



10 December 2020

Yvette Selby-Mohamadu
Existing Chemicals Risk Assessment Division
Office of Pollution Prevention and Toxics
United States Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460-001
(via Federal eRulemaking Portal: <http://www.regulations.gov>)

RE: EPA-HQ-OPPT-2019-0238: 1,4-Dioxane: Supplemental Analysis to the Draft Toxic Substances Control Act (TSCA) Risk Evaluation

Dear Ms. Selby-Mohamadu:

The American Cleaning Institute® (ACI)¹ and the Household & Commercial Products Association (HCPA)² are pleased to provide the following comments and data regarding the US Environmental Protection Agency's (EPA's) supplemental analysis to the draft risk evaluation of 1,4-dioxane under the Toxic Substances Control Act. ACI and HCPA support the Agency's efforts to elicit additional public comment on the draft assessment of the potential risk of byproduct 1,4-dioxane in consumer products.

ACI and HCPA appreciate EPA's additional effort in conducting the supplemental analysis to the draft risk evaluation to address concerns raised by the Science Advisory Committee on Chemicals (SACC) panel and stakeholders. Further HCPA and ACI recommend that EPA's risk evaluation of 1,4-dioxane complies with LCSEA's requirement that "the Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or

¹ACI represents the \$60 billion U.S. cleaning product supply chain. ACI members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors. ACI serves the growth and innovation of the U.S. cleaning products industry by advancing the health and quality of life of people and protecting our planet. ACI achieves this through a continuous commitment to sound science and being a credible voice for the cleaning products industry.

² The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell \$180 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives.

susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." ACI and HCPA agree with EPA's determination that these consumer products do not present an unreasonable risk of injury to the health of consumers and bystanders and that additional information may improve the certainty of product concentration data. In light of recent concerns raised by stakeholders, including state water agencies, we recommend that EPA reconsider evaluating General Population risks associated with drinking water as a part of the risk evaluation. We recommend that EPA also evaluate corresponding industrial and institutional (I&I) and commercial products conditions of use that were considered for consumers and we will be providing use information towards that effort. ACI and HCPA also recommend consumer products affiliated with laundering and hard surface cleaning (e.g., fabric conditioners, all-purpose cleaners) be considered for evaluation. We will be responding specifically to the Conditions of Use (COU) corresponding to the evaluations of laundry and dishwashing products and will present data on dish soap and laundry detergent to provide information reflective of products currently available.

1,4-dioxane in cleaning products

Background

The cleaning products industry is trending towards lower levels of 1,4-dioxane in ethoxylated ingredients and products which contain them. This trend is underway for various reasons not least of which is minimization of an undesirable by-product. In California, concentrations of 1,4-dioxane are required to be disclosed if greater than 10 ppm per the requirements of the Cleaning Product Right to Know Act of 2017.³ This information is required to be posted online for any manufacturer of a cleaning product sold in California (dishwasher detergent, dish soap, laundry detergent, and surface cleaners are all within scope) as of 1/1/2020. The applies to both consumer and commercial uses. As of this writing, we are unaware of any product that disclose levels of 1,4-dioxane above the 10 ppm threshold. Therefore, all of our member's products are reasonably assumed to be under 10 ppm, including the concentrated products.

Separately, New York has passed a law in 2019 banning the presence of 1,4-dioxane in cleaning products above 2 ppm in 2022 and 1 ppm in 2023,⁴ and the regulatory activity to implement the law are underway. Manufacturers and suppliers have already initiated efforts to minimize 1,4-dioxane either by reformulation of cleaning products or via further reduction of 1,4-dioxane in raw materials.

Methodology development, optimization and validation for cleaning products

Because of these downward trends, and as the industry is unaware of a reliable method for detecting 1,4-dioxane at these low levels in complex matrices, ACI and member companies are working to demonstrate the minimum method principles that should be in place to detect 1,4-dioxane in cleaning products appreciably lower than regulatory requirements. To date, we have verified the analytical method principles on five cleaning product formulations representing hand dishwashing detergents, consumer laundry detergents and an institutional and industrial (I&I) laundry detergent and have been able to achieve a limit of detection (LOD) and limit of quantitation (LOQ) of 0.023 ppm and 0.087 ppm, respectively.

³ https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB258

⁴ <https://www.nysenate.gov/legislation/bills/2019/s4389>

Formulations

The proposed test formulations (Attachment 1) are meant to be representative of the base technology used in many products currently on the consumer and I&I/commercial markets, without meaning to reference any one single product or brand. The two hand dish formulations are both based on a blend of linear alkylbenzene sulfonates (LAS), ether sulfate and amine oxide. Classic hand dish technology used a blend of LAS, ether sulfate in approximately this same ratio and diethanolamide. Diethanolamide is being replaced by other technologies and amine oxide is one of the materials most commonly substituted for the diethanolamide. The formulators recognize that the single greatest contributor to 1,4 dioxane in hand dish formulations is the ether sulfate and so this blend of materials was chosen to be a benchmark. These comments apply equally well to consumer and to institutional hand dish formulations. The targets of 15 and 30% active surfactant were selected as these are believed to represent typical actives level of products currently in the market

The proposed laundry formulations are also intended to be representative of the base technology used in many products currently on the market, without meaning to reference any one single product or brand. The two consumer formulations are both based on a blend of anionic and nonionic surfactants, with the total amount of anionic being 2x the total amount of nonionic, which is typical of consumer laundry formulations. The anionic surfactants used are again a blend of LAS and ether sulfate, which is fairly common in consumer laundry formulations and the nonionics are a blend of two materials, one with a relatively high hydrophilic-lipophilic balance (HLB) value and one with a relatively low HLB value. This is also common practice and experience has shown that this blend delivers good performance in typical household laundry cleaning. The target active levels of 15 and 30% surfactant were selected as these are believed to represent the typical actives level of products currently in the market.

The I&I laundry formulation uses a different ratio of nonionic to anionic surfactants, with nonionics being present in a larger amount than the anionics. Again, this is typical of I&I laundry formulations without meaning to reference and one single product or brand. The higher total surfactant level is again, meant to represent a typical actives level found in I&I laundry detergent formulations.

Initial Results

The average measured 1,4-dioxane in the products was between 0.94 ppm and 3.6 ppm (Attachment 2). Triplicate samples were prepared from each of the five formulations. The results were calculated from three individual sample preparations for each product, two injections per each preparation. In order to measure for the method's accuracy, triplicate samples were prepared from each of the five formulations and spiked with 0.02 ppm of 1,4 dioxane and analyzed for residual 1,4-dioxane. The results were corrected for the concentration of 1,4-dioxane in the samples, and percent recovery was determined to be between 97% and 100%.

New York State Department of Environmental Conservation (NYS DEC) Cleaning Product Measurements

In addition to the regulatory activities in NYS, a recent NYS DEC webinar on 1,4-dioxane limits for household cleaning, personal care, and cosmetic product, ([November 18, 2020](#)) announced that the NYS Pollution Prevention Institute has been assessing 1,4-dioxane concentrations in on-the-

shelf consumer products. The data on a number of cleaning products revealed a median detection range from non-detectable to 2.5 ppm.

Anecdotal Cleaning Product Measurements

Background

A company undertook a cursory landscape scan of cleaning products found on store shelves.

Laundry products

The company looked at 22 different products that are representative of the top-selling brands, and these are all < 10 ppm, with ~70% being <7 ppm. At this point, they are not ready to share the actual range without any additional context or perspectives from other products in the marketplace. The industry does not want to give the false impression that lower numbers are easy to achieve. The overall level depends on which surfactants are used and the cleaning power of the detergent.

Hand dish products

The company also looked at the top three selling variants and these are all <4 ppm, in line with the hand dish soap measurements in ACI's study.

US EPA Draft Supplemental Analysis to the Draft Risk Assessment for 1,4-Dioxane

Table 3.1 – Summary of Hazard Identification and Dose-Response Values

The hazard points of departure (PODs) /human equivalent concentration (HEC)/Slope Factor Values in Table 3.1 Summary of Hazard Identification and Dose-Response Values differ, in some cases significantly, from the corresponding values in Table 4-13 of the Draft Risk Evaluation. We recommend that EPA provide a detailed explanation for these changes in either the response to comment or final risk evaluation.

Additional Supporting Documents – Consumer Exposure Assessment Model Input Parameters *CEM Inputs – All Scenarios (Surface Cleaner)*

ACI and HCPA would like further clarification and possible expansion of the “Surface Cleaner” scenario. The scenario includes inputs for a bathroom surface cleaner, but does not address other surface cleaners, such as all-purpose cleaners, that may be used with some frequency on multiple surfaces. We welcome further discussion with EPA concerning this scenario.

Weight Fractions – Dish Soap

We would like clarification as to basis for the range of 0.7-204 ppm for dish soap as the upper limit does not have a reference. In addition, the 204 ppm seems to be outside of range with current data for this product category and appears to be from a 2008 or 2009 study that is no longer available⁵ nor does there appear to be a corresponding reference in the Data Quality Evaluation for Data Sources on Consumer Exposure for this reference.

⁵ A study conducted by the Organic Consumers Association is noted in the TSCA Work Plan Problem Formulation and Initial Assessment of 1,4-dioxane but does not appear to be readily available. The 204 ppm value is also noted here: <https://www.organicconsumers.org/news/carcinogen-expert-david-steinman-speaks-press-event-unveiling-ocas-new-study-assessing-14>

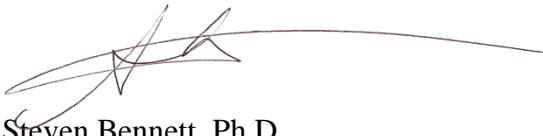
Closing

ACI and HCPA appreciate this opportunity to provide comments and looks forward to further engagement with EPA.

Sincerely,

A handwritten signature in cursive script that reads "Kathleen Stanton".

Kathleen Stanton
Associate Vice President, Technical & International Affairs

A handwritten signature in cursive script that reads "Steven Bennett".

Steven Bennett, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs

Attachment 1

Representative Formulations

Hand Dish Detergent Formulations

	Surfactant active		
	15%	30%	
LAS Acid	10.00	20.00	
SLES - 3EO (30%)	16.00	32.00	
lauryl dimethyl amine oxide (30%)	2.00	4.00	
SXS (40%)	2.00	5.00	For viscosity control
50% caustic	2.50	5.00	To neutralize LAS acid, adjust if necessary
BIT (Proxel GXL)	0.05	0.05	Preservative to prevent microbial spoilage
water	67.45	33.95	to 100%
total	100.00	100.00	
final pH	6.5 - 7.5	6.5 - 7.5	

Laundry Detergent Formulations

	Consumer		I&I	
	15% surfactant	50% surfactant	50% surfactant	
LAS acid	9.00	30.00	17.40	
SLES - 3 EO (30%)	4.50	15.00		
91-6	3.00	10.00	20.00	
91-2.5	2.00	6.66	13.30	
50% caustic	1.50	5.00	3.00	To neutralize LAS acid, adjust if necessary
BIT (Proxel GXL)	0.10	0.10	0.10	Preservative to prevent microbial spoilage
water	79.90	33.24	46.20	to 100%
total	100.00	100.00	100.00	
final pH	8.0 - 8.5	8.0 - 8.5	8.0 - 8.5	

Attachment 2

Detailed Results of Analysis for 1,4-Dioxane in Finished Cleaning Products

Sample	Prep	Injection	1,4-Dioxane (µg/g)	Average	Standard Deviation	%RSD
Hand Dish, 30%	1	1	3.60	3.6	0.08	2.22
		2	3.68			
	2	1	3.50			
		2	3.48			
	3	1	3.61			
		2	3.65			
Consumer Laundry, 15%	1	1	0.98	1.0	0.02	2.05
		2	1.03			
	2	1	1.02			
		2	0.98			
	3	1	1.00			
		2	1.01			
Hand Dish, 15%	1	1	1.87	1.9	0.03	1.35
		2	1.92			
	2	1	1.90			
		2	1.89			
	3	1	1.87			
		2	1.92			
Consumer Laundry, 50%	1	1	2.81	2.7	0.05	1.66
		2	2.73			
	2	1	2.74			
		2	2.76			
	3	1	2.68			
		2	2.69			
I&I Laundry, 50%	1	1	0.94	0.94	0.01	1.49
		2	0.93			
	2	1	0.93			
		2	0.94			
	3	1	0.97			
		2	0.95			

Results of Accuracy/Recovery of Spiked Finished Cleaning Products

Sample	Prep	% Recovery	Average % Recovery
Hand Dish, 30%	1	96	97
	2	97	
	3	98	
Consumer Laundry, 15%	1	98	100
	2	103	
	3	99	
Hand Dish, 15%	1	98	99
	2	99	
	3	100	
Consumer Laundry, 50%	1	99	100
	2	98	
	3	102	
I&I Laundry, 50%	1	96	98
	2	98	
	3	100	

Attachment 1

Representative Formulations

Hand Dish Detergent Formulations

	Surfactant active		
	15%	30%	
LAS Acid	10.00	20.00	
SLES - 3EO (30%)	16.00	32.00	
lauryl dimethyl amine oxide (30%)	2.00	4.00	
SXS (40%)	2.00	5.00	For viscosity control
50% caustic	2.50	5.00	To neutralize LAS acid, adjust if necessary
BIT (Proxel GXL)	0.05	0.05	Preservative to prevent microbial spoilage
water	67.45	33.95	to 100%
total	100.00	100.00	
final pH	6.5 - 7.5	6.5 - 7.5	

Laundry Detergent Formulations

	Consumer		I&I	
	15% surfactant	50% surfactant	50% surfactant	
LAS acid	9.00	30.00	17.40	
SLES - 3 EO (30%)	4.50	15.00		
91-6	3.00	10.00	20.00	
91-2.5	2.00	6.66	13.30	
50% caustic	1.50	5.00	3.00	To neutralize LAS acid, adjust if necessary
BIT (Proxel GXL)	0.10	0.10	0.10	Preservative to prevent microbial spoilage
water	79.90	33.24	46.20	to 100%
total	100.00	100.00	100.00	
final pH	8.0 - 8.5	8.0 - 8.5	8.0 - 8.5	

Attachment 2

Detailed Results of Analysis for 1,4-Dioxane in Finished Cleaning Products

Sample	Prep	Injection	1,4-Dioxane ($\mu\text{g/g}$)	Average	Standard Deviation	%RSD
Hand Dish, 30%	1	1	3.60	3.6	0.08	2.22
		2	3.68			
	2	1	3.50			
		2	3.48			
	3	1	3.61			
		2	3.65			
Consumer Laundry, 15%	1	1	0.98	1.0	0.02	2.05
		2	1.03			
	2	1	1.02			
		2	0.98			
	3	1	1.00			
		2	1.01			
Hand Dish, 15%	1	1	1.87	1.9	0.03	1.35
		2	1.92			
	2	1	1.90			
		2	1.89			
	3	1	1.87			
		2	1.92			
Consumer Laundry, 50%	1	1	2.81	2.7	0.05	1.66
		2	2.73			
	2	1	2.74			
		2	2.76			
	3	1	2.68			
		2	2.69			
I&I Laundry, 50%	1	1	0.94	0.94	0.01	1.49
		2	0.93			
	2	1	0.93			
		2	0.94			
	3	1	0.97			
		2	0.95			

Results of Accuracy/Recovery of Spiked Finished Cleaning Products

Sample	Prep	% Recovery	Average % Recovery
Hand Dish, 30%	1	96	97
	2	97	
	3	98	
Consumer Laundry, 15%	1	98	100
	2	103	
	3	99	
Hand Dish, 15%	1	98	99
	2	99	
	3	100	
Consumer Laundry, 50%	1	99	100
	2	98	
	3	102	
I&I Laundry, 50%	1	96	98
	2	98	
	3	100	