Background Document on Phthalates, Styrene, and Formaldehyde in Children's Products

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SAFER CONSUMER PRODUCTS
CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Department of Toxic Substances Control

CalEPA
California Environmental Protection Agency

OVERVIEW

The Safer Consumer Products (SCP) Regulations define the process and criteria we use to evaluate consumer products for possible designation as Priority Products. A Priority Product is a consumer product that (1) contains one or more Candidate Chemicals that have the potential to harm people or the environment, and (2) has been formally listed in the California Code of Regulations through rulemaking. As part of the process of evaluating consumer products, we issue a Priority Product Work Plan (Work Plan) every three years, which identifies the product categories the SCP Program may evaluate over that period. In addition to the factors outlined in the SCP Regulations, we evaluate the product categories based on the Work Plan's stated policy goals.

This document summarizes our preliminary findings on phthalates, styrene, and formaldehyde in children's products, which falls under DTSC's current Work Plan product category of children's products. Additionally, we evaluated these product-chemical combinations based on the Work Plan priorities of:

- Protecting the health of children and workers from potential exposures to Candidate Chemicals in consumer products.
- Reducing potential releases of Candidate Chemicals from consumer products to indoor air and dust.

The release of this document is part of our external engagement process, which helps us decide whether to conduct additional research or potentially list one or more products containing Candidate Chemicals as Priority Products. Further, this document identifies additional information needed to fill data gaps.

Based on our evaluation, we are concerned about the potential for adverse impacts from exposure to phthalates, styrene, and formaldehyde in a variety of children's products frequently used by sensitive subpopulations, particularly young children.

INTRODUCTION

DTSC conducted a high-level review of chemicals in children's products to determine which Candidate Chemicals to prioritize for additional research. We selected phthalates, styrene, and formaldehyde based on their prevalence in children's products, the availability of existing research, and the severity of their hazard traits. Other Candidate Chemicals considered during the high-level review are listed in Appendix 1.

For this screening research phase, we cast a wide net for any relevant research related to phthalates, styrene, and formaldehyde in any consumer product intended for use by children (generally under age 12). This included, but was not limited to these types of products:

- toys and games,
- cosmetics and personal care products,
- jewelry,
- clothing and footwear,
- any product designed or intended to help a child with sucking or teething, to facilitate sleep, relaxation, or feeding,
- food contact articles, and
- child safety seats and equipment.

DTSC is particularly concerned about children's exposures to chemicals in consumer products. Children come into direct contact with products, have exposure-prone behaviors, and their bodies are still developing. Young children spend more time on floors and indoors, where contaminants settle, and they exhibit frequent hand-to-mouth behavior [1, 2]. While some children's products are intended for mouthing, young children, especially under age three, may put any product in their mouths [3]. Children's small body size and underdeveloped organs and detoxification pathways heighten their susceptibility [4]. Early life chemical exposures during critical windows of development may lead to lifelong health and economic impacts [5]. In other words, children are not little adults.

DTSC is requesting additional information from interested parties about the presence of and potential adverse impacts from phthalates, styrene, or formaldehyde (and other Candidate Chemicals) in children's products. We are also requesting information about the feasibility of removing these chemicals from children's products. Please see the **Questions to Interested Parties** section below for our specific questions.

PRELIMINARY SCREENING RESULTS

This document provides an overview of our preliminary screening research results on phthalates, styrene, and formaldehyde in children's products. Phthalates exhibit hazard traits of endocrine toxicity, developmental toxicity, and reproductive toxicity. Styrene is a volatile organic compound (VOC) that exhibits neurotoxicity and carcinogenicity. Formaldehyde – also a VOC – exhibits respiratory toxicity and carcinogenicity.

The High Priority Chemicals Data System (HPCDS), a database of information manufacturers are required to report to the states of Oregon and Washington, was a key data source on the presence of chemicals in children's products [6]. Overall, our research found compelling evidence that there is

potential for exposure to phthalates, styrene, and formaldehyde from children's products and that there is potential for these exposures to cause or contribute to adverse impacts.

Phthalates

Phthalates are a chemical class defined by their chemical structure – a benzene ring with two ester functional groups [7]. Sub-classes of phthalates include ortho-phthalates, isophthalates, and terephthalates [8]. Ortho-phthalates are by far the most used, researched, and regulated [8], but the use of other types of phthalates is increasing [9].

SCP's Candidate Chemicals List contains numerous phthalates:

- The entire class of ortho-phthalates, as defined by the California Environmental Contaminant Biomonitoring Program [10, 11].
- Several individual ortho-phthalates that are present on authoritative lists, such as those managed by the European Chemical Agency (ECHA), the National Toxicology Program (NTP), the California Office of Environmental Health Hazard Assessment (OEHHA) [10].
- One terephthalate and two halogenated phthalate esters.

Phthalates are used in hundreds of children's products, most commonly as a plasticizer to produce polyvinyl chloride (PVC) and in the production of other plastics [12]. They are also used as solvents and fragrance carriers in children's cosmetics and personal care products [13, 14]. U.S. EPA's High Production Volume List indicates that at least 26 phthalates are used commercially in the United States [15]. When used as plasticizers, phthalates are not bound to the polymers and can migrate out of products in all stages of the product life cycle, which can result in exposure by multiple routes, including dermal, ingestion, and inhalation [16–19]. Biomonitoring of phthalate metabolites has demonstrated widespread exposure to phthalates in the U.S. population [20–22]. Children are highly exposed through direct contact, mouthing, and environmental exposures [4, 20].

Research has shown phthalates to be endocrine disruptors with the potential for adverse effects on reproduction and development in animals and humans [34, 35]. Toxicity research has generally focused on a relatively small number of ortho-phthalates [8]. However, evidence indicates that nearly all chemicals in this sub-class may share the same hazard traits [36]**,** and the same may be true of the larger phthalate class [8]. For example, almost all of the phthalates on our Candidate Chemicals List are listed by one or more authoritative sources as a reproductive toxicant [10]. While toxicity data for iso- and terephthalates is scarce, we believe their structural and functional similarities with ortho-phthalates warrant further investigation.

State and federal regulations restrict the use of eight specific ortho-phthalates in products intended for children under age 12 and restrict two additional ortho-phthalates in products intended for children

under age three [37, 38]. In all cases, products covered under these regulations are limited to toys and products intended to facilitate sleeping, relaxation, feeding, sucking, or teething [37, 38].

Styrene

Styrene is a chemical building block used to make polymers. Common styrene-based polymers used in children's products include polystyrene, particularly expanded polystyrene (EPS) foam used in items like bike helmets and safety seats [39], and acrylonitrile-butadiene styrene (ABS) used to make plastic building bricks [40]. Styrene is most frequently reported in polymeric components of toys and clothing [41].

Styrene is a VOC that is a neurotoxicant [42, 43] and a probable human carcinogen [44, 45]. Inhalation is the key pathway for exposure to styrene, though exposure to styrene can also occur orally through mouthing of objects and diet [46]. There is widespread exposure of styrene among the general population from various sources, including tobacco smoke, diet, and consumer products [46–48]. Styrene concentrations in young infants' blood have been found to be nearly double those of young adults [49].

While ABS is often touted as a safe plastic in toys, significant levels of residual styrene have been detected in toys made of ABS [48, 50]. Styrene has been detected at low levels in the air at child care facilities, suggesting potential consumer product sources [51, 52]. Most of the literature on health risks from residual styrene focuses on polystyrene food packaging and migration into food products [53]. More research is needed to better understand potential exposures to styrene from children's products made of styrene co-polymers.

While the effects of chronic, low-level styrene exposure on children's health are not well-studied, styrene is neurotoxic and carcinogenic at higher levels observed in occupational settings [42, 43]. Children's unique characteristics, as discussed above, make them particularly susceptible to potential adverse impacts from styrene in children's products [1].

In California, styrene will be banned from cosmetics beginning in 2027 [54]. Nearly all other styrene-related state regulations have focused on banning the use of polystyrene, aka Styrofoam™, in food packaging and single use plastics [55]. A handful of municipalities have also passed ordinances banning the sale of other types of products containing polystyrene, such as coolers and water toys [55]. However, there are no state or federal regulations specifically related to styrene or styrene polymers in children's products.

Formaldehyde

Formaldehyde is a well-known carcinogen [56, 57] and respiratory toxicant [42, 58]. Formaldehyde is a common precursor for compounds and materials used in children's products, such as resins, adhesives,

plastics, and solvents [59]. Children's products made from these materials may contain residual formaldehyde as a contaminant [59]. Due to its high toxicity, manufacturers rarely intend for formaldehyde to remain in the final product.

A single product can contain formaldehyde in multiple components [60]. Reports to HPCDS most commonly identify formaldehyde as a contaminant in polymers, textiles, surface coatings, and inks/dyes/pigments used in toys, clothing/footwear, and arts and crafts [60]. In products where formaldehyde serves no function (i.e., contaminant), the most common reported concentrations range from 100 to 500 ppm. However, a significant percentage of HPCDS reports of formaldehyde as a contaminant (12% or 90 reports) include components containing from 1,000 to over 10,000 ppm formaldehyde [60]. It remains unclear to what extent children's products contain residual formaldehyde during the use phase or whether their concentrations reported to HPCDS indicate intentional use or contamination.

Inhalation is the key route of exposure to formaldehyde from children's products, as it can off-gas from products during and after use due to its high volatility. While research on children's exposures to formaldehyde in children's products is generally lacking, available studies show that some children's products contain and emit formaldehyde. Some of these products include clothes [61], bedding [62], and wooden toys [63]. Indoor air quality assessments show frequent detections of formaldehyde in postnatal care centers, child care facilities, and elementary schools [64–68]. An assessment of 25 child care facilities in California found that about 88% had formaldehyde levels in indoor air that exceeded California's accepted exposure levels for eight hours per day as well as for extended, chronic exposure (OEHHA 8-hour and Chronic Reference Exposure Levels (RELs)) [65].

State and federal regulations provide protection against intentionally added formaldehyde in cosmetics and in wood composite products, including children's cosmetics and composite wood furniture and toys. In March 2024, U.S. EPA published its draft risk evaluation for formaldehyde under the Toxic Substances Control Act (TSCA) and identified conditions of use relevant to children's products that contribute to unreasonable risk. Specifically, U.S. EPA found that people who frequently use certain consumer products, including crafting supplies and textiles treated with formaldehyde, are at risk [69].

NEXT STEPS

DTSC is asking interested parties to address the questions listed below. Written comments can be submitted via our online information management system, CalSAFER. The comment period will close on December 2, 2024, at 11:59 p.m. Pacific Standard Time. In addition, DTSC will hold a virtual public workshop on November 20, 2024. Further details about this workshop will be available on our Workshops and Events webpage. This external engagement process will help inform additional research that may result in the proposal of one or more Priority Products.

This workshop and public comment period will focus on phthalates, styrene, and formaldehyde in children's products, with the goal of soliciting information on data gaps, availability and feasibility of alternatives, and methods to reduce contamination.

QUESTIONS TO INTERESTED PARTIES

Product Categories and Candidate Chemicals

- What product sub-categories should we prioritize when considering Candidate Chemicals in children's products?
- Which studies, if any, on cumulative and aggregate exposures to phthalates, styrene, and formaldehyde (or other Candidate Chemicals – see Appendix 1) in children's products should we be aware of?

Phthalates

- In the screening phase, we researched phthalates as a broad class, including ortho-phthalates and iso- and terephthalates.
    - Which isophthalates and terephthalates are used in children's products as alternatives to ortho-phthalates?
    - What evidence of shared hazard traits among classes of phthalates should we consider (i.e., among ortho-phthalates or among all phthalates)?
- What should we know about how manufacturers select plasticizers?
    - While preliminary research identifies alternatives for phthalates, are there instances when alternatives are not feasible?
- Are phthalates ever present as contaminants in any children's products?
- Are any children's products that contain phthalates recyclable, or are they expected to be sent to the landfill?

Styrene

- What studies on potential effects of chronic, low-level exposure to styrene on children's health should DTSC be aware of?
- What methods might be used to minimize the presence of residual monomeric styrene in products made of styrene-based co-polymers?
- Does the level of styrene contamination in children's products vary by the type of polymer used in the product? Which co-polymers are most and least likely to release styrene (e.g., polystyrene vs. ABS)?

- If styrene cannot be fully removed, what would be an achievable minimum concentration of residual styrene in children's products?
    - DTSC has the option of setting an Alternatives Analysis Threshold (AAT) when a chemical of concern is an intentionally added ingredient in a Priority Product; manufacturers of priority product that contain the Chemical of Concern at a concentration below this level are exempt from performing an Alternatives Analysis, but must notify DTSC and document that they meet the criteria for exemption. When a chemical of concern is present as a contaminant, DTSC must set an AAT. For more information, see the AAT portion of our training series.
- How much residual styrene is typically present in car seats and helmets made with EPS? What are the safety performance requirements for these products?
- Is there evidence of migration of styrene from styrene-based polymers intended for mouthing by children?
- Which types of children's products that use styrene-based polymers might present the highest risk of exposing children to styrene monomer?
- What evidence is there for hazard traits and potential for exposure to styrene dimers and trimers in children's products?

Formaldehyde

- What methods might be used to minimize the presence of formaldehyde in children's products?
- What would be a feasible minimum concentration of formaldehyde in children's products?
    - DTSC has the option of setting an Alternatives Analysis Threshold (AAT) when a chemical of concern is an intentionally added ingredient in a Priority Product; manufacturers of priority product that contain the Chemical of Concern at a concentration below this level are exempt from performing an Alternatives Analysis, but must notify DTSC and document that they meet the criteria for exemption. When a chemical of concern is present as a contaminant, DTSC must set an AAT. For more information, see the AAT portion of our training series.
- Are formaldehyde monomers released from formaldehyde-containing polymers/resins after being incorporated into children's products (e.g., phenol formaldehyde, melamine formaldehyde, urea formaldehyde)?

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APPENDIX 1: ADDITIONAL CHEMICALS CONSIDERED IN PRE-SCREENING

The following Candidate Chemicals were identified in children's products during pre-screening exploratory research, but were not prioritized with phthalates, styrene, and formaldehyde. These may be considered for further research in the future. DTSC welcomes any additional information on these chemicals in children's products.

2-(4-tert-butylbenzyl) propionaldehyde (Lilial)	Cobalt and cobalt compounds	Musk xylene
2-methylnaphthalene	Copper	Naphthalene
4-(1,1,3,3-tetramethylbutyl) phenol (4-tert-Octylphenol)	Cyclosiloxanes	Nickel
Acetaldehyde	Ethylbenzene	Nonanaldehyde
Antimony and antimony compounds	Ethylene glycol	Organophosphate flame retardants
Arsenic	Isophorone	Parabens
Benzophenone	Manganese and manganese compounds	Strontium
Benzophenone-3	Methyl ethyl ketone (MEK)	Toluene
Bisphenols	Methylbenzene	Zinc