underestimate of the contribution from all personal care and cleaning products since only 3 products were used in this calculation.

Table 5. Estimated contribution of 1,4-dioxane to wastewater influent resulting from product use.

	1,4-dioxane contribution (µg/L)		
Influent contribution source	**C_p = Max**	**C_p = Mean**	**C_p = 1 ppm**
Laundry water influent, $f_{\text{lw}}(C_{\text{lw}})$	1.55	0.51	0.11
Shower water influent, $f_{\text{sw}}(C_{\text{sw}})$	2.15	0.32	0.10
Contribution due to total product use	3.70	0.83	0.21

Discussion

To better understand the significance of the contribution of 1,4-dioxane from personal care and cleaning products, it is helpful to compare these estimated values to measured values of 1,4-dioxane in WWTP influent (C_{wwtp}). The Los Angeles County Sanitation Districts (LACSD) have indicated that 1,4-dioxane is present in influent to their water reclamation plants at a consistent value of about 1 µg/L. They commented that, based on the near uniformity of this value across all of their plants, this was an indication of a widespread, residential source such as what might come from the use of personal care and cleaning products.[27] The mean contribution of 1,4-dioxane from the use of laundry detergent, shampoo, and body wash calculated above (0.83 µg/L) supports their suggestion and indicates that personal care and cleaning products are likely responsible for a significant portion of this input.

LACSD also presented data confirming that 1,4-dioxane is not removed by standard wastewater treatment processes.[27] As a result, the influent concentration of 1,4-dioxane is often representative of the effluent concentration of 1,4-dioxane. Effluent may be subject to the California State Water Resources Control Board's (State Water Board) notification level of 1 µg/L[28] depending on how it will be used. As a result, WRPs may be able to avoid installing costly treatment processes if the effluent concentrations are significantly below 1 µg/L, and optimally below the United States Environmental Protection Agency's health reference concentration of 0.35 µg/L.[29] Based on the above estimates and their alignment with WRP influent data, it appears that even with an approximate mean concentration of around 4.5 ppm in laundry detergent, shampoo, and body wash that might be representative of current products (Table 1), the burden on WRPs still approaches the 1 µg/L notification level.

Table 5 also presents the estimated contribution from personal care and cleaning products under a hypothetical scenario in which manufacturers reduce the 1,4-dioxane concentration in all three of these product types to 1 ppm. In this scenario, the 1,4-dioxane burden on WRPs could be reduced by 75%, to below the Water Board notification level and USEPA health reference concentration. This could in turn reduce the need for the installation of additional costly treatment.

Uncertainty

Uncertainties associated with the above estimates and values come primarily from product use patterns and 1,4-dioxane concentrations in products. First, product use patterns, such as the amount and frequency of body wash use and the volume of water used per shower, vary widely across the population (e.g., by gender and age groups). Although the USEPA Exposure Factors Handbook has highlighted that "very little information is available about the exact way the different kinds of products are used by consumers," [15] we have used the most reliable and readily available data to estimate the central tendency of the product use pattern. A full probability distribution modeling approach can be used to capture the variability of product use, but it was outside the scope of this effort. Second, product concentration data used for the above estimates are based only on two publicly available studies, as the FDA study was not available at the time of this work. In addition, the I&I products were not considered in our estimates, which likely underestimates the influent 1,4-dioxane contribution from personal care and cleaning products. As such, we have provided references for all our derived estimate values and welcome resources to reduce the uncertainties in these estimates.

RATIONALE AND IMPLICATIONS

After considering reasonably obtainable commercial lab capabilities, alignment with other regulations, and estimated impacts on the California water supply, we are seeking input on an Alternatives Analysis Threshold of 1 ppm in personal care and cleaning products. This value appears to be achievable by commercial laboratories, and therefore would meet the requirements of the regulations that the AAT be no lower than the Practical Quantitation Limit. Additionally, 1 ppm is in line with pending legislation within the United States. Finally, we believe that setting an AAT of 1 ppm would encourage manufacturers to reduce 1,4-dioxane concentrations in their products to a level that would significantly reduce the burden on water reclamation plants and the California drinking water supply, avoid the need for installation of costly treatment to remove 1,4-dioxane, and preserve California's recycled water capabilities.

TIMELINE

DTSC has not yet proposed a Priority Product(s) and will determine whether to do so after considering all input received during this stakeholder engagement phase. Nevertheless, a theoretical timeline is provided below to allow stakeholders to better understand when the AAT value would have to be met or else an Alternatives Analysis would have to be conducted if a Priority Product is proposed.

Date	Action
Summer 2020	Priority Product proposed, Proposed Priority Product Profile and AAT released, comment period opened.
Summer 2021	Notice of Proposed Action to adopt the Proposed Priority Product through rulemaking; workshop held
Summer 2022	Regulations go in to effect. Within 180 days, manufacturers of the Priority Product must submit either a Preliminary Alternatives Analysis or an Alternatives Analysis Threshold notification verifying that the concentration of 1,4-dioxane in their product is less than the AAT.

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