Supporting Materials for a Safe Use Determination for Styrene in Fiber Care Baths, Inc. Bathware Products Manufactured Utilizing 1st and 2nd Laminations Systems and LV-9800 Acrylated Gel-Coat

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Summary

This document presents an evaluation of a request from Fiber Care Baths, Inc. (Fiber Care) for a Safe Use Determination (SUD)[1] for styrene in Fiber Care bathware products, including tub showers, tubs, shower pans, shower stalls, walk-in baths, and handicapped access stalls, manufactured utilizing 1st and 2nd laminations systems and LV-9800 acrylated gel-coat. The evaluation is specific to the information provided to the Office of Environmental Health Hazard Assessment (OEHHA) and is not directly applicable to any other product or exposure scenario.

OEHHA utilized a screening-level approach to evaluate this request. In this approach, an upper-end estimate of the level of exposure to styrene was determined based on styrene emission factors, additional product information, indoor air quality models, and several assumptions. The emission factors utilized in this assessment were derived from chamber studies of samples of a type of bathware product identified by Fiber Care as containing typical concentrations of styrene monomer resulting from the application of materials with specified styrene monomer concentrations in a standardized manufacturing process utilizing 1st and 2nd laminations systems and LV-9800 acrylated gel-coat.

According to information provided in the SUD request, styrene is only present in Fiber Care bathware products in two lamination composite layers as well as in an acrylated gel-coat. The concentration of styrene monomer in the first lamination composite layer is 13.8% by weight. The concentration of styrene monomer in the second lamination composite layer is 12.2% by weight. The acrylated gel-coat contains 5% styrene monomer by weight. Emission factors determined from analyses of samples of finished products manufactured with all three styrene-containing materials were below the limit of detection (LOD) of 0.04 microgram per meter squared per hour ($\mu g/m^2$-hr) at all time points measured throughout a seven-day chamber study.

[1] Title 27, Cal. Code of Regulations, section 25204.

OEHHA used this information to generate an upper end estimate of exposure to styrene, assuming that the emission factors were constant over time at the LOD of 0.04 µg/m^2-hr, and compared this estimate to the level of exposure to styrene associated with a one in 100,000 excess cancer risk, which is the No Significant Risk Level (NSRL) of 27 micrograms (µg) per day.

Based on the screening-level analysis discussed in this document, and the NSRL of 27 µg/day, the estimated exposure to styrene from Fiber Care bathware products where styrene monomer content does not exceed 13.8% by weight in the first lamination composite layer, 12.2% by weight in the second lamination composite layer, and 5% by weight in the LV-9800 acrylated gel-coat, corresponds to a calculated excess cancer risk of less than one in 100,000 for occupants of homes and other buildings (e.g., hospitals, long-term care facilities) with Fiber Care bathware products installed. Thus, OEHHA determined that exposure of occupants to styrene from Fiber Care bathware products manufactured by the company's specified standardized process utilizing 1st and 2nd laminations systems and LV-9800 acrylated gel-coat, which results in bathware product styrene emission levels that do not exceed 0.04 µg/m^2-hr, is below the NSRL. A warning for styrene exposure from Fiber Care bathware products meeting these specifications is not required for occupants of homes and other buildings where these products are installed.

A number of factors may increase or decrease the estimated exposure level described above. The assumptions made in OEHHA's evaluation are likely to overestimate exposure levels from the average use of Fiber Care bathware products.

This SUD request was limited to exposures to styrene from Fiber Care bathware products manufactured by the specified standardized process utilizing 1st and 2nd laminations systems and LV-9800 acrylated gel-coat, without additional sources of styrene monomer in the products (see Section 1.1 below for a description of the products covered). Exposures to other listed substances, if any, that may result from the use of the specified Fiber Care bathware products were not reviewed by OEHHA in the context of this request.

1. Introduction

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of Proposition 65 [2]. On August 17, 2018, OEHHA announced that it had received a request from Fiber Care Baths, Inc. (Fiber Care) for a Safe Use Determination (SUD) for the use of styrene

[2] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq*, is commonly known as Proposition 65 and is hereafter referred to as Proposition 65.

in Fiber Care bathware products manufactured by a specified standardized process utilizing 1st and 2nd laminations systems and LV-9800 acrylated gel-coat, pursuant to Title 27 of the California Code of Regulations, section 25204[3].

Styrene is on the Proposition 65 list of chemicals known to the state to cause cancer. For chemicals that are listed as causing cancer, the "No Significant Risk Level (NSRL)" is defined as the level of exposure that would result in no more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. The NSRL for styrene is 27 micrograms per day (µg/day)[4].

A public comment period on this SUD request was held from August 17 to September 18, 2018. No public comments were received.

Based on information provided in the SUD request, OEHHA has identified the styrene exposures for analysis to be the exposures to occupants of homes and other buildings that have Fiber Care bathware products installed. Occupational exposures during installation of Fiber Care bathware products is expected to be minimal compared to exposures to occupants of homes and other buildings that have these products installed.

This document first provides a brief description of Fiber Care bathware products covered by the SUD request, including how they are manufactured, followed by a brief summary of the exposure analysis submitted by Fiber Care and OEHHA's analysis of styrene exposure to building occupants from installed Fiber Care bathware products.

1.1 Product Description and Use

The following is based on information provided in the SUD request and additional communications with Fiber Care.

Fiber Care manufactures shower enclosures (such as tub showers, tubs, shower pans, shower stalls, walk-in-baths, and handicapped access stalls) for new construction homes, apartment complexes, and institutions. These bathware products have a lifespan of 20-25 years. During the manufacturing process, the bathware products are initially surfaced with either continuous cast acrylic (no styrene present) or LV-9800 acrylated gel-coat, which is applied to a prepared product mold. The products within the scope of the SUD request are those surfaced with the LV-9800 acrylated gel-coat, which contains styrene. In 2016, approximately 80% of Fiber Care bathware products were surfaced with the LV-9800 acrylated gel-coat. For such products, following application of a layer of the LV-9800 acrylated gel-coat 0.015 to 0.025 inches thick,

[3] All further references are to sections of Title 27 of the Cal. Code of Regulations.
[4] Section 25705(b)(1).

each individual unit is cured (a process in which cross-linking of polymers occurs, resulting in hardened materials). After curing, the coated mold undergoes the first lamination step, involving the application of a layer 0.06 to 0.1 inches thick of filled fiberglass resin, which contains styrene. This layer is reinforced with corrugated cardboard, core mat, and wood and cured for about 10 minutes. The unit then undergoes the second lamination step, involving application of a second layer of styrene-containing filled fiberglass resin, followed by additional reinforcement. The composite laminate bathware product is allowed to cure for about 30 minutes, after which it is removed from the product mold and inventoried.

Fiber Care reported that styrene monomer is present in these bathware products only in the LV-9800 acrylated gel-coat (5% by weight) and the 1st and 2nd lamination layers (13.8% and 12.2% by weight, respectively) as determined by use of a standardized test method (ASTM D2369-10). All of these bathware products are manufactured using the same production line and the variation in composite layer thickness from unit to unit reported by Fiber Care is 1/16th of an inch (1/16") or less. Thus, the products are reasonably anticipated to contain styrene monomer in the acrylated gel-coat and lamination layers at the content levels specified above, according to the information provided by Fiber Care. The maximum surface area of the bathware products covered by this SUD request is 11.58 m^2 (124.66 ft^2; product ID: ET72-042-80 LR).

1.2 Exposure Analysis Provided by Fiber Care Baths, Inc.

In the analysis provided by Fiber Care, styrene exposure from the company's bathware products manufactured utilizing 1st and 2nd laminations systems and LV-9800 acrylated gel-coat was assessed for occupants of homes and other buildings where these products are installed. Inhalation was the sole exposure pathway included in the analysis.

Fiber Care submitted styrene emission data from chamber studies of samples taken from the back walls of two finished units of a typical bathware product (i.e., a tub/shower product) chosen to be representative of the products covered by the SUD request, and used these data to estimate styrene exposure from use of these products. Fiber Care indicated that the thickness of the styrene monomer-containing composite layer (i.e., the combined thickness of the LV-9800 acrylated gel-coat, and the 1st and 2nd lamination layers) of this particular product reflects an upper-bound application of these styrene monomer-containing materials across all manufactured products covered by the SUD request.

Styrene emissions were measured in controlled environmental chambers using 12" by 12" square samples cut from the back walls of two finished units of the selected tub/shower product. These product samples were evaluated under identical conditions

at 23°C, each for a study duration of seven days. Emission factors were determined for each sample at six time points over the course of the studies. All styrene emission factors were below the 0.04 μg/m^2-hr detection limit.

The exposure analysis provided by Fiber Care concluded that styrene exposure to building occupants from these installed bathware products is estimated to be no more than 0.01 μg/day. The analysis used a styrene emission factor of 0.04 μg/m^2-hr, based on the LOD from the chamber studies, together with a product emitting surface area of 7.43 m^2, which is lower than the maximum surface area of the bathware products covered by the request, i.e., 11.58 m^2. The analysis also used an air change rate of 0.45/hr, which is higher than the default value of 0.23/hr used by the California Department of Public Health (CDPH, 2017), and assumed an exposure duration of 30 years, rather than lifetime exposure (i.e., 70 years).

Table 1 lists the parameters used in the analysis provided by Fiber Care for estimating styrene exposure by inhalation, the sole relevant exposure pathway, to building occupants from these bathware products, and for deriving a lifetime average daily dose of 0.01 μg/day.

Table 1. Lifetime average daily inhalation dose (LADD) estimate from Fiber Care Baths, Inc.

Parameter	Value	Basis
Emission rate (**ER**, μg/m^2/hr)	0.04	Fiber Care, Table 1
Emitting surface area (**A**, m^2)	7.43	Fiber Care, Table 1
Room Volume (**V**, m^3)	17	Fiber Care, Table 1
Air change rate (**N**, /hr)	0.45	Fiber Care , Table 1
Indoor air concentration (**C**, μg/m^3)	0.04	= **ER** × (**A/V**) × (1/**N**)
Breathing rate (**Br**, m^3 /day)	20	Fiber Care, Table 2
Time spent in bathroom (hr/day)	0.5	Fiber Care , Table 2
Exposure frequency (**EF**, day/yr)	350	Fiber Care, Table 2
Exposure duration (**ED**, yr)	30	Fiber Care, Table 2
Styrene LADD (μg/day)	0.01	= (**C** × **Br** × (0.5/24) × **EF** × **ED**) / (70 × 365)

Note that this table combines information presented separately in the Fiber Care submission as air concentration calculation (Table 1) and LADD calculation (Table 2).

2. OEHHA Analysis of Styrene Exposure to Building Occupants from Fiber Care Baths, Inc. Bathware Products

OEHHA conducted a screening-level exposure analysis to derive an upper-end estimate of styrene exposure to building occupants from installed Fiber Care bathware products manufactured by the specified standardized process described in Section 1.1. OEHHA's upper-end estimate of styrene exposure to building occupants is 0.41 μg/day (Table 2).

Styrene exposure to professional installers of Fiber Care bathware products is assumed to be minimal given the limited duration of exposure and relatively low styrene emission factor from the product (at a rate below the LOD of 0.04 μg/m^2-hr when tested at 23°C in a seven-day chamber study).

The sole pathway of exposure included in OEHHA's analysis is the inhalation of styrene present in the indoor air. As a volatile organic compound (VOC), styrene exposure from routes other than inhalation (e.g., dermal, ingestion) resulting from the use of bathware products is considered to be negligible. In reaching this conclusion, OEHHA took into consideration findings from human dermal absorption studies available in the published literature. For example, Weschler and Nazaroff (2014) reported that dermal intake of styrene was only 1.9-5.2% of inhalation intake even when volunteers were exposed to relatively high air styrene concentrations (e.g., an average air concentration of 1369 milligrams per meter cubed [mg/m^3]).

The model used, assumptions made, and exposure parameter values applied by OEHHA in the screening level exposure analysis are discussed below.

In estimating upper-end lifetime daily inhalation exposure to styrene for building occupants from installed Fiber Care bathware products, OEHHA used a screening-level approach and applied the CDPH- indoor air quality (IAQ) model for VOCs from indoor sources, using chamber study measurements (CDPH, 2017), to a conservative exposure scenario. The identified exposure scenario is a small studio apartment in which styrene volatilizes from a bathware product into indoor air over time. Although the rate of styrene emission from the bathware product is expected to decrease over time, OEHHA's estimate of upper-end exposures using the CDPH IAQ model assumes continuous emission of styrene at a constant rate over time.

Table 2 summarizes the exposure parameters OEHHA used to estimate styrene exposures by the inhalation route and the results of OEHHA's exposure assessment. Age-adjusted exposure parameters were calculated based on age-specific values specified in Section 25721(d)(2)(A) (inhalation rate) and the US Environmental Protection Agency (US EPA) Exposure Factors Handbook (2011) (time spent indoors).

Table 2. Parameters used in and results of the OEHHA analysis of styrene exposures to building occupants with Fiber Care. bathware products[1] installed

Parameter	Unit	Value	Basis
A. Emission factor	μg/m^2-hr	0.04	Provided by Fiber Care
B. Maximum surface area of bathware product	m^2	11.58	Provided by Fiber Care
C. Number of bathware products installed in the indoor space	Unitless	1	Assumed
D. Volume of the indoor space	m^3	78	Assumed, based on the size (= 325 ft^2) of a micro apartment in San Francisco, CA (Gabbe, 2015)
E. Air change rate	/hr	0.23	CDPH (2017)
F. Percentage time spent indoors	Unitless	82.4%	Age-weighted value calculated based on US EPA (2011; Table 16-1)
G. Hours spent indoors	hr/day	19.78	= 24 × F
H. Steady-state styrene indoor concentration	μg/m^3	0.026	= (A × B) / (D × E)
I. Breathing rate	m^3/day	19	Age-weighted value calculated based on Section 25721(d)(2)(A)
J. Styrene inhalation dose	μg/day	0.41	= (G × H × I) / 24

[1] Manufactured by the specified standardized process described in Section 1.1, utilizing 1st and 2nd laminations systems and LV-9800 acrylated gel-coat.

The inhalation dose for building occupants with Fiber Care bathware products installed is estimated to be 0.41 μg/day (Line J, Table 2), based on the assumptions listed below:

1. OEHHA assumed that one bathware product with a surface area of 11.58 m^2 is installed in a small studio apartment. In this "single large bathware product in a small studio apartment" scenario, the ratio of surface area emissions from the bathware product to the indoor air volume is maximized, and results in a maximum indoor styrene concentration from among the range of possible scenarios that are within the scope of the SUD request (e.g., three bathware products installed in a larger house).
2. The air change rate, 0.23/hr, in this scenario is assumed to be the default value for a new California single-family home based on ventilation flow rate requirements (CDPH, 2017). This rate is close to the median of air change rate of 0.26/hr

measured from 108 randomly selected new single houses without mechanical ventilation (CDPH, 2017).

3. Time activity data were obtained from US EPA (2011; Table 16-1) for total time spent indoors. An age-weighted average of time spent indoors of 82.4% (Line F, Table 2) is used for the inhalation dose calculation.
4. Steady-state styrene indoor concentration was estimated by applying the CDPH screening model for VOCs (CDPH, 2017) to the small studio apartment scenario to derive an upper-bound estimate of styrene air concentration, assuming the studio is well-mixed and the indoor styrene concentration is the same across the entire studio apartment. In addition, the styrene emission factor from the bathware product was assumed to be constant, and equal to the detection limit of 0.04 $\mu g/m^2$-hr. This latter assumption is conservative since emissions of VOCs such as styrene from bathware products are expected to decrease over time.
5. The age-weighted breathing rate is calculated based on the age-specific values in Section 25721(d)(2)(A) as 19 m^3/day (Line I, Table 2).
6. The modelled daily inhalation dose is assumed to be the same as the lifetime average daily exposure over 70 years for occupants of buildings with Fiber Care products installed.

The lifetime average daily exposure to styrene via inhalation for building occupants was estimated to be 0.41 µg/day (Line J, Table 2). This calculated upper-end lifetime exposure estimate for occupants is 1.5% of the NSRL for styrene of 27 µg/day. Therefore, occupant exposure to styrene from these specific Fiber Care bathware products falls below the level posing significant cancer risk.

2.1 Uncertainties Associated with the Building Occupants Exposure Estimate

There are many uncertainties associated with the indoor air quality (IAQ) models and parameters used in the exposure assessment for building occupants. The IAQ model OEHHA uses is intended for quick evaluation of building materials (CDPH, 2017). To predict indoor concentrations, the VOC emission factors derived from chamber measurements are applied to a steady-state mass-balance model with several simplifying assumptions, including an assumption of steady state conditions with respect to emission rates and building ventilation, zero outdoor concentrations, perfect mixing within the building, and no net losses of VOC from air due to other effects such as irreversible or net sorption on surfaces (i.e., net sink effects) and chemical reactions. Not all of these assumptions hold true in real life conditions. However, as discussed below, the simplifying assumptions utilized in this assessment more likely overestimate exposure.

Several uncertainties are associated with the emission factors used to estimate the inhalation exposure. The emission factors were determined from seven-day chamber studies, which may overestimate the true exposure for occupants as VOC emissions tend to decline over time. As there is no scientific consensus (Won et al., 2008) on how to extrapolate short-term emission factors (such as seven-day or 14-day) to long-term exposure (20 or 70 years), we estimate the lifetime average daily inhalation exposure based on the empirical emission factors measured up to seven days in the chamber. The use of the LOD in the absence of detected levels of styrene emissions in the chamber is itself a conservative assumption; the use of a constant styrene emission factor over 70 years is a very conservative assumption. However, higher emission rates likely occur intermittently when the bathware product is subjected to a higher temperature, such as when the bathware product (e.g., bathtub) is filled with hot water. Use of an emission factor tested at 23°C to estimate lifetime average daily inhalation exposure may underestimate short-term exposure from styrene emission at a higher temperature. Overall, uncertainties associated with use of the emission factor detection limit at 23°C from a seven-day chamber study are expected to result in an overestimate of occupant exposure over the 70-year lifetime.

In addition, the use of the default air change rate (0.23/hr) for a single-family home likely results in an overestimate of the indoor air concentration of styrene. Further, air change rates for bathrooms with an exhaust fan, whether run continuously or intermittently, are usually higher than those for a residence as a whole (CARB, 2009). Using the default of 0.23/hr for the air change rate in this assessment may result in an overestimate of the indoor air concentration of styrene.

Conclusions

This screening-level analysis, which relied on relatively conservative assumptions, only applies to the exposure scenario discussed in this document. OEHHA is not drawing conclusions for other exposure scenarios or other products.

Based on this screening level exposure analysis for occupants of homes or other buildings with Fiber Care Baths, Inc. bathware products installed, where the styrene monomer content in the product does not exceed 13.8% by weight in the first lamination composite layer, 12.2% by weight in the 2nd lamination composite layer, and 5% by weight in the LV-9800 acrylated gel-coat, and there are no additional sources of styrene monomer in the product, an upper-end estimate of styrene exposure is 0.41 µg/day, which is 1.5% of the NSRL for styrene. The estimated exposure to styrene for building occupants with these bathware products installed corresponds to an excess cancer risk of less than one in 100,000.

Therefore, styrene exposures to occupants from the specified Fiber Care bathware products fall below the level posing significant risk. This determination is specific to Fiber Care bathware products manufactured utilizing 1st and 2nd laminations systems (with respective concentrations of styrene monomer of 13.8% and 12.2% by weight) and application of the LV-9800 acrylated gel-coat (with 5% styrene monomer by weight), without additional sources of styrene monomer in the products.

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