the toy association
Inspiring Generations of Play
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January 2, 2025

Ms. Robin Christensen
Deputy Director, Safer Consumer Products Program
Department of Toxic Substances Control

Re: Comments Regarding Phthalates, Styrene and Formaldehyde in Children's Products

Dear Ms. Christensen,

Thank you for the opportunity to provide input in response to questions posed by the Department of Toxic Substances Control (DTSC) in its October 17, 2024, document relating to the possibility of adding phthalates, styrene and formaldehyde as Candidate Chemicals for Children's Products under the Safer Consumer Products requirements.

These comments are provided on behalf of The Toy Association and its 900+ members, representing manufacturers, importers, designers, retailers, inventors, and toy safety testing labs, many of which have a large presence in California, all working to ensure safe and fun play for families[1]. Toy safety is the number one priority for the industry. The Toy Association and its members have been global leaders in advancing toy safety for decades.

Where applicable to toys, please find below responses to DTSC's "Questions to Interested Parties". As you continue this work, The Toy Association and the toy industry look forward to continuing an open dialogue with DTSC and welcome this and future opportunities to share information related to the safety of toys.

**Product Categories and Candidate Chemicals**

*What product sub-categories should we prioritize when considering Candidate Chemicals in children's products?*

As background, it is important to note that toys to be sold in the U.S. market are already subject to stringent comprehensive mandatory requirements – including those related to the safety of materials that are specified in 16 CFR 1250, ASTM F963, the Federal Hazardous Substances Act, the Consumer Product Safety Act, the Child Safety Protection Act and Consumer Product Safety Improvement Act of 2008, among others. Under existing regulations, before being offered for sale, toys are required to be tested and certified compliant, undergoing a battery of tests to simulate normal use and reasonably foreseeable misuse specific to how a child interacts with its environment.

Specifically, orthophthalates in plasticized materials and formaldehyde in composite woods, if used in toys, are already regulated by existing requirements and the other listed chemicals such

[1] Report by John Dunham and Associates, Economic Impact of the Toy Industry on the State of California.

as other subcategories of phthalates and styrene monomers do not present at levels that would trigger SCP action.

In addition, and importantly, such requirements incorporate recognized developmental abilities of children at different ages, as well as their capabilities, known behaviors and physiology. For example, it is widely known that young children under three years of age exhibit mouthing behavior consistent with their early development and then coinciding with, and ultimately *ending*, following the teething milestone and before three years of age[2]. Oral exposure and ingestion are recognized as among the primary routes of exposure of concern for certain substances.

Given these facts, any contemplated regulations for children's toys should not be considered in a vacuum. The Toy Association believes that if any additional regulations above and beyond current requirements are considered these should focus on those substances and products not already regulated.

**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?*

**Orthophthalates (Common Phthalates)**

Orthophthalates have been the most widely used and studied subcategory of phthalates over the years, across various applications not limited to children's products, and particularly as plasticizers. Regulatory actions restricting the use of certain phthalates, such as di(2-ethylhexyl) phthalate (DEHP), di-butyl phthalate (DBP), and di-isobutyl phthalate (DIBP) and others are widely applied, particularly for childcare articles and toys. For example, DEHP, DBP, and DIBP have been regulated in the European Union and North America. They are subject to rigorous safety evaluations and are restricted under various regulations (e.g., REACH in the EU[3], CPSIA[4] and TSCA[5] in the U.S.). 1000 ppm (0.1 %) is the established content threshold for regulated orthophthalates. Given that a narrow range of orthophthalates are suitable for use as a plasticizer in toys (based on viscosity, solvation power, boiling point, etc. -- this means roughly 7-10 carbons in the moieties esterified to the benzene ring) and toys may not legally use any of these due to various restrictions, it would be extremely unlikely that significant amounts of these compounds exist in toys. Toys do not intentionally utilize or contain them beyond possible *de minimis* amounts due to environmental contamination.

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[2] Among the relevant references for this information are CPSC staff work related to DEHP, DINP and other phthalates, and Juberg, et al, An observational study of object mouthing behavior by young children, and others.
[3] European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation.
[4] The Consumer Product Safety Improvement Act (CPSIA), passed by U.S. Congress in 2008 and implemented and enforced by the U.S. Consumer Product Safety Commission (CPSC).
[5] Toxic Substances Control Act (TSCA) under authority of U.S. Environmental Protection Agency.

**Terephthalates**

One of the terephthalates, di-2-ethylhexyl terephthalate, often termed DOTP or DEHT is widely used as a plasticizer in toys and other goods. This compound, like the other terephthalates, does not present the same toxicity risk as the orthophthalates, as only orthophthalates are rapidly metabolized in the gut to their monoesters, these metabolites being the biologically-active compounds to which the orthophthalates' endocrine effects are attributed. Isophthalates and terephthalates are metabolized via conjugation pathways which differ from those of orthophthalates.

Terephthalates used as plasticizers in toys exhibit no demonstrable reproductive or developmental toxicity, neurotoxicity, or carcinogenicity. Ethylene terephthalate is a precursor in the production of some polyethylene terephthalate (PET or PETE) plastics, but exposures would be in an industrial setting, if at all, and have no relevance to consumer products. While PET is primarily used in plastic container production and textile manufacturing, and there are concerns over potential leaching of chemicals from some such PET products, it is considered safe for food contact applications, and use in toys is not a concern.

**Isophthalates**

We are not aware of any isophthalates being directly utilized in toys; in fact, we do not believe commercial quantities of isophthalate plasticizers are available in domestic or international markets. We also do not believe that halogenated phthalates are used in toys, as their use is typically driven by a need for flame retardancy beyond that required of toys, such as in electrical components.

Endocrine and reproductive effects: Isophthalates (such as isophthalic acid derivatives) have not been as thoroughly studied as orthophthalates; while the available data suggests that certain isophthalate esters might also act as endocrine disruptors, the effects appear less pronounced than those of orthophthalates. The available data suggests that iso-phthalates do not have the same or a similar level of hormonal toxicity as ortho-phthalates.

Bioaccumulation and persistence: Like terephthalates, isophthalates likely have the same minimal bioaccumulation and persistence as the orthophthalates.

*What evidence of shared hazard traits among classes of phthalates should we consider (i.e., among ortho-phthalates or among all phthalates)?*

As noted, orthophthalates are already restricted in toys and children's products. Terephthalates are considered safer alternatives, with much more favorable toxicity profiles and entirely different metabolic pathways.

DOTP is regularly used as a plasticizer in toys. Additional documents included with this comment submission include two (2) that provide a toxicology summary of DOTP by Eastman Chemical, producer of Eastman 168 DOTP plasticizer, as well as a link to a review of non-ortho-phthalates for reference[6].

[6] A review of common non-ortho-phthalate plasticizers for use in food contact materials - ScienceDirect

*What should we know about how manufacturers select plasticizers?*

Manufacturers select plasticizers based on a number of parameters, which may differ from application to application. Among these are any regulatory restrictions, viscosity, boiling point, solvation power (i.e., how efficiently the plasticizer will plasticize the base polymer), compatibility with the base resin and any additives, and resistance to extraction in the anticipated environments in which the final product will be used.

*While preliminary research identifies alternatives for phthalates, are there instances when alternatives are not feasible?*

Alternative plasticizers are chosen carefully with considerations for new material assessment including but not limited to safety assessment on mechanical/physical, electrical/flammability, chemical, and hygiene; performance and reliability: manufacturability and scalability, compatibility with existing materials and equipment; process validation and availability and consistency of supply. Alternatives or substitutes must not compromise existing functional safety and performance requirements. The alternative assessment and substitution process is very complex, costly and time-consuming.

Toys to be sold in the U.S. market are subject to comprehensive mandatory requirements including those specified in 16 CFR 1250, ASTM F963, the Federal Hazardous Substances Act (FHSA), the Consumer Product Safety Act (CPSA), the Child Safety Protection Act (CSPA), and Consumer Product Safety Improvement Act of 2008 (CPSIA). Products with alternative formulations must meet the same requirements and be tested and certified compliant, including undergoing a battery of tests to simulate normal use and reasonably foreseeable misuse specific to how a child interacts with its environment, before being offered for sale.

*Are phthalates ever present as contaminants in any children's products?*

*De minimis* amounts of orthophthalates (at levels typically well below 100 ppm), are occasionally observed, especially in cases involving use of recycled raw materials or production lines where phthalate-containing and phthalate-free materials are being produced in the same factory. These levels are not considered to present a significant risk of adverse health effects, and due to the ubiquitousness of these compounds in non-children's products, it is not practicable to reduce them below current levels.

**Styrene**

We note the following points related to styrene, in general, and its use in products:

ABS and other styrenic polymers such as various grades of impact polystyrene and styrene-containing elastomers are used extensively in consumer and children's products such as medical devices, food contact materials and toys – and these materials are often selected specifically for the added safety features their use imparts to consumer products. Residual content of styrene is strictly controlled by resin manufacturers, and no significant risk has been identified from the normal use of ABS or styrenic-based polymers.

Despite ongoing research into chemical safety, there has been **no** new evidence from recent studies that suggests styrene from ABS or other polymers poses an unrecognized or underestimated health risk. ABS, and styrene release from these materials, especially under normal conditions of use, are considered safe by regulatory agencies based on current data. It is important to bear in mind that ABS polymers used in toys are not alloys or blends of the three monomers, but true terpolymers, with the acrylonitrile and 1,3-butadiene moieties covalently bound to a polystyrene backbone. Any residual styrene monomer is trapped within the polymer matrix and does not migrate out to any appreciable extent, thus exposure potential is very low.

Styrene is largely bound within the polymer matrix of ABS and other styrenic polymers, and residual styrene levels are low. Styrene release from ABS and other styrene-containing polymers is extremely low under normal conditions of use, particularly in toys and children's products. Styrene emissions are typically detectable only under extreme conditions such as high temperatures during the manufacturing process, conditions which are not typical of consumer use scenarios.

Similarly, styrene monomer's potential health risks primarily arise from chronic industrial exposure or high-level occupational exposure (such as in manufacturing environments), not from consumer products. The low levels of styrene monomer released from ABS and other polymers that are present in products for consumers (children or others) are not likely to pose any significant health risk, especially given that migration limits are well below any toxicological thresholds established by regulatory agencies.

The primary reported health concerns for styrene are carcinogenicity and neurotoxicity (the latter presenting initially as ototoxicity/hearing loss and color vision impairment, and almost exclusively of relevance to occupational settings). As for carcinogenicity, the International Agency for Research on Cancer (IARC) has categorized styrene monomer as Class 2B, "possibly carcinogenic to humans", due to equivocal rodent data and limited evidence of relevance to humans. The health and environmental effects of styrene monomer and potential routes of exposure have been extensively studied, and advisory or regulatory exposure or content limits established where appropriate by multiple regulators and others, including NIOSH[7], ATSDR[8], ACGIH[9], Environment Canada, and ECHA[10].

Exposure limits for occupational settings have been established by OSHA[11], Cal-OSHA[12], ACGIH, the New Jersey Health Department, and ECHA to protect workers from excessive inhalation and dermal exposures in industries which utilize styrene monomer. Consumer exposures may be by inhalation from building materials in indoor air, cigarette smoking, or automobile exhaust, but these exposures are orders of magnitude less than in occupational settings. Consumer oral exposures are largely from drinking water and from food (due to naturally occurring amounts, microbial metabolism, and any styrene leaching from food contact containers or processing equipment composed of styrenic polymers).

Limits for drinking water have been established by U.S. EPA and potential consumer exposures from indirect food additives (i.e., migration from containers or processing equipment) are limited by U.S. FDA and EFSA[13]. Styrene monomer residues in and migration from ABS (and other styrenic polymers) have been extensively reviewed by regulatory bodies worldwide; the U.S.

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[7] National Institute for Occupational Safety and Health
[8] Agency for Toxic Substances and Disease Registry
[9] American Conference of Governmental Industrial Hygienists
[10] European Chemicals Agency
[11] Occupational Safety and Health Administration (U.S.)
[12] Cal-OSHA aka California Division of Occupational Safety and Health (DOSH)
[13] European Food Safety Authority

FDA, ECHA, EFSA, OEHHA[14], and others have each concluded that styrene migration from ABS does not present a risk to human health in normal use scenarios. These conclusions are based on robust risk assessments and exposure models.

Accordingly, ABS is used extensively in children's products such as toys, medical devices, and food contact materials – and is often selected specifically for the added safety features its use imparts to consumer products.

*What studies on potential effects of chronic, low-level exposure to styrene on children's health should DTSC be aware of?*

The Danish Ministry of Environment and Food published a study in 2018 related to the exposure of styrene monomer (and several other monomers) in toys. The study specifically addresses oral and ingestion routes, while mentioning inhalation and dermal contact as well (specifically related to children). There are several key points made in the study that the toy industry believes would be helpful to DTSC during this process. The study can be found at the following link. https://www2.mst.dk/Udgiv/publications/2019/02/978-87-7038-036-2.pdf

Despite ongoing research into chemical safety, there has been **no** new evidence from recent studies that suggests styrene from ABS poses an unrecognized or underestimated health risk. ABS, and styrene release from ABS, especially under normal conditions of use, are considered safe by regulatory agencies based on current data. Keep in mind that ABS polymers used in toys generally are not alloys or blends of the three monomers, but true terpolymers, with the acrylonitrile and 1,3-butadiene moieties covalently bound to a polystyrene backbone. Any residual styrene monomer is trapped within the polymer matrix and does not migrate out to any appreciable extent; thus exposure potential is very low.

*What methods might be used to minimize the presence of residual monomeric styrene in products made of styrene-based co-polymers?*

The most common method is a devolatilization process; please see separate enclosed document (United States patent 4439601 dated March 27, 1984) as an example. This process involves heating the semi-finished polymer under vacuum in order to drive off and capture remaining volatiles, including residual monomers such as styrene. This process is state-of-the-art, and while very low levels of styrene monomer may remain after it, these levels are as low as is practicable to achieve. As mentioned above, what may remain is trapped and does not present a significant exposure risk.

*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?*

We are not aware of any studies on this question but would speculate that the level of residual styrene monomer in a polymer is correlated far more with the process used to produce and finish it than with the specific polymer. The residual level would also depend on the specific ratios of the monomers used to produce the end polymer and their volatility, thus a general answer to this question is not possible.

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[14] California Office of Environmental Health Hazard Assessment

*How much residual styrene is typically present in car seats and helmets made with EPS? What are the safety performance requirements for these products?*

Child car seats are outside the scope of the “toy” industry and definition of “toy”, as are most helmets (bike helmets and other helmets intended for use in sports).

*Is there evidence of migration of styrene from styrene-based polymers intended for mouthing by children?*

See previous mention of and link to the study by the Danish Ministry of Environment and Food (2018) that examined oral exposure routes, among others; link provided above.

*What evidence is there for hazard traits and potential for exposure to styrene dimers and trimers in children’s products?*

The polymerization process for any styrenic polymer involves careful selection of temperature, pressure, solvent, and catalyst used in the reaction vessel. These parameters are chosen to minimize the creation of styrene dimers and trimers and any other “side products” and maximize the yield of the desired polymer. As these substances exhibit relatively low boiling points not substantially different from that of the monomer, any amounts present after polymerization would be expected to be eliminated or reduced to *de minimis* levels by the devolatilization steps. Any remaining after these process steps would be trapped within the plastic matrix, thus presenting minimal exposure risk.

Given the comprehensive regulations already in place for styrene migration from ABS products and the low likelihood of harmful exposure to styrene in children’s products, further rulemaking specifically targeting styrene residues is unnecessary. Existing safety standards provide sufficient protection for consumers (adults or children), and the burden of additional regulation would be both unnecessary and detrimental to industry innovation, as ABS is a widely used and safe material for children's products. As noted above, children’s toys are already subject to comprehensive safety standards including mandatory testing and certification, that encompasses material safety, mechanical and physical safety, and more.

In summary, styrene monomer release from ABS and other styrene-containing polymers is minimal, and existing regulatory frameworks already ensure that styrene migration from ABS in children's products is well below any levels of concern. All of this supports the conclusion that styrene content and migration from polymers used in children’s products present no significant health risks and these minimal risks are already more than adequately addressed by multiple regulators; further, no compelling new evidence has emerged that would alter this conclusion. We therefore urge DTSC to focus its limited resources on other chemical/product combinations that present more exigent health and environmental risks.

***Formaldehyde***

*What methods might be used to minimize the presence of formaldehyde in children’s products?*

If formaldehyde-based resins are necessary for performance reasons, manufacturers can opt for low-emission versions, such as low- or no-formaldehyde resins, which release far less formaldehyde compared to standard urea-formaldehyde (UF) or phenol-formaldehyde (PF) resins. Other methods include:

Another technique is use of proper curing and cross-linking of resins to optimize curing processes (temperature, pressure, and humidity controls) to ensure the resins cross-link properly and contain and release less residual formaldehyde. Using added cross-linking agents during resin formulation or composite wood production can reduce the formaldehyde emissions by binding the formaldehyde molecules into the resin structure, thus making them less likely to volatilize.

Additionally, use of VOC (Volatile Organic Compound) Control, such as use-enhanced ventilation systems, air filtration, and the use of activated carbon or other absorbent materials to capture volatile compounds. And Post-Manufacturing Conditioning: After production, allowing products to "off-gas" or age in a controlled environment before they reach consumers can help minimize formaldehyde emissions.

Chemical additives to reduce formaldehyde emissions: (a) Certain chemical additives such as urea, ammonium salts, or metal oxides, can be used to neutralize formaldehyde emissions. These additives can bind to free formaldehyde and convert it into less volatile compounds, reducing emissions. (b) Antioxidants and Inhibitors: These chemicals can help stabilize formaldehyde-based resins, reducing the likelihood of formaldehyde release over time.

Use of Formaldehyde-Free or Low-Formaldehyde Textiles. These treatments are often used to make fabrics wrinkle-resistant, but alternatives are available, such as citric acid-based treatments or silicone-based finishes.

There are multiple potential uses for formaldehyde in toys, including three use cases in which formaldehyde is intentionally-added, such as composite wood (addressed in these comments above and below), fabric finishes if purchased as remnants of a mill run, and polyoxymethylene plastics (AKA polyacetal, POM, Celcon, Delrin, etc.). In the case of POM, any residual formaldehyde is held within the matrix unless subjected to high heat (well beyond temperatures seen in consumer use); these plastics are also typically used for internal components such as gears and plastic springs, further limiting access by, and exposure to, the consumer.[15]

*What would be a feasible minimum concentration of formaldehyde in children's products?*

This would vary by use case. For wood, the EPA/CARB limits are likely as low as would be consistently feasible without using formaldehyde-free glue; and we would need to survey some POM manufacturers for achievable levels, but producers typically are careful to devolatilize and incorporate anti-emission additives.

*Are formaldehyde monomers released from formaldehyde-containing polymers/resins after being incorporated into children's products (e.g., phenol formaldehyde, melamine formaldehyde, urea formaldehyde)?*

Urea-formaldehyde resin is one of the most common adhesives used in the production of plywood, particleboard, and MDF (medium-density fiberboard). Formaldehyde emissions from composite wood-based children's products are already regulated as below.

The Formaldehyde Emission Standards for Composite Wood Products under the Formaldehyde Emission Standards for Composite Wood Products Act (Title VI of the Toxic Substances Control

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[15] Please see U.S. Patent 2,994,687 related to Process of Polymerizing Formaldehyde, August 1, 1961., provided with these comments.

Act, TSCA) align with California's own CARB II requirements. These standards apply to manufacturers, importers, and retailers of certain composite wood products. The regulations aim to reduce formaldehyde emissions from these products, which include particleboard, MDF (medium-density fiberboard), and hardwood plywood.

Limits set by both the federal and CARB regulations are aligned (following Phase 2 implementation of the TSCA regulation) and are set at 0.05 - 0.13 ppm for composite wood.

For all composite wood products to be sold in the U.S., manufacturers must meet these limits, and products must bear labels indicating compliance. The federal and CARB limits have already significantly reduced formaldehyde emissions in children's products. As such, there does not seem to be a need for additional regulation related to children's products.

Phenol-formaldehyde resins, typically used for industrial applications like plywood, laminates, and as a binder for phenolic boards, are generally less problematic in terms of formaldehyde emissions compared to UF resins due to the higher degree of polymerization and stronger cross-linking that occurs between phenol and formaldehyde. This makes the formaldehyde less volatile.

Melamine-formaldehyde resins are commonly used for decorative laminates and coatings. These resins typically have lower formaldehyde emissions compared to urea-formaldehyde resins due to the chemical structure of melamine, which forms stronger bonds with formaldehyde, reducing the free formaldehyde available to volatilize. The release of formaldehyde is more controlled and limited, especially in well-cured MF products.

**Summary**

Thank you again for the opportunity to provide responses and information, where applicable to the toy industry, to DTSC's request for information as it relates to Children's Products. The toy industry has a long history of working to develop and promote standards to ensure that all toys are safe for all children, at the state, federal and international levels. Importantly, these standards setting efforts include the combined expertise of medical and child-development experts, toxicologists, government, engineers, testing labs, consumer safety specialists and consumer representatives, industry, and others – and are subject to ongoing review in order to keep pace with evolving technology and innovation. Existing regulations cover materials used in toys, including but not limited to those mentioned here, as we have described above.

We note that DTSC may be relying on information collected under the Oregon and Washington State reporting requirements as a primary basis for concluding that the substances are used widely in children's products. We urge caution in interpreting the data in such a way, as there are aspects of those state reporting requirements designed to *encourage* reporting (and even over-reporting) --- including but not limited to penalties for non-reporting and no penalties for over-reporting, as well as inherent costs and impracticability of testing every product for every chemical. These underlying factors in the WA and OR state schemes call for careful analysis in assessing regulatory needs from the information and should not be considered in isolation.

Please also refer to comments filed separately by others, especially those submitted by the Juvenile Products Manufacturers Association (JPMA), the American Chemistry Council (ACC), as well as individual chemical manufacturers, as each provides relevant expertise to their respective product and material categories.

As outlined in these comments, we believe that at this time there is no need to propose the addition of phthalates, styrene and formaldehyde as Candidate Chemicals as they relate to Children's Products, and in particular toys, given the strict safety standards to which toys are subject and already comply. However, as you continue to consider such topics, and consistent with our industry's commitment to the safety of toys, we look forward to continuing this dialogue and discussion and offer our Association and industry as resources to DTSC. Please do not hesitate to reach out to me or my colleagues Jos Huxley, Sr. VP, Technical Affairs (jhuxley@toyassociation.org), or Charlotte Hickcox, Director, State Government Affairs, (chickcox@toyassociation.org) if you have additional questions.

Sincerely,

Joan Lawrence
Senior Vice President, Standards & Regulatory Affairs

About The Toy Association and the toy industry:

The Toy Association is the North American based trade association; our membership includes more than 900 businesses, from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs, and all members are involved in bringing safe & fun toys and games to children. The toy sector is a global industry of more than US $90 billion worldwide annually, and our members account for more than half of this amount.

Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard that has been adopted as a mandatory toy safety standard for all toys sold in the U.S. under CPSIA in 2008. It also serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children. The Toy Association continues to work with medical experts, government, consumers and industry to provide technical input to ensure that toy safety standards keep pace with innovation and potential emerging issues.

The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.