



FRAGRANCE CREATORS
ASSOCIATION®

July 14, 2023

VIA WEBSITE: <https://hwtr.ecology.commentinput.com/?id=aUG8fNS4B>

Safer Products for Washington
Hazardous Waste and Toxics Reduction Program
WA Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

Re: Comments of Fragrance Creators Association on the *Draft Identification of Priority Chemicals Report to the Legislature: Safer Products for Washington Cycle 2, Implementation Phase 1 (Publication number 23-04-038)*, dated June 2023

Fragrance Creators Association (“Fragrance Creators”) appreciates this opportunity to comment on the Washington State Department of Ecology’s (“Department’s”) Draft Identification of Priority Chemicals Report to the Legislature: Safer Products for Washington Cycle 2, Implementation Phase 1, dated June 2023 (“Draft”).

Fragrance Creators is the principal trade association representing the U.S. fragrance industry.¹ The organization’s member companies create and manufacture fragrances and scents for home care, personal care, fine fragrance, and industrial and institutional products. Fragrance Creators also represents companies that market finished products containing fragrance, as well as those that supply fragrance ingredients, including natural extracts and other raw materials, that are used in perfumery and fragrance mixtures. Fragrance Creators’ members also support the Research Institute for Fragrance Materials (“RIFM”), a nonprofit, scientific organization that supports the global fragrance industry in the safe use of fragrance materials, conducts comprehensive scientific programs covering all relevant human health and environmental endpoints, maintains the world’s largest and most complete database on fragrance materials, and offers education and guidance on scientific and safety issues that are relevant to the fragrance industry.²

The fragrance industry is proud of our history of safety and has invested in RIFM since the 1960s. The Department’s Draft includes a variety of chemicals and chemical classes proposed to be prioritized under Cycle 2 of the Safer Products for Washington Program (“Program”). Fragrance Creators provides initial feedback on the Department’s Draft below and looks forward to the opportunity to continue to engage with the Department as its regulatory process proceeds.

¹ More information on Fragrance Creators can be found at <https://www.fragrancecreators.org/>.

² More information on RIFM can be found at <https://www.rifm.org/>.

COMMENTS

In its Draft, the Department includes two fragrance materials among the classes on chemicals proposed to be identified as priority chemical classes. These substances, outlined below, have been thoroughly reviewed by the fragrance industry and are safe as currently used by our members. Below, Fragrance Creators presents data on the safety of these two ingredients as currently used in fragrance. Should the Department move forward with including these two ingredients within the broader classes, Fragrance Creators urges that they not be regulated in future rounds for their use in fragrance. We ask the Department to take the below data into account as it finalizes its Draft and continues to implement its regulatory program.

Exposure Data via Fragrance Use

Exposure must be included in risk assessment when such data are available. Fragrance Creators has provided estimated exposure values for the two outlined substances below (Table 1). These data reflect the use of these substances in fragrance and were estimated by RIFM through fragrance material surveys. A survey of concentrations of fragrance mixtures used in final products are conducted by RIFM approximately every six years. Consumer product companies provide usage data to these surveys. Estimations are calculated using the Creme RIFM Aggregate Exposure Model V3.1.

Table 1. Exposure values for two fragrance materials among the classes on chemicals proposed to be identified as priority chemical classes

Material CAS #	Total Chronic Systemic Exposure (mg/kg/day)	Chronic Inhalation Exposure (mg/kg/day)
90-17-5	0.0060	0.0011
1330-20-7	0.0000011	0.0000001

For the systemic endpoints, risk is evaluated by calculating the ratio of the lowest available no-observed-adverse-effect-level (NOAEL) to the observed exposure; this ratio is called the margin of exposure (MOE) and must be greater than 100 to be considered safe.

In the absence of target or read-across data on a material, RIFM utilizes an exposure-based waiving approach to support the material's safe use for the repeated dose toxicity, reproductive toxicity, and respiratory toxicity endpoints. This involves a comparison of the material's total chronic systemic exposure value (repeated dose toxicity, reproductive toxicity) or chronic inhalation exposure value (respiratory toxicity) to the Threshold of Toxicological Concern (TTC). The TTC is a level of exposure for all chemicals, below which there is no appreciable risk to human health ([Kroes, 2007](#)). Even when target or read-across data are available for a material, RIFM uses the exposure-based waiving approach as further weight of evidence.

A similar approach was developed for the skin sensitization endpoint, whereby exposures calculated from concentrations in each product category are compared to the Dermal Sensitization Threshold (DST), a level of exposure below which there is no appreciable risk of sensitization ([Safford, 2008](#)).

I. Brominated and/or Chlorinated Substances Class: Trichloromethyl phenyl carbinyl acetate (CAS # 90-17-5)

Although it was not specifically mentioned in the Draft, Fragrance Creators believes that trichloromethyl phenyl carbinyl acetate (CAS # 90-17-5) could also meet the broad definition of Brominated and/or Chlorinated Substances outlined in the Draft. However, this substance does not present the human health and environmental concerns seen in this broader category, and thus it should not be grouped into this class of chemicals under the legislation.

Trichloromethyl phenyl carbinyl acetate has not received GHS classification for human health under any hazard class/category ([ECHA](#)). Trichloromethyl phenyl carbinyl acetate has received a GHS classification for environmental under the Aquatic Chronic 3 category (H412: harmful to aquatic life with long lasting effects), but not under any other hazard class/category ([ECHA](#)). This substance was determined to not be persistent, bioaccumulative, or toxic (**not PBT**; [ECHA](#)).

A summary of the toxicity profile for trichloromethyl phenyl carbinyl acetate is available below (Table 2). The available data on trichloromethyl phenyl carbinyl acetate do not suggest any safety concerns for genotoxicity or skin sensitization. Although some adverse effects were observed in repeated dose toxicity and developmental toxicity studies, these effects occurred at very high doses much greater than those of realistic exposure scenarios, as shown by the RIFM industry-wide usage survey data. Exposure-based waiving supports the safe use of trichloromethyl phenyl carbinyl acetate for the respiratory toxicity endpoint. Environmentally, data suggest no concern for fishes or algae, but some adverse effects on aquatic invertebrates (long-term only); however, because this material is highly biodegradable in water, long-term exposures should not occur in realistic scenarios. Additional study details and calculations can be made available if needed.

Table 2. Toxicity studies on Trichloromethyl phenyl carbinyl acetate (CAS # 90-17-5)

Toxicological endpoint	Conclusions	Reference
Genotoxicity	Not mutagenic or clastogenic	Wellington, 2000; Gudi, 2000. Report to RIFM Database.
Repeated dose	NOAEL = 30 mg/kg/day, MOE = 5000	Dunster, 2008. Report to RIFM Database.
Developmental	NOAEL = 500 mg/kg/day, MOE = 83333	ECHA, 2021
Respiratory	Below TTC level	N/A

Skin sensitization	Non-sensitizer	Buehler, 1993; Quest, 1980; Kligman, 1971. Report to RIFM Database.
Environmental fate	76% degradation after 28 days	ECHA, 2018
Environmental toxicity	Fishes: no concern (short-term and long-term) Invertebrates: no concern (short-term), concern (long-term) Algae: no concern	ECHA, 2021 ; ECHA, 2022 ; ECHA, 2021 ; ECHA, 2019 ; ECHA, 2021

Conclusion: Overall, review of the available toxicity data on trichloromethyl phenyl carbonyl acetate shows **no reason for concern at current use levels in fragrance.**

II. Benzene, Ethyl Benzene, Toluene and Xylene Substances Class: Xylene (mixed) (CAS # 1330-20-7)

Xylene has received GHS classification for human health under the Acute Toxicity 4 category (H312: harmful in contact with skin; H332: harmful if inhaled) and Skin Irritation 2 category (H315: causes skin irritation), but not under any other hazard class/category on the basis of “data conclusive but not sufficient for classification” ([ECHA](#)). Xylene has not received GHS classification for environmental under any hazard class/category on the basis of “data conclusive but not sufficient for classification” ([ECHA](#)). This substance was determined to not be persistent, bioaccumulative, or toxic (**not PBT**; [ECHA](#)).

A summary of the toxicity profile for xylene is available below (Table 3). A [RIFM safety assessment for Xylene](#) has been published. The available data on Xylene do not suggest any safety concerns for genotoxicity. Xylene has been conservatively classified as a skin sensitizer based on mixed evidence, but application of the Dermal Sensitizer Threshold (DST) approach demonstrates that Xylene is currently used at safe levels in which no sensitization is expected. No adverse effects were observed up to very high doses in studies assessing repeated dose toxicity and fertility. Although some adverse effects were observed in a developmental toxicity study, these effects occurred at doses greater than those of realistic exposure scenarios, as shown by the RIFM industry-wide usage survey data. Exposure-based waiving further supports the safe use of Xylene for the systemic endpoints as well as the respiratory toxicity endpoint. Environmentally, data suggest no concern for fishes, invertebrates, or algae, particularly because this material is readily biodegradable in water. Additional study details and calculations can be made available if needed.

Table 3. Toxicity studies on Xylene (CAS # 1330-20-7)

Toxicological endpoint	Conclusions	Reference
Genotoxicity	Not mutagenic or clastogenic	ECHA, 1983 ; ECHA, 1978 ; ECHA, 1990
Repeated dose	NOAEL = 500 mg/kg/day, MOE = 454545455, Below TTC level	NTP, 1987. Report to RIFM Database.
Developmental	NOAEL = 0.3 mg/kg/day, MOE = 272727, Below TTC level	Mirkova, 1983. Report to RIFM Database.
Fertility	NOAEL = 563 mg/kg/day, MOE = 511818182, Below TTC level	ECHA, 1983
Respiratory	Below TTC level	N/A
Skin Sensitization	Sensitizer; clears reactive DST	Urbisch, 2015; Piroird, 2015; Hoffmann, 2018; Basketter, 2012; Basketter, 2003; Jung, 2012; Kligman, 1996. Report to RIFM Database.
Environmental fate	Degradation after 5 days: 60% Degradation after 28 days: 98% (m-xylene), 94% (p-xylene), 90% (o-xylene)	ECHA, 2015
Environmental toxicity	Fish: no concern (short-term or long-term) Invertebrates: no concern (short-term or long-term) Algae: no concern	ECHA, 1988 ; ECHA, 2017 ; ECHA, 1988 ; ECHA, 1998 ; ECHA, 2005 ; ECHA, 1988 ; ECHA, 2015 ;

Conclusion: Overall, review of the available toxicity data on Xylene shows **no reason for concern at current use levels in fragrance.**

* * *

Thank you for your consideration. A wide array of data are available and can be provided if further support is needed. Please do not hesitate to contact Fragrance Creators should you have any questions or if there is any additional information we can provide to assist with the finalization of the Draft. We look forward to the opportunity to continue to engage with the Department as it develops and implements Cycle 2 of the Program.

Sincerely,



Dan Selechnik, Ph.D.

Director, Regulatory Science

Fragrance Creators Association

DRAFT