September 5, 2019

Via Electronic Mail

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Department of Toxic Substances Control
1001 I Street
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Re: PCPC Comments on DTSC Work Plan Implementation for 1,4-Dioxane in Personal Care and Cleaning Products

Dear Dr. Williams:

The Personal Care Products Council (PCPC)[1] is pleased to provide the following comments concerning the Department of Toxic Substances Control's (DTSC) proposed Work Plan Implementation for 1,4-Dioxane in Personal Care and Cleaning Products. PCPC's comments are based largely on information presented and discussed during DTSC's workshop on August 21, 2019. We want to thank DTSC for granting PCPC an extension of time in which to file these comments, following a DTSC request to PCPC for additional detail and information regarding the possible presence of 1,4-Dioxane in personal care products.

1,4-Dioxane is an unintended contaminant (by-product) produced during manufacture of ethoxylated personal care product ingredients, such as ethoxylated alcohol salts. Many ethoxylated ingredients are used as surfactants, providing gentle cleansing functionality due to their ability to remove materials, such as sebum, from skin. As such, ethoxylated ingredients play an essential role in maintaining personal hygiene. Ethoxylated ingredients are also used as emulsifiers, providing formulators with a valuable tool

[1] Based in Washington, D.C., the Personal Care Products Council (PCPC) is the leading national trade association representing global cosmetics and personal care products companies. Founded in 1894, PCPC's approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on and trust every day – from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance – personal care products companies are global leaders committed to product safety, quality, and innovation.

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for producing high performance personal care products with attributes that appeal to consumers. Ethoxylated ingredients have been shown to be safe for human use while also having a good sustainability profile due to possessing attributes such as readily biodegradability, good performance at low water temperatures and hardness, effectiveness at low use levels and allowing for finished products to be concentrated. There are currently no drop-in replacements for ethoxylated ingredients that provide the same benefits at a reasonable cost.

The FDA (Food and Drug Administration) has tracked 1,4-Dioxane levels in finished personal care products since the late 1970s[1]. Current and historical FDA data show that 1,4-Dioxane levels in personal care products have declined during this period. For example, in 1981 the FDA detected an average 1,4-Dioxane level of 50 ppm (parts per million). By 2008, another FDA survey found that about 6% of products contained 1,4-Dioxane levels between 1-5 ppm, about 6% were between 5-10 ppm, and about 8% were between 10-12 ppm. No 1,4-Dioxane was detected in the majority (80%) of products tested[2]. Most recently, a 2019 study (published by FDA scientists) measured 1,4-Dioxane levels in randomly selected products marketed for use by children. An average 1,4-Dioxane level of 1.54 ppm was detected, with around half of the products analyzed containing no detectable levels of 1,4-Dioxane[3]. The incremental reduction of 1,4-Dioxane levels in finished products over time demonstrates the personal care industry's ongoing commitment to reducing 1,4-Dioxane levels to below the internationally recognized safety threshold of 10 ppm[4].

The presence of 1,4-Dioxane and other contaminants in groundwater and drinking water should be monitored to ensure levels do not exceed thresholds of toxicological concern. However, to best understand and thereby successfully mitigate concern, careful consideration and source apportionment of 1,4-Dioxane is critical. In a comprehensive assessment, Simonich et al.[5] monitored effluent from wastewater treatment plants (WWTPs) that predominantly receive domestic sewerage at 40 sites across the conterminous United States. Of these 40 sites, six were in California, mainly in the San Francisco and Los Angeles areas. The concentrations reported are representative of down-the-drain household emissions, which encompass the contribution from personal care and cleaning products. The mean reported effluent concentration was 1.11 µg/L (approximately 0.001 ppm), with 1.75 and 3.30 µg/L reported as the 90th percentile and the maximum concentration, respectively. Using these data, Simonich et al.[5] conservatively estimated the contribution of down-the-drain 1,4-Dioxane emissions to drinking water by creating a distribution of dilution factors at U.S. drinking water intakes using the iSTREEM model. Drinking water concentrations were predicted by combining the distribution of measured effluent concentrations with distribution of nationwide dilution factors derived from iSTREEM. The median drinking water concentration resulting from domestic down-the-drain emissions under mean stream flow conditions was predicted to be 0.0041 µg/L and the 90^{th} and 99^{th} percentile 0.030 and 0.16 µg/L, respectively. DTSC's background document states that "…Los Angeles County Sanitation Districts (LACSD) have indicated that 1,4-Dioxane is present in influent to their water reclamation plant reclamation plants at a consistent value of about 1 µg/L." This is comparable to the average value measured in effluent (1.11 µg/L) by Simonich et al.[5]

Despite the similar concentrations of 1,4-dioxane reported by the LACSD in influent and by Simonich et al. in effluent, the concentrations of 1,4-Dioxane found in drinking water by the USEPA[6] in California are much higher than even the 99^{th} percentile predicted contribution from domestic down-the-drain sources (3.22-4.9 µg/L verses 0.16 µg/L, respectively), see Figure 1. Adamson et al.[7] summarized the trends from the USEPA unregulated contaminants monitoring survey (2013-2015) and identified the state of California having highest number of detections in public water systems (PWS) and the Los Angeles County area with some of the highest PWS concentrations nationally.

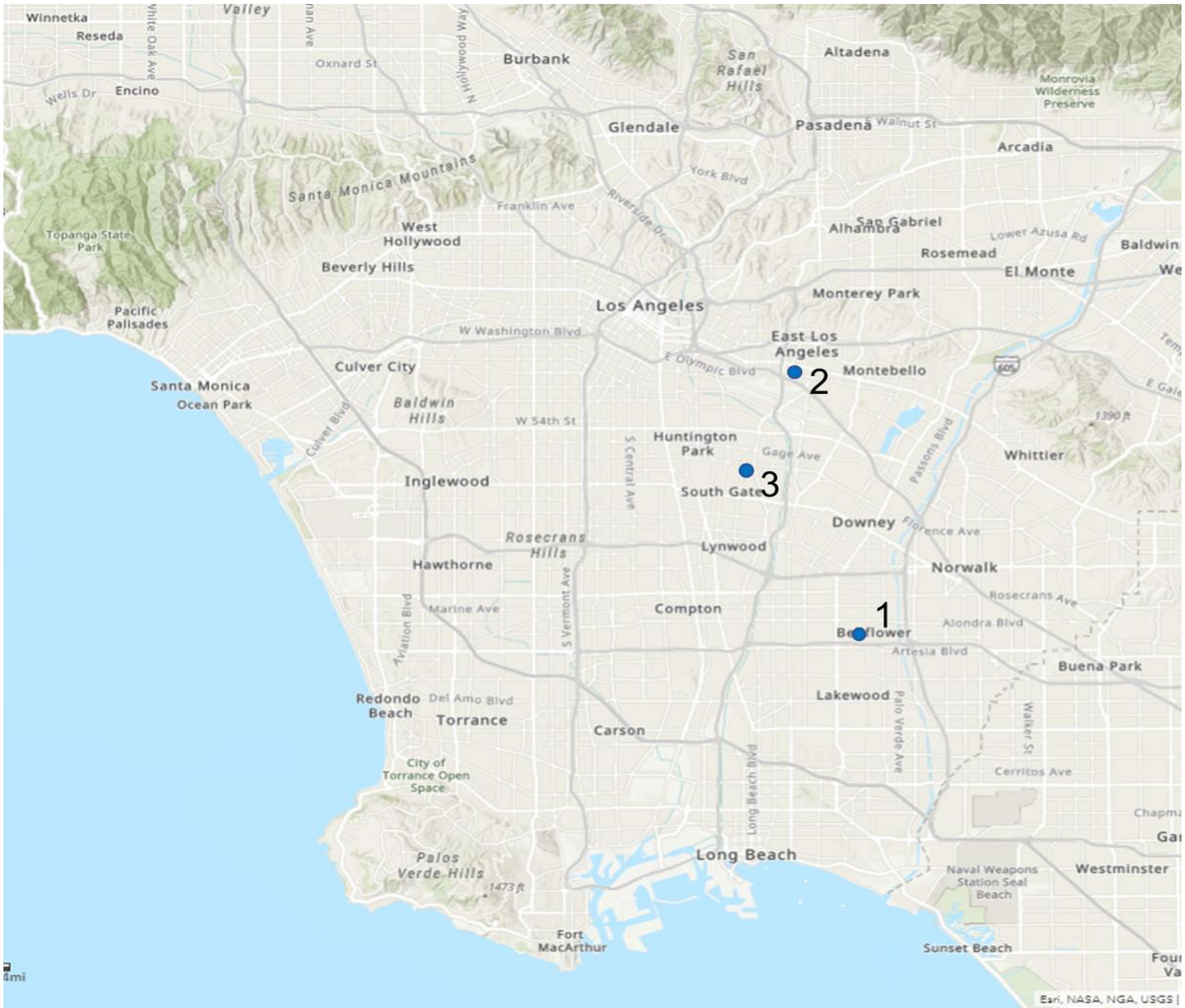

Figure 1. The locations of the three highest detected concentrations of 1,4-dioxane in public water systems (PWS) in California collected by the USEPA from 2011-2015[6]. The three sites correspond to the 1) Bellflower-Somerset MWC, 3.22 µg/L (mean) and 18 µg/L (maximum). 2) California Water Company-East Los Angeles, 3.89 µg/L (mean) and 9 µg/L (maximum). 3) Tract 180 Mutual Water Company, 4.9 µg/L (mean) and 8.9 µg/L (maximum). PWS summary data were compiled by the Environmental Working Group[8].

The USGS also has a significant database of 1,4-Dioxane monitoring data collected from wells throughout the United States[9]. Of the 1024 samples from California, 22 detects were recorded from 2006 – 2018, see Figure 2. The majority of these detections were from groundwater wells predominantly in the Los Angeles County area (Figure 2). The concentrations ranged from 0.33 – 17 µg/L, with a mean of 3.6 µg/L. These results demonstrate that 1,4-Dioxane is present in the groundwater and the locations of wells where 1,4-Dioxane is present are near some of the most contaminated PWS in the country according to the USEPA dataset[6].

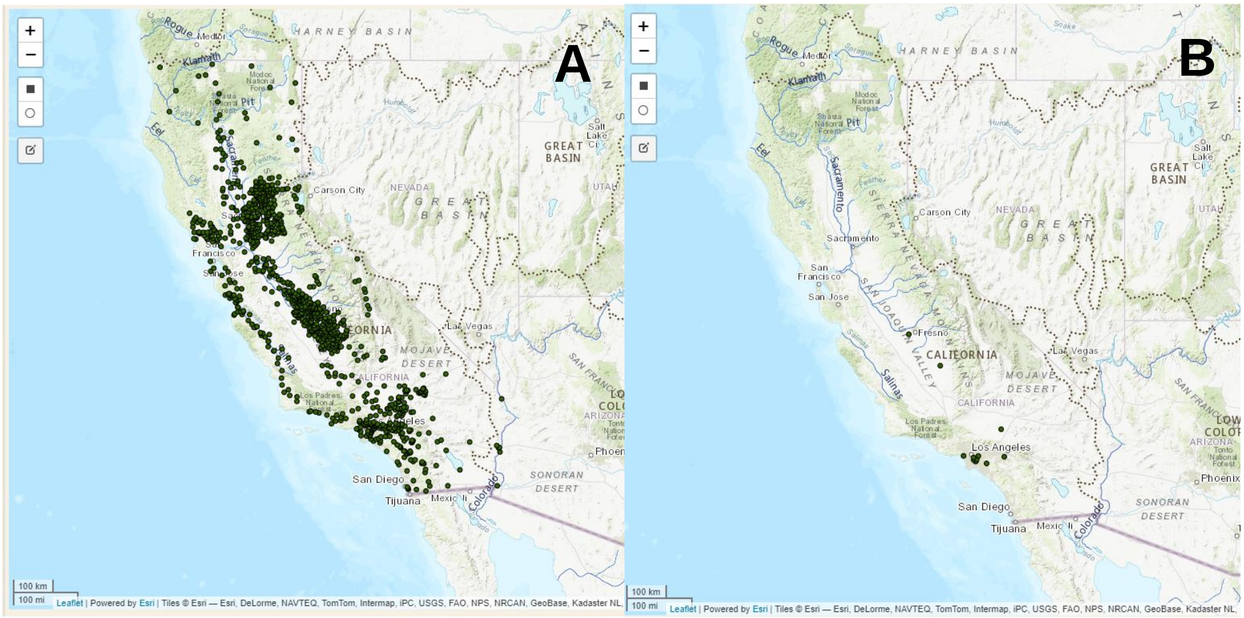

Figure 2. A) USGS monitoring sites where 1,4-dioxane was analyzed in California (n=945 sites). B) USGS monitoring sites where 1,4-dioxane was detected in California (n=12 sites). Each monitoring site is indicated by a green circle, 7 of these sites are located in Los Angeles County. 1024 total measurements were made across these sites, resulting in 22 detects (2% detection frequency). The mean concentration detected was 3.6 µg/L, ranging from of 0.33 to 17 µg/L. All data retrieved from the National Water Quality Monitoring Council Water Quality Database[9].

The 1,4-Dioxane present in the down-the-drain emissions released to surface water would not be expected to contaminate groundwater prior to reaching a drinking water intake. DTSC's background document states that the "…majority of 1,4-Dioxane in drinking water is due to historical contamination of groundwater" and this point is critical to understanding the high concentrations of 1,4-Dioxane found in drinking water in Los Angeles County. The production of chlorinated solvent products was prevalent in this region until these operations were discontinued in accordance with the 1996 Montreal Protocol banning these ozone-depleting substances. Due to their environmental contamination, several sites became Superfund National Priority List sites.

Groundwater monitoring data from the Superfund National Priority List shows that 1,4-Dioxane was detected at 31 sites nationwide[10]. Four of these sites are located in the Los Angeles Country area; see Figure 3. Groundwater concentrations at Site 2, the Omega Chemical Corporation Superfund National Priority List site were found at a maximum of 26000 µg/L, with the other three 1,4-Dioxane contaminated Superfund National Priority List sites in the Los Angeles Country ranging from 920 µg/L to 19000 µg/L. Further provided in Figure 3 is the delineation of the groundwater basin, Coastal Plain of Los Angeles, which demonstrates that three of these identified 1,4-Dioxane contaminated Superfund sites are within the same groundwater basin which covers a large portion of Los Angeles County. The average summer baseflow (e.g. groundwater contribution to streamflow) of Los Angeles River was 150 cubic feet per second at Firestone Blvd (April – September 2010)[11]. This provides a mechanism for the highly mobile in groundwater 1,4-Dioxane to enter surface water; therefore, drinking water abstracted from surface water or groundwater within the region could be contaminated by the Superfund sites.

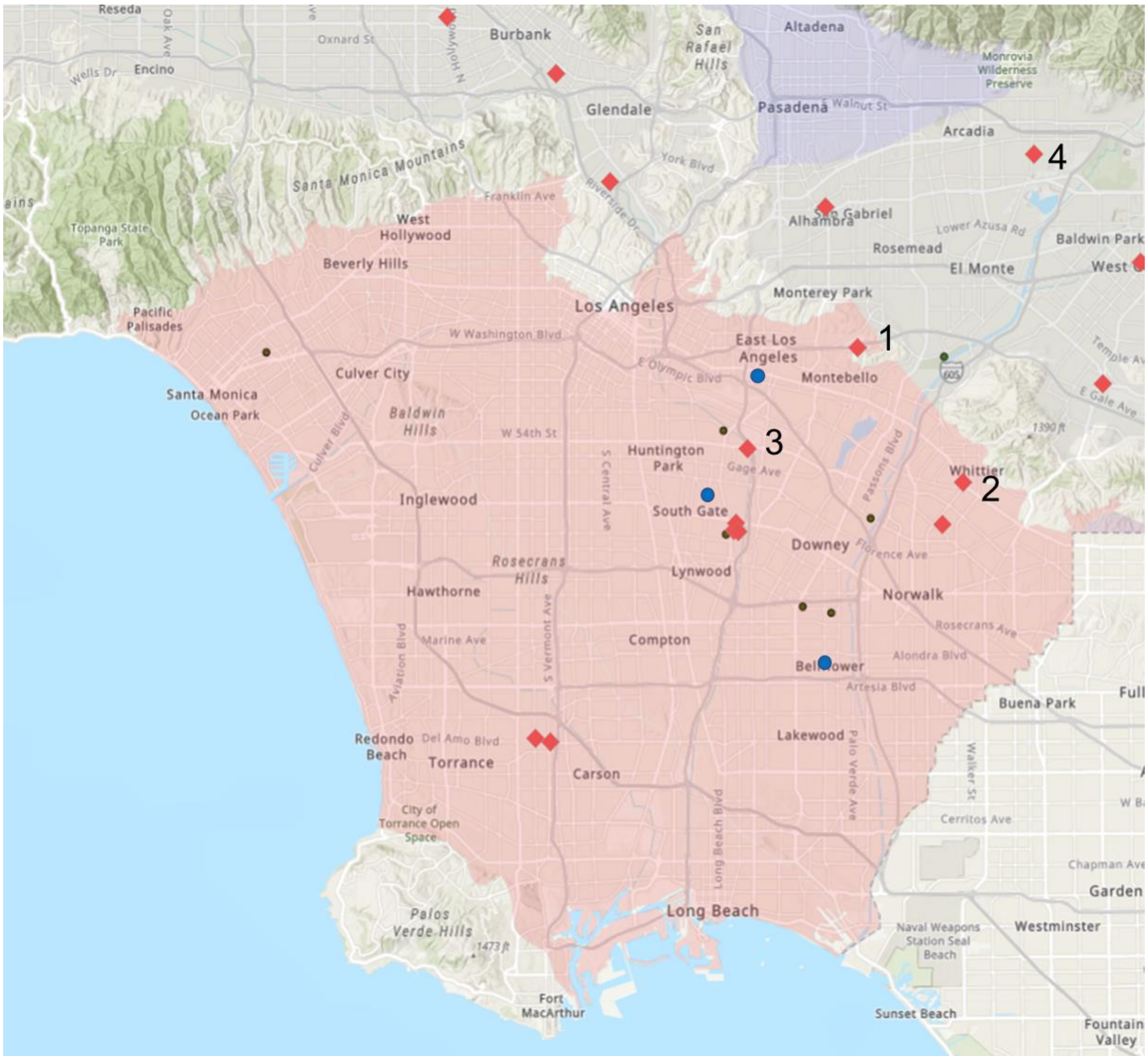

Figure 3. The location of Superfund National Priority List Sites in and near Los Angeles County, red diamonds. The Superfund sites where 1,4-dioxane were detected are numbered[10]. 1) Operating Industries Inc., 19000 µg/L (leachate); 2) Omega Chemical Corporation, 26000 µg/L (groundwater); 3) Pemaco Maywood, 920 µg/L (groundwater); 4) San Gabriel Area 1, 6500 µg/L (groundwater). Blue circles: PWS where regionally high concentrations of 1,4-dioxane were detected (e.g. Figure 1). Small green circles: USGS monitoring wells where 1,4-dioxane was detected (e.g. Figure 2). The boundary of the Coastal Plain of Los Angeles groundwater basin is shaded in red.

The monitoring data from Simonich et al.[5], which characterizes down-the-drain contributions of 1,4-Dioxane to WWTP effluent throughout the US (median value, 1.11 µg/L) is consistent with the influent value reported by the DTSC (1 µg/L) for the LACDS. Simonich et al. then modelled the 1,4-Dioxane contribution to drinking water resulting from these effluent concentrations and reported a median value of 0.0041 ug/L, with the 90th and 99th percentile of 0.03 and 0.16 µg/L, respectively. Even at the 99th percentile, which could be seen as the worst case for this scenario, the 1 µg/L reporting value is not exceeded in drinking water. It is imperative to account for surface water dilution in these calculations as demonstrated by the data and predictions reported by Simonich et al. Furthermore, there are concentrations above the 1 µg/L reporting limit detected in drinking water sources in Los Angeles County.

The above data demonstrate that Los Angeles Country is a national 1,4-Dioxane groundwater contamination hot spot due to contribution from adjacent superfund sites. This contaminated groundwater can enter the surface water as baseflow and thereby contribute to significant 1,4-Dioxane contamination of drinking water sources abstracted from both surface water and groundwater. For example, at the drinking water facility Bellflower-Somerset MWC (Figure 3), the mean 1,4-Dioxane value from 2011-2015 was 3.22 µg/L[8]. The probabilistic range of drinking water concentrations reported by Simonich et al.[5] were divided by the mean Bellflower-Somerset MWC value to derive the predicted contribution of 1,4-Dioxane from down-the-drain sources. At the median Simonich et al. value, 0.1% of the 1,4-Dioxane in drinking water would be from down-the-drain sources and this rises to 0.93% and 5% at the 90th and worst-case 99th percentile, respectively. Therefore, in terms of the 1,4-Dioxane concentrations detected in drinking water, down-the-drain sources are estimated to contribute only a small fraction, while the legacy contamination from Superfund National Priority List sites in the region could explain majority of the contamination.

In summary, ethoxylated personal care ingredients are safe, essential ingredients for a variety of personal care products and not easily replaced by alternatives. Although 1,4-Dioxane is produced as an unintended contaminant during manufacture of ethoxylated ingredients, historical FDA survey data show decreasing levels in finished cosmetic products over time. Indeed, current 1,4-Dioxane levels are generally well below the well-established safety threshold of 10 ppm in personal care products. Although personal care products contribute to 1,4-Dioxane levels in drinking water via down-the-drain exposure following consumer use, the contribution of these products is extremely low compared with legacy inputs from contaminated Superfund sites, even when a worse case exposure scenario is considered. With this in mind, we believe that protection of California's increasingly scarce drinking water supply from 1,4-dioxane contamination can only realistically be achieved by addressing the major proven sources of 1,4-Dioxane such as legacy groundwater contamination.

Thank you for the opportunity to provide these comments.

Sincerely,

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Senior Environmental Scientist

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