**UNITED STATES**
**CONSUMER PRODUCT SAFETY COMMISSION**
**4330 EAST WEST HIGHWAY**
**BETHESDA, MD 20814**

This document has been electronically approved and signed.

**DATE:** August 3, 2016

**BALLOT VOTE SHEET**

**TO:** The Commission
Todd A. Stevenson, Secretary

**THROUGH:** Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director

**FROM:** Patricia M. Pollitzer, Assistant General Counsel
David M. DiMatteo, Attorney, OGC

**SUBJECT:** Draft Notice of Proposed Rulemaking: *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics*

BALLOT VOTE DUE: Tuesday, August 9, 2016

The Office of the General Counsel is providing for Commission consideration the attached notice of proposed rulemaking for determinations that certain plastics with specified additives would not contain the specified phthalates prohibited in children's toys and child care articles. Based on these determinations, the specified plastics with specified additives would not require third party testing for compliance with the mandatory phthalates prohibitions on children's toys and child care articles.

Please indicate your vote on the following options:

I. Approve publication of the attached notice of proposed rulemaking in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

II. Approve publication of the attached notice of proposed rulemaking in the *Federal Register*, with changes. (Please specify.)

_____

_____

_____

_____

_____ _____

(Signature) (Date)

III. Do not approve publication of the attached notice of proposed rulemaking in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

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_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice for Notice of Proposed Rulemaking: Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics

[Billing Code 6355-01-P]

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Part 1308**

**[Docket No. CPSC-]**

**Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics**

**AGENCY**: U.S. Consumer Product Safety Commission.

**ACTION**: Notice of proposed rulemaking.

**SUMMARY**: The Consumer Product Safety Commission (Commission, or CPSC) is proposing a rule to determine that certain plastics with specified additives would not contain the specified phthalates prohibited in children's toys and child care articles. Based on these determinations, the specified plastics with specified additives would not require third party testing for compliance with the mandatory phthalates prohibitions on children's toys and child care articles.

**DATES**: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]**.

**FOR FURTHER INFORMATION CONTACT:** Randy Butturini, Project Manager, Office of Hazard Identification and Reduction U.S. Consumer Product Safety Commission, 4330 East West Hwy, Room 814, Bethesda, MD 20814; 301–504–7562: email; *rbutturini@cpsc.gov*.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

*1. Third Party Testing and Burden Reduction*

Section 14(a) of the Consumer Product Safety Act, (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that manufacturers of products subject to a consumer product safety rule or similar rule, ban, standard, or regulation enforced by the CPSC, must certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). For children's products, certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* Public Law 112-28 (August 12, 2011) directed the CPSC to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation." Public Law 112-28 also authorized the Commission to issue new or revised third party testing regulations if the Commission determines "that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." *Id*. 2063(d)(3)(B).

*2. Prohibitions in Section 108 of the CPSIA*

Section 108 of the CPSIA prohibits children's toys and child care articles that contain six specified phthalates in concentrations above 0.1 percent in "accessible plasticized component parts and other component parts made of materials that may contain phthalates." The prohibited phthalates in section 108 of the CPSIA are listed in Table 1. Children's toys and child care articles subject to the content limits in section 108 of the CPSIA require third party testing for compliance with the phthalate content

limits before the manufacturer can issue a Children's Product Certificate (CPC) and enter the children's toys or child care articles into commerce.

**Table 1: Statutorily Prohibited Phthalates**

| **Permanent Prohibition on Phthalates in Children's Toys and Child Care Articles** |
|---|
| DEHP: di-(2-ethylhexyl) phthalate |
| DBP: dibutyl phthalate |
| BBP: benzyl butyl phthalate |
| **Interim prohibition on phthalates in Children's Toys and Child Care Articles** |
| DINP: diisononyl phthalate |
| DIDP: diisodecyl phthalate |
| DnOP: di-n-octyl phthalate |

The CPSIA required the Commission to appoint a Chronic Hazard Advisory Panel (CHAP) to "study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles." The CHAP issued its report in July 2014[1]. Based on the CHAP report, the Commission published a notice of proposed rulemaking (NPR) [2] proposing to make the interim prohibition on DINP in children's toys and child care articles permanent, and proposing to lift the interim

[1] http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf.
[2] https://www.federalregister.gov/articles/2014/12/30/2014-29967/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates.

statutory prohibitions on DIDP and DnOP in children's toys and child care articles. In addition, the NPR proposed adding four new phthalates to the prohibited list of phthalates that cannot exceed 0.1 percent concentration in accessible component parts of children's' toys and child care articles. Table 2 contains the list of phthalates that the NPR proposed to prohibit in children's toys and child care articles.

**Table 2: Proposed Prohibited Phthalates**

| **Phthalates** |
|---|
| DEHP: di-(2-ethylhexyl) phthalate |
| DBP: dibutyl phthalate |
| BBP: benzyl butyl phthalate |
| DINP: diisononyl phthalate |
| DIBP: diisobutyl phthalate |
| DPENP: di-n-pentyl phthalate |
| DHEXP: di-n-hexyl phthalate |
| DCHP: dicyclohexyl phthalate |

## B. Contractor's Research on Phthalates in Consumer Products

CPSC contracted with Toxicology Excellence for Risk Assessment (TERA) to conduct research on phthalates and provide CPSC with two research reports on phthalates relevant to this rulemaking. TERA conducted a literature search on the production and

use of 11 specified phthalates in consumer products (Task 11 Report) [3]. The 11 phthalates researched by TERA are based on the phthalates assessed by the CHAP and the recommendations made in the CHAP report. Additionally, the CPSC contracted with TERA to conduct a literature search on whether specified plastics could be determined not to contain any of the 11 phthalates in concentrations above the CPSIA limit of 0.1 percent (Task 12 Report) [4].

TERA used a tiered literature research approach to identify sources for review from among the "universe" of available data. The tiers were used to provide a structured search method to locate relevant sources and eliminate unrelated material. TERA used books, factsheets, journal articles, patents, and other sources as primary and secondary literature sources. The use of this tiered approach resulted in a comprehensive review of the available literature that is representative of the information available on the potential for the presence of any of the 11 phthalates in the 4 specified plastics.

TERA screened over 119,800 studies identified by the above described tiered search method for relevance to the 11 phthalates and 4 plastics. CPSC staff reviewed the information provided in the contractor report and formulated recommendations for Commission consideration based on TERA's research.

The plastics researched by TERA were:

- Polypropylene (PP);

[3] http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/TERAReportPhthalates.pdf. The work was conducted as a task order (Task 11) under CPSC contract CPSC-D-12-0001.
[4] http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/ReportonPhthalatesinFourPlastics.pdf. The work was conducted as a task order (Task 12) under CPSC contract CPSC-D-12-0001.

- Polyethylene (PE);
- High-impact polystyrene (HIPS); and
- Acrylonitrile butadiene styrene (ABS).

TERA's research included the following factors:

- The raw materials used in the production of the specified plastics;
- The manufacturing processes used worldwide to produce the plastics;
- Typical applications for the specified plastics in consumer products, especially toys and child care articles, focusing on circumstances where the plastic could contain phthalates at concentrations greater than 0.1 percent;
- The potential use of recycled materials containing the specified phthalates in the production of the plastics; and
- The potential for phthalate contamination during packaging, storage, use, or other factors.

## C. CPSC Staff Analysis

### *1. Polypropylene (PP)*

TERA's research indicated the production of PP plastic uses a PP monomer, ethylene, and other monomers, a hydrocarbon solvent, catalysts, nucleating agents or fillers, and a number of other additives, depending on the type of PP and other manufacturing considerations. Additives can be included in PP to achieve various chemical and mechanical characteristics. PP can include the following additives:

- *Hydrocarbon solvents:* Examples of solvents used are hexane and heptane;

- *Catalysts*[5]: Catalysts used in producing PP are the Ziegler-Natta catalysts[6];
- *Fillers*: Fillers are added to plastics to enhance their performance (*e.g.*, impact resistance, shrink resistance), and reduce manufacturing costs. Examples of fillers used in PP include talc, calcium carbonate, and fiberglass;
- *Primary antioxidants*: Antioxidants inhibit oxidative deterioration of a material. Primary antioxidants donate hydrogen atoms to prevent free radical creation. Examples of primary antioxidants include hindered phenol, such as butylated hydroxytoluene, and hindered amine light stabilizers;
- *Secondary antioxidants*: Secondary antioxidants prevent degradation by breaking down free radicals and hydroperoxides, and synergize with the primary antioxidants. Examples of secondary antioxidants include phosphites and thioesters;
- *Neutralizing agents*: Neutralizing agents adjust the acidity of the chemicals during production, and can include calcium and zinc stearate, zeolites, calcium and zinc oxides, and metallic salts of lactic or benzoic acid;
- *Antistatic agents*: Antistatic agents reduce the buildup of static electricity, and can include cationic compounds, anionic compounds, and nonionic compounds;
- *Slip agents*: Slip agents are added to reduce a plastic surface's coefficient of friction. Examples of slip agents include modified fatty acids or fatty amides;

[5] The Merriam-Webster online dictionary defines a "catalyst" as "a substance that causes or accelerates a chemical reaction without itself being affected." A catalyst is not consumed, altered, or incorporated into one of the reaction's products.
[6] A Ziegler–Natta catalyst, named after Karl Ziegler and Giulio Natta, is a class of catalyst used in the production of some plastics.

- *Metal deactivators*: Transition metals like copper and iron can accelerate plastic degradation. Metal deactivators, such as N,N'-dibenzaloxaldihydrazide, combine with the metal ions and prevent catalytic degradation of the plastic;
- *Quenchers*: Quenchers scavenge stray free radicals and decompose unwanted peroxides. Examples of quenchers are organic nickel complexes, nickel salts of thiocarbamate, and nickel complexes with alkylated phenol phosphonates;
- *UV stabilizers*: Ultraviolet (UV) stabilizers are added to PP to protect the plastic from degradation in sunlight. Examples of UV stabilizers are hindered amine light stabilizers, carbon black, titanium dioxide, zinc oxide, derivatives of benzophenone, benzotriazoles, phenyl, aryl, or acrylic esters, formamidines, and oxanilides;
- *Nucleating agents*: Nucleating agents are additives that increase the crystallization of a plastic from a liquid solution. Examples of nucleating agents for PP include carboxylic acids, benzyl sorbitols, and salts of organic phosphates;
- *Flame retardants*: Examples of flame retardants include brominated flame retardants, cycloaliphatic chlorines; antimony trioxide, ferric oxide, zinc oxide, zinc borate, barium metaborates; phosphorus flame retardants, magnesium hydroxide, and aluminum hydroxide;
- *Blowing or foaming agents*: Blowing and foaming agents create gas bubbles during molding, resulting in a foamed plastic. Examples of blowing and foaming agents include sodium bicarbonate, sodium borohydride,

polycarbonic acid, citric acid, 4,4'oxybis(benzenesulfonyl hydrazide), azodicarbonamide, or para-toluenesulfonyl semicarbazide;

- *Antiblocking agents*: Antiblocking agents are used to prevent plastic films from sticking together through cold flow or static electricity. Examples of antiblocking agents include natural and manufactured waxes, metallic salts of fatty acids, silica compounds, and some polymers (*e.g.*, polyvinyl alcohol, polyamides, polyethylene, polysiloxanes, and fluoroplastics);
- *Lubricants*: Lubricants are used in PP (and other plastics) to lower the molten material's coefficient of viscosity and prevent the plastic from sticking to metal surfaces. The lubricants allow the plastic's hydrocarbon chains to slip past each other in the melt. Examples of lubricants include metal soaps, hydrocarbon waxes, polyethenes, amide waxes, fatty acids, and fatty alcohols, (*e.g.*, calcium or zinc stearates); or
- *Colorants*: Colorants for plastics typically consist of dyes, in which the color-producing material is dissolved in a carrier medium, and pigments, in which very small particles of the color-producing material are suspended in the carrier medium. Examples of colorants used in PP include heavy metal-based oxides, sulfides, chromates, and other complexes, including cadmium, zinc, titanium, lead, molybdenum; and ultramines (sulfide-silicate complexes containing sodium and aluminum; azo pigments).

The research showed that among all of these raw materials and additives, only Ziegler-Natta catalysts may contain one or more of the prohibited phthalates. Ziegler-Natta catalysts are generally titanium-based catalyst systems in combination with an

organoaluminum co-catalyst, and an internal donor (a molecule that contributes an electron to the chemical reaction), such as DBP, DIBP or DEHP. As described in the Task 12 Report, these catalysts may survive the plastic's polymerization process, and the phthalates may be present in the final plastic pellets, theoretically at concentrations of about 1 mg/kg (1 part per million, "ppm"). The Task 12 Report references an industry analysis in the context of European regulations that indicates that phthalate concentrations in PP do not exceed 0.15 mg/kg (0.15 ppm) and are often below the measurement threshold of the analytical method of 0.01 mg/kg (0.01 ppm).

*2. Polyethylene (PE)*

TERA's research indicated that PE is manufactured using PE monomers or certain copolymers or other monomers, and a number of additives. Additives can be included in PE to achieve various chemical and mechanical characteristics. PE can include the following additives:

- *Plasticizers*[7]: Examples of plasticizers for PE include glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, EVA polymer, DOP[8];

[7] The Task 12 Report indicated that several prohibited phthalates are used as plasticizers in PE. CPSC staff reviewed the report's references for this information. As cited in the Task 12 Report, Bhunia et al. (2013) reported several phthalates used in food packaging plastic films, including PE, referencing Sablani and Rahman (2007). In the latter reference, staff did not find any support for the claimed uses of phthalates. In fact, in the section on plasticizers, Sablani and Rahman (2007) stated that most plasticizers are used in PVC and that as a result of studies on migration of plasticizers from food packaging, ". . . industry has replaced PVC with other polymers, **such as PE or regenerated cellulose not associated with plasticizers**." (emphasis added)

[8] The isomer of DOP was not specified. DOP can include DEHP.

- *Initiators*: Initiators help form the plastic macromolecules from the solution. Examples of PE initiators are benzoyl peroxide, azodi-isobutyronitrile, and oxygen;
- *Promoters*: Promoters in PE improve paint adhesion and resistance to some solvents. PE promoters include sodium and calcium (in metal or hydride form);
- *Catalysts*: Catalysts for PE include the Ziegler-Natta catalysts, and metallocene catalysts (*e.g.*, zirconium, titanium);
- *Fillers*: silane and titanate coupling agents are used as fillers in PE;
- *Antistatic agents*: PE antistatic agents include polyethylene glycol alkyl esters;
- *Flame retardants*: PE flame retardants include antimony trioxide, and halogenated substances;
- *Anti-blocking agents*: Fine silicas are an example of a PE antiblocking agent;
- *Slip agents*: PE slip agents include fatty acid amides such as oleamide and erucamide;
- *Blowing agents*: PE blowing agents include 4,4'-oxybisbenzenesulfonohydrazine and azocarbonamide;
- *Cross-linking agents*: Cross-linking agents set up chemical bonds between the plastic macromolecules and assists in "curing" the plastic. Examples of cross-linking agents include dicumyl peroxide, and vinyl silanes;
- *Antioxidants*: PE antioxidants include 4-methyl-2,6-t-butyl phenol, 1,1,3-tris-(4-hydroxy-2-methyl-5-butylphenyl)butane, bis-[2-hydroxy-5-methyl-3-(1-methylcyclohexyl)phenyl]methane, and dilauryl-β,β'-thiodipropionate;

- *Carbon black*; or
- *Colorants*: PE colorants are often based on cobalt, cadmium, and manganese.

As with PP, PE catalysts include an internal donor, such as DBP, DIBP, or DEHP, although the phthalate concentration in the final plastic is generally well below 0.15 mg/kg (0.15 ppm).

One reference in the Task 12 report indicated that DOP can be used as a plasticizer in PE. Staff reviewed the cited references, as well as citations within the references, and found that uses of DOP in PE are mentioned in patents for specialized materials with no known current consumer product application, or may be used in materials, such as pavement marking, which are not children's products. One cited patent described use of phthalates in a PE microporous film used as an internal separator for lithium ion batteries.

The Task 12 Report cited a patent for a material made with PE plastic and DBP for use as a surface for outdoor athletic track, basketball, volleyball, and playgrounds. CPSC staff found no information indicating that such a product has been manufactured and marketed for consumer use. Furthermore, the applications for the material do not include children's toys or child care articles that are subject to the phthalate content restrictions.

*3. High-impact polystyrene (HIPS)*

TERA's research indicated that HIPS is a plastic blend generally produced from styrene, polybutadiene rubber, benzene, and a number of other substances. Additives can

be included in HIPS to achieve various chemical and mechanical characteristics. HIPS can include the following additives:

- *Catalysts*: The Ziegler-Natta catalysts
- *Internal lubricant*: Zinc stearate is a lubricant for HIPS;
- *Chain transfer/transition agent*: Chain transfer/transition agents regulate the length of the HIPS macromolecules. HIPS chain transfer/transition agents include tertdocecylmercaptan and liquid paraffin;
- *Stabilizer*: Tert-butylcatechol is a stabilizer for HIPS;
- *Diluents*: Diluents are used to reduce the concentration of a plastic as a means to reduce the plastic's viscosity and to modify its processing conditions. Examples of HIPS diluents include ethylbenzene, and toluene; or
- *Colorants*: HIPS colorants include azo dyes, anthraquinone dyes, perinone dyes, or xanthene dyes.
- *Other additives*: Additional materials used in the manufacture of HIPS include:
    - Aluminum chloride, ethyl chloride, hydrochloric acid;
    - Iron oxide, potassium oxide, chromium oxide; and
    - Bifunctional peroxides.

As with PP and PE, the polybutadiene used in HIPS production is made with the use of catalysts that include an internal donor, such as DBP, DIBP, or DEHP. Although no testing for phthalate content was located, because the use of phthalate in HIPS is as a catalyst, the concentration in the final product is expected to be well below 0.1 percent.

*4. Acrylonitrile butadiene styrene (ABS)*

TERA's research indicated that ABS plastic is manufactured with specific monomers, such as acrylonitrile, butadiene, and styrene, trans-1,4-butadiene, cis-1,4-butadiene, and 1,2-butadiene. Additives are included in ABS to achieve various chemical and mechanical characteristics. ABS can include the following additives:

- *Plasticizers*: ABS plasticizers include hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, long chain fatty acid esters, and aromatic sulfonamide;
- *Hydrocarbon solvents*: hexane, heptane, and ethyl benzene;
- *Stabilizers against heat or light degradation*: Stabilizer examples include phenolic antioxidants, thiol-containing antioxidants, phosphites, thioesters, substituted benzophenones and benzotriazoles, and hindered amines;
- *Lubricants*: ABS lubricants include metallic stearates, montan waxes or amide waxes[9];
- *Antioxidants*: Phenolic-based or phosphate-based antioxidants are used in the manufacture of ABS;
- *Molecular weight regulator*: An example of an ABS molecular-weight regulator is *tert*-dodecyl mercaptan;
- *Initiators/catalysts*: ABS initiators and catalysts include potassium persulfate, sodium persulfate, oil-soluble initiators in a redox system (cumene hydroperoxide, sodium pyrophosphate, dextrose, and iron (II) sulfate);

[9] The TERA Task 12 Report did not specify ABS lubricants. CPSC staff supplemented the Task 12 Report with additional research.

- *Activators*: Activators prepare the ABS surface for electroplating. The activators in ABS are often palladium and tin salts in an acid solution[10];
- *Emulsifiers*: Emulsifiers are chemicals that promote the mixing of hydrophilic and hydrophobic materials. ABS emulsifiers include salts of rosin, fatty sodium lauryl sulfate, and oleate;
- *Colorants*: ABS colorants include phthalocyanines, perylenes, cromophtals, titanium dioxide, carbon black, black iron oxide, ultramarine blue, red iron oxide, and aluminum flake[11].

*5. Additional CPSC Staff Research*

TERA's research did not include an examination of the colorants in polyethylene, high-impact polystyrene, or acrylonitrile butadiene styrene. TERA's research also did not include an examination of the lubricants, activators, and antioxidants that could be used in the production of ABS. CPSC staff conducted additional research into these component parts of the plastics.

*6. Potential Phthalate use in the Four Plastics*

The Task 11 Report indicates that phthalates are used generally as plasticizers or softeners of certain plastics, primarily polyvinyl chloride (PVC), as solvents, and as components of inks, paints, adhesives, and sealants. Except for the general category of inks and colorants, the Task 11 Report did not indicate uses of the prohibited phthalates

[10] The TERA Task 12 Report did not specify ABS activators. CPSC staff supplemented the Task 12 Report with additional research.

[11] The TERA Task 12 Report did not specify ABS colorants. CPSC staff supplemented the Task 12 Report with additional research.

in any of the four plastics, in the raw materials, or in the types of additives that might be used in the four plastics.

The four plastics may also be used as ingredients in a variety of materials. For example, PP may be used in formulations for concrete, paints, and lubricating grease. These materials would not be considered to be PP plastic. PE, HIPS, ABS also may be used as additives in materials that would not be considered plastics.

The TERA Task 11 and Task 12 Reports indicate that the phthalates researched are not associated with the chemistry and applications of the plastics PP, PE, HIPS, or ABS. When these plastics are plasticized, materials other than the phthalates are used as plasticizers (*e.g.*, hydrocarbon processing oil, phosphate esters, long chain fatty acid esters, and aromatic sulfonamide for ABS). TERA found one reference in which DnOP (also referred to as DOP) was used as a plasticizer for PE. However, the only application cited was a patent for a microporous plastic film used in the production of lithium-ion batteries. TERA's research included references prior to and after the enactment of the CPSIA, none of which indicated any phthalate use in the four plastics.

*7. Studies Where Phthalates Were Detected*

TERA's investigation of the uses of the four plastics shows that all four are used to make plastic consumer products and component parts. None of these applications specifically includes phthalates, although a few studies of the phthalate content of products were located.

Several studies evaluated food, beverage, and cosmetics packaging made with PP, PE, and polystyrene (PS). These studies generally measured migration of specified

chemicals, including phthalates, from products purchased in retail stores. The references provided few or no details about all the materials used in the products, including whether other plastics were present, whether other component parts were present such as coatings, finishes, inks, or adhesives, or whether residues of the contained products were present.

The Task 12 Report also cited a Korean study of various products that reported low levels of phthalates in a toy car made with ABS. The study provided no details about other materials used in the product, including whether other plastics were present, or whether other component parts were present such as coatings, finishes, inks, or adhesives.

The Task 12 Report's detailed description of the raw materials and manufacturing processes for PP, PE, HIPS, and ABS plastics showed that phthalates are not present after these plastics are produced. However, the Task 11 Report describes uses of phthalates in materials on these plastics, such as coatings, inks, and adhesives. Because consumer products purchased in stores likely consist of a number of different component parts, some of which may have contained phthalates, the studies described above should not be considered to be evidence that phthalates were used in the manufacture of the PP, PE, HIPS, or ABS plastic component parts of consumer products subject to the phthalate content restrictions.

*8. Phthalates in Recycled Materials*

All four plastics may be recycled and reprocessed into new products. However, degradation of the original plastics during the recycling process and mixing with other plastics or materials in the recycling steam can reduce the quality of the recovered plastic and limit further commercial uses. In some cases, recovered plastics are mixed with

virgin plastics to improve the products' quality and utility. The Task 12 Report indicated that few studies were located for analysis of phthalates in recycled plastics. One study found no phthalates in recycled PP carpet. Two studies analyzed solid waste consisting of PP or PE. One study reported detection of phthalates in recovered waste PP and PE material, but not in samples of virgin PP or PE plastic. The other study reported phthalates in recovered PE. The authors of the latter study suggested that the source of phthalates could have been the products that had been in contact with the plastic.

HIPS and ABS are generally used as rigid materials; available information does not indicate use of phthalates in such materials or associated with recycled HIPS or ABS.

Some studies indicated the potential for low, but detectable, levels of phthalates in plastics, such as PP or PE packaging that contained or had been in contact with a phthalate-containing product. Products made with such materials could contain residual phthalates, although at levels well below the maximum allowed concentration in children's products[12].

*9. Staff Conclusions Based on TERA Research*

With the exception of the catalysts for polymerization, and certain, specific uses of phthalates in products without consumer product applications, neither of the TERA task reports, nor research by CPSC staff found that phthalates are used as a component part of the four plastics. In the case of the phthalate catalysts used in plastics

[12] The highest level recorded by Huber and Franz was 200 ppm for one sample of DBP. The other samples' concentrations ranged from 3.1 to 96.3 ppm.

manufacturing, the phthalate concentration in finished plastics is significantly below the maximum allowable concentration.

The two TERA task reports and CPSC staff research show that very little information exists that indicates that manufactured PP, PE, HIPS, and ABS plastics could contain the researched phthalates. The research located references, including patents, for uncommon and specialized products, and products that generally do not have applications to children's toys and child care articles.

Staff found no evidence that phthalates are present at concentrations above 0.1 percent in any of the four plastics (either virgin or using recycled material) for consumer products, especially children's products.

**D. Determinations for Specified Plastics**

*1. Legal Requirements for a Determination*

As noted above, section 14(a)(2) of the CPSA requires third party testing for children's products that are subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Children's toys and child care articles must comply with the phthalates prohibitions in section 108 of the CPSIA. 15 U.S.C. 2057c. In response to statutory direction, the Commission has investigated approaches that would reduce the burden of third party testing while also assuring compliance with CPSC requirements. As part of that endeavor, the Commission has considered whether certain materials used in children's toys and child care articles would not require third party testing.

To issue a determination that a plastic (including specified additives) does not require third party testing, the Commission must have sufficient evidence to conclude

that the plastic and specified additives would consistently comply with the CPSC requirement to which the plastic (and specified additives) is subject so that third party testing is unnecessary to provide a high degree of assurance of compliance. Under 16 CFR part 1107 section 1107.2, "a high degree of assurance" is defined as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."

For a material determination, a high degree of assurance of compliance means that the material will comply with the specified chemical limits due to the nature of the material or due to a processing technique that reduces the chemical concentration below its limit. For materials determined to comply with a chemical limit, the material must continue to comply with that limit if it is used in a children's product subject to that requirement. A material on which a determination has been made cannot be altered or adulterated to render it noncompliant and then used in a children's product.

Phthalates are not naturally occurring materials, but are intentionally created and used in specific applications (*e.g.*, plastics, surface coatings, solvents, inks, adhesives, and some rubberized materials). One application of phthalates in children's toys and child care articles is as a plasticizer, or softener for plastic component parts.[13] The addition of a plasticizer converts an otherwise rigid plastic into a more flexible form, such as in a child's rubber duck or a soft plastic doll. Because plastics can contain the prohibited phthalates, third party testing is required before a CPC can be issued for children's toys and child care articles with accessible plastic component parts. However,

[13] The Merriam-Webster online dictionary defines a plasticizer as "a chemical added especially to rubbers and resins to impart flexibility, workability, or stretchability."

some specific plastics with certain additives might not use any of the prohibited phthalates as a plasticizer, or for any other purpose. For these specific plastics and accompanying additives, compliance with the requirements of section 108 of the CPSIA can be assured without requiring third party testing. As a means to reduce the third party testing burden on children's product certifiers while continuing to ensure compliance, the CPSC is proposing to make determinations that specified plastics with certain additives comply with the phthalate content requirements of section 108 of the CPSIA based on evidence indicating that such materials will not contain the prohibited phthalates.

Based on the discussion in section C of this preamble, the Commission proposes to determine that the specified four plastics and accompanying additives would comply with the phthalates prohibitions with a high degree of assurance. These determinations mean that third party testing for compliance with the phthalates prohibitions is not required for certification purposes for the specified four plastics. The Commission proposes to make these determinations to reduce the third party testing burden on children's product certifiers while continuing to assure compliance.

*2. Statutory Authority*

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. Public Law 110-314, sec. 3, Aug. 14, 2008. As noted previously, section 14 of the CPSA, which was amended by the CPSIA, requires third party testing for children's products subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Section 14(d)(3)(B) of the CPSA, as amended by Public Law 112-28, gives the Commission the authority to "prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party

testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." *Id.* 2063(d)(3)(B). These statutory provisions authorize the Commission to issue a rule determining that specified plastics and additives will not exceed the phthalates prohibitions of section 108 of the CPSIA, and therefore, specified plastics do not require third party conformity assessment body testing to assure compliance with the phthalates limits in section 108 of the CPSIA.

The proposed determinations would relieve the four specified plastics and accompanying additives from the third party testing requirement of section 14 of the CPSA for purposes of supporting the required certification. However, the proposed determinations would not be applicable to any other plastic or additives beyond those listed in the proposed rule.

The proposed determinations would only relieve the manufacturers' obligation to have the specified plastics and accompanying additives tested by a CPSC accepted third party conformity assessment body. Children's toys and child care articles must still comply with the substantive phthalates content limits in section 108 of the CPSIA regardless of any relief on third party testing requirements.

*3. Description of the Proposed Rule*

This proposed rule would create a new Part 1308 for "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics." The proposed rule would determine that the specified four plastics and accompanying additives do not contain the statutorily prohibited phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP) in concentrations above 0.1 percent, and thus, are not required to be third party tested to assure compliance with section 108 of the CPSIA. As

discussed in section A.2 of the preamble, the agency is currently involved in rulemaking to determine whether to continue the interim prohibitions in section 108 and whether to prohibit any other children's products containing any other phthalates. TERA's examination covered all phthalates that are subject to the current permanent and interim prohibitions, as well as the additional phthalates the Commission proposed restricting in the phthalates proposed rule. If the Commission issues a final rule in the phthalates rulemaking before finalizing this determinations rulemaking, the Commission would modify the determinations proposed rule so that the determinations rule covers the same phthalates restricted by the final phthalates rule.

Section 1308.1 of the proposed rule explains the statutorily-created requirements for children's toys and child care articles under section 108 of the CPSIA and the third party testing requirements for children's products.

Section 1308.2(a) of the proposed rule would establish the Commission's determinations that the following plastics do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

- Polypropylene, with any of the following additives:
  - the plasticizers polybutenes, dioctyl sebacate, paraffinic oil, isooctyl tallate, mineral plasticizing oils, and polyol;
  - hydrocarbon solvents;
  - catalysts;
  - fillers;
  - nucleating agents;
  - primary and secondary antioxidants;

- neutralizing agents;
- antistatic agents;
- slip agents;
- metal deactivators;
- quenchers;
- UV stabilizers;
- flame retardants;
- blowing or foaming agents;
- antiblocking agents;
- lubricants; or
- colorants.

- Polyethylene, with any of the following additives:
  - the plasticizers glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer;
  - catalysts;
  - initiators;
  - promoters;
  - antistatic agents;
  - fillers;
  - flame retardants;
  - anti-blocking agents;
  - slip agents;

- blowing agents;
- cross-linking agents;
- antioxidants;
- carbon black; or
- colorants.

- High-impact polystyrene, with any of the following additives:
  - catalysts;
  - internal lubricants;
  - chain transfer/transition agents;
  - stabilizers;
  - diluents;
  - colorants;
  - aluminum chloride, ethyl chloride, hydrochloric acid;
  - iron oxide, potassium oxide, chromium oxide; or
  - bifunctional peroxides.
- Acrylonitrile butadiene styrene, with any of the following additives:
  - the plasticizers phosphate esters, long chain fatty acid esters and aromatic sulfonamide;
  - hydrocarbon solvents;
  - stabilizers;
  - lubricants;
  - antioxidants;
  - molecular weight regulators;

- initiators/catalysts,
- activators;
- emulsifiers; or
- colorants.

Section C.2 of the preamble provides a more detailed discussion of the additives for each of the four plastics with the specified additives including definitions of the additives and various examples of the types of additives.

Section 1308.2(b) of the proposed rule states that accessible component parts of children's toys and child care articles made with the specified plastics, and specified additives listed in paragraph (a) of that section, are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107. Proposed § 1308.2(b) is included in the rule to make clear that when the listed plastics and accompanying additives are used in children's toys and child care articles, manufacturers and importers are not required to conduct the third party testing required in section 14(a)(2) of the CPSA and 16 CFR part 1107. Section 1308.2(c) of the proposed rule states that accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107. Proposed § 1308.2(c) is intended to make clear that if a manufacturer or importer uses any other plastic or additive in a children's toy or child care article not listed in proposed § 1308.1(a), that children's toy or child care article must be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107. Finally, the determinations in proposed § 1308.2(a) would only remove the obligation to have children's toys and child care articles tested by

a third party conformity assessment body. Regardless of any third party testing relief that the proposed rule would provide, the manufacturer or importer must still comply with the underlying phthalates content prohibitions in section 108 of the CPSIA.

## E. Effective Date

The Administrative Procedure Act (APA) generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). Because the proposed rule would provide relief from existing testing requirements under the CPSIA, the Commission proposes a 30 day effective date for the final rule.

## F. Regulatory Flexibility Act

### *1. Introduction*

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency is required to publish a notice of proposed rulemaking, unless the agency certifies that the NPR will not have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives which accomplish the statutory objectives and may reduce the significant economic impact of the proposed rule on small entities. Specifically, the IRFA must contain:

- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;

- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
- an identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

*2. Reason for Agency Action and Legal Basis for the Proposed Rule*

The Commission is proposing this NPR to reduce the burden of third party testing on toy and child care article manufacturers, especially the burden on those that are small entities. Based on an extensive literature review seeking information on the raw materials used in the manufacture of the specified plastics, the worldwide manufacturing practices of the plastics, the typical applications, and the potential for exposure to the specified phthalates through the use of recycled materials or due to contamination, the Commission concludes that there is a high degree of assurance that polypropylene, polyethylene, high impact polystyrene, and acrylonitrile butadiene styrene with the accompanying additives in the proposed rule will not contain any of the prohibited phthalates in concentrations above 0.1 percent when used in children's toys and child care articles. Therefore, third party testing is not necessary to assure that children's toys and child care articles with accessible component parts made from these plastics and accompanying additives do not contain the prohibited phthalates.

*3. Small Entities to Which the Proposed Rule Would Apply*

The proposed rule would apply to small entities that manufacture or import children's toys or child care articles that contain accessible polyethylene, polypropylene, high impact polystyrene, or acrylonitrile butadiene styrene and any accompanying additives in component parts. Toy manufacturers are classified in North American Industry Classification System (NAICS) category 33993 ("Doll, Toy, and Game Manufacturing"). According to the U.S. Bureau of the Census, in 2012 there were 559 toy manufacturers in the United States, of which 552 had fewer than 500 employees and would be considered small entities according to the Small Business Administration (SBA) criteria.[14] Of the small manufacturers, 326 had fewer than five employees.

Toy importers may be either wholesale merchants or retailers. The proposed rule would not apply to toy wholesalers or retailers if they obtain their merchandise from domestic manufacturers or importers. Toy wholesalers are classified in NAICS category 42392 ("Toy and Hobby Goods and Supplies Merchant Wholesalers"). According to the U.S. Bureau of the Census, there were 2,096 firms in this category.[15] Of these, 2,021 had fewer than 100 employees and would be considered small businesses according to SBA criteria. Toy retailers are classified in NAICS category 45112 ("Hobby, Toy, and Game Stores"). There could be about 5,800 toy retailers that would meet the SBA criteria to be considered a small entity.[16] The number of these small toy retailers that import toys, as opposed to obtaining their product from domestic sources is not known.

[14] 2012 County Business Patterns.
[15] 2012 County Business Patterns
[16] The SBA considers a toy retailer (NAICS 45112) to be a small entity if its annual sales are less than $27.5 million. According to the U.S. Bureau of the Census, in 2007, the average receipts for toy manufacturers with more than 500 employees was almost $500 million. The average receipts for the next largest category for which summary data was published, toy retailers with at least 100 but fewer than 500 employees were about $12 million. There were 5,864 firms in this NAICS category, of which 5,839 had fewer than 500 employees. (U.S. Census Bureau, Number of Firms, Number of Establishments,

The phthalate regulations also apply to manufacturers and importers of child care articles. Child care articles include many types of products for which the CPSC has recently promulgated or proposed new or amended mandatory safety standards. These include toddler beds, full size and non-full size cribs, bassinets and cradles, bedside sleepers, high chairs, hook-on-chairs, and booster seats. Other child care articles include sleepwear, and crib or cradle bumpers. In its ongoing market research, CPSC staff has identified 364 suppliers of these products that would be considered small according to criteria established by the SBA. Additionally, there could be other child care articles, not listed above, for which CPSC has not yet developed a mandatory or proposed standard, but which nevertheless are covered by the phthalate requirements.

Child care articles would also include products such as teethers (if they are not medical devices), pacifiers, and bottle nipples. Manufacturers of these products are classified in NAICS category 326299 ("All other rubber product manufacturing"). There are 617 firms classified in this NAICS code of which 573 are considered to be small.[17] However, this NAICS category includes many other products and most of these firms probably do not manufacture child care articles.

Although, as discussed above, the number of small companies that supply children's toys or child care articles to the U.S. market might be close to 10,000, the number that actually supply products with accessible polyethylene, polypropylene, high impact polystyrene, or acrylonitrile, butadiene styrene component parts is not known.

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Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2007.)

[17] U.S. Bureau of the Census, "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2011," 2011 County Business Patterns.

Also not known is the number of children's toys and child care articles that contain these plastics. To develop comprehensive estimates of the number of products that contain these plastics and the number of firms that supply the products it would probably be necessary to survey a representative sample of toy and child care article suppliers to solicit information on their use of the four plastics or to collect a representative sample of children's toys and child care articles and analyze the accessible components to determine which ones contained one or more of the four plastics.

Although comprehensive estimates of the number of children's toys and child care articles that contain components made from the four plastics are not available, there is some evidence that these plastics are extensively used in children's toys. One source stated that polypropylene and high density polyethylene are used in 38 and 25 percent, respectively, of injection molded toys. Low density polyethylene and acrylonitrile butadiene styrene, are each used in less than 10 percent of the injection molded toys. Polystyrene may also be used in injection molded toys, but the source does not specify the proportion that is high impact polystyrene.[18] The Commission requests comments to better determine the impact the proposed determinations would have on small entities.

*4. Reporting, Recordkeeping, and Other Compliance Requirements and Impact on Small Businesses*

The proposed rule would determine that there is a high degree of assurance that four specific plastics with any of the accompanying additives will not contain any prohibited phthalates at concentrations above 0.1 percent prohibition level. As a result of the proposed determinations, manufacturers, importers, and private labelers of children's

[18] Donald V. Rosato, *Plastics End Use Applications*, Springer, New York, (2011).

toys and child care articles that have accessible components that consist of these plastics and any accompanying additives will not have to obtain third party tests to certify that the accessible components do not contain the prohibited phthalates in concentrations above 0.1 percent.

The proposed rule would not impose any additional reporting, recordkeeping, or other compliance requirements on small entities. In fact, because the proposed rule would eliminate a testing requirement, there would be a small reduction in some of the recordkeeping burden under 16 CFR part 1107 and 16 CFR part 1109 because manufacturers would no longer have to maintain records of third party phthalate tests for the component parts manufactured from these four plastics.

A determination that specified plastics with accompanying additives used in children's toys and child care articles do not require third party testing is expected to be entirely beneficial to manufacturers and importers using those plastics in accessible component parts because manufacturers and importers could forego testing they otherwise would be required to conduct. However, staff believes the magnitude of that benefit is uncertain and could depend on factors such as:

- the extent to which manufacturers have already reduced their testing costs by using component part testing (as allowed in 16 C.F.R. part 1109);
- the volume of children's toys and child care articles that contain PE, PP, HIPS, or ABS;
- whether importers who certify children's products are unsure what plastics are being used in the toys and child care articles they import, so they could not take

advantage of the determinations without additional testing to assure that a component part is composed of one of the four plastics.

The Commission welcomes comments on the potential impact of the proposed rule on small entities. Comments are especially welcome on the following topics:

- The extent to which PP, PE, HIPS, or ABS are used in children's toys and child care articles, especially those manufactured or imported by small firms;
- The potential reduction in third party testing costs that might be provided by the Commission making the determinations, including the extent to which component part testing is already being used;
- Any situations or conditions in the proposed rule that would make it difficult to make use of the determinations to reduce third party testing costs; and
- Although the Commission expects that the impact of the proposed rule will be entirely beneficial, any potential negative impacts of the proposed rule.

*5. Other Federal Rules*

We have not identified any Federal rules that duplicate or conflict with the proposed rule.

*6. Alternatives Considered to Reduce the Burden on Small Entities*

Under section 603( c) of the RFA, an initial regulatory flexibility analysis should "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities." Because the proposed rule is intended to reduce the cost of third party testing on small businesses and will not impose

any additional burden, the Commission did not consider alternatives to the proposed rule that would reduce the burden of this rule on small businesses.

**G. Environmental Considerations**

The Commission's regulations provide a categorical exclusion for Commission rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required. The Commission's regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

**List of Subjects in 16 CFR Part 1308**

Business and industry, Consumer protection, Imports, Infants and children, Product testing and certification, Toys.

Accordingly, the Commission proposes to add 16 CFR part 1308 to read as follows:

**PART 1308— Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics**

Sec.

1308.1 Prohibited children's toys and child care articles containing specified phthalates and testing requirements.

1308.2 Determinations for specified plastics.

Authority: Sec. 3, Pub. L. 110-314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

**§ 1308.1 Prohibited children's toys and child care articles containing specified phthalates and testing requirements.**

Section 108(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Section 108(b)(1) of the CPSIA prohibits on an interim basis any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP). Materials used in children's toys and child care articles subject to section 108(a) and (b)(1) of the CPSIA must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA), unless listed in § 1308.2.

**§ 1308.2 Determinations for specified plastics.**

(a) The following plastics do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Polypropylene (PP), with any of the following additives:

(i) the plasticizers polybutenes, dioctyl sebacate, paraffinic oil, isooctyl tallate, mineral plasticizing oils, and polyol;

(ii) hydrocarbon solvents;

(iii) catalysts;

(iv) fillers;

(v) primary and secondary antioxidants;

(vi) neutralizing agents;

(vii) antistatic agents;

(viii) slip agents;

(ix) metal deactivators;

(x) quenchers;

(xi) UV stabilizers;

(xii) nucleating agents;

(xiii) flame retardants;

(xiv) blowing or foaming agents;

(xv) antiblocking agents;

(xvi) lubricants; or

(xvii) colorants.

(2) Polyethylene (PE), with any of the following additives:

(i) the plasticizers glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer;

(ii) initiators;

(iii) promoters;

(iv) catalysts;

(v) fillers;

(vi) antistatic agents;

(vii) flame retardants;

(viii) anti-blocking agents;

(ix) slip agents;

(x) blowing agents;

(xi) cross-linking agents;

(xii) antioxidants;

(xiii) carbon black; or

(xiv) colorants.

(3) High-impact polystyrene (HIPS), with any of the following additives:

(i) catalysts;

(ii) internal lubricants;

(iii) chain transfer/transition agents;

(iv) stabilizers;

(v) diluents;

(vi) colorants;

(vii) aluminum chloride, ethyl chloride, hydrochloric acid;

(viii) iron oxide, potassium oxide, chromium oxide; or

(ix) bifunctional peroxides.

(4) Acrylonitrile butadiene styrene (ABS), with any of the following additives:

(i) the plasticizers phosphate esters, long chain fatty acid esters and aromatic sulfonamide;

(ii) hydrocarbon solvents

(iii) stabilizers;

(iv) lubricants;

(v) antioxidants;

(vi) molecular weight regulators;

(vii) initiators/catalysts,

(viii) activators;

(ix) emulsifiers; or

(x) colorants.

(b) Accessible component parts of children's toys and child care articles made with the specified plastics, and specified additives, listed in paragraph (a) of this section are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

(c) Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Dated: _____

_____

Todd A. Stevenson, Secretary
Consumer Product Safety Commission

# Briefing Package

## Recommendation for Determinations on Phthalates Testing in Specified Plastics

August 3, 2016

*The views expressed in this report are those of the CPSC staff, and they have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.*

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**UNITED STATES**
**CONSUMER PRODUCT SAFETY COMMISSION**
**BETHESDA, MD 20814**

This document has been electronically approved and signed.

**Memorandum**

Date: August 3, 2016

TO: The Commission
Todd Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

FROM: George A. Borlase, Ph.D., P.E., Assistant Executive Director
Office of Hazard Identification and Reduction
Randy Butturini. P.E., SCPM, Lead General Engineer
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Health Sciences Directorate

SUBJECT : **Recommendation for Determinations on Phthalates Testing in Specified Plastics**

## Executive Summary

CPSC contracted with Toxicology Excellence for Risk Assessment ("TERA") to conduct a literature review on the manufacture and applications of 11 specified phthalates, and the potential for four specified plastics to contain those phthalates in concentrations above 0.1 percent. TERA identified over 119,800 studies for screening by their search method, which TERA believes is representative of the relevant studies available. CPSC staff recommends that the Commission determine that polypropylene, polyethylene, high-impact polystyrene, and acrylonitrile butadiene styrene do not contain any of the 11 phthalates in concentrations above 0.1 percent. If the Commission makes this determination, accessible component parts of children's toys and child care articles subject to CPSC's phthalate restrictions made from these plastics would not require third party testing for certification purposes.

# 1 Introduction

## 1.1 CPSIA and Public Law 112-28

Section 14 of the Consumer Product Safety Act ("CPSA"),[1] as amended by the Consumer Product Safety Improvement Act of 2008 ("CPSIA"),[2] requires third party testing of children's products subject to an applicable rule, ban, standard or regulation. Section 108 of the CPSIA prohibits six specified phthalates in "accessible plasticized component parts and other component parts made of materials that may contain phthalates," of children's toys and child care articles in concentrations above 0.1 percent. The prohibited phthalates are listed in Table 1. Thus, children's toys and child care articles subject to the content limit require passing third party testing results for the phthalate content limits for the manufacturer to issue a Children's Product Certificate ("CPC"), before the children's toys or child care articles can be entered into commerce.

**Table 1: Prohibited Phthalates**

| **Permanently-Prohibited Phthalates** | **CASRN[3]** |
|---|---|
| DEHP: di-(2-ethylhexyl) phthalate | 117-81-7 |
| DBP: dibutyl phthalate | 84-74-2 |
| BBP: benzyl butyl phthalate | 85-68-7 |
| **Prohibited phthalates in children's toys that can be placed in a child's mouth and in child care articles** | |
| DINP: diisononyl phthalate | 28553-12-0, 68515-48-0 |
| DIDP: diisodecyl phthalate | 26761-40-0, 68515-49-1 |
| DnOP: di-n-octyl phthalate | 117-84-0 |

Additionally, the CPSIA directed the Commission to appoint a Chronic Hazard Advisory Panel ("CHAP") to "study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles." Based on the CHAP report,[4] the Commission proposed a rule to update the list of prohibited phthalates under section 108 of the

[1] https://www.cpsc.gov/PageFiles/105435/cpsa.pdf.
[2] http://www.cpsc.gov/PageFiles/129663/cpsia.pdf.
[3] CASRN is an acronym for *Chemical Abstracts Service Registry Number*.
[4] http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf.

CPSIA.[5] The proposed rule would add four phthalates to the list of phthalates whose concentration cannot exceed 0.1 percent in children's toys and child care articles, would make the interim content prohibition on DINP permanent as a prohibited phthalate in children's toys and child care articles in concentrations above 0.1 percent, and would remove the interim content prohibitions on DIDP and DnOP. Table 2 lists the proposed rule's prohibited phthalates.

**Table 2: Proposed Prohibited Phthalates**

| Phthalate | CASRN |
|---|---|
| DEHP: di-(2-ethylhexyl) phthalate | 117-81-7 |
| DBP: dibutyl phthalate | 84-74-2 |
| BBP: benzyl butyl phthalate | 85-68-7 |
| DINP: diisononyl phthalate | 28553-12-0, 68515-48-0 |
| DIBP: diisobutyl phthalate | 84-69-5 |
| DPENP: di-n-pentyl phthalate | 131-18-0 |
| DHEXP: di-n-hexyl phthalate | 84-75-3 |
| DCHP: dicyclohexyl phthalate | 84-61-7 |

On August 12, 2011 Public Law 112-28 ("Pub. L. no. 112-28") was enacted. Section 2(a)(3)(B) of Pub. L. no. 112-28 states that the Commission:

> … may prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

## 1.2 Phthalate Characteristics

Phthalates are not naturally occurring materials, but are intentionally created and used in specific applications (*e.g.*, plastics, surface coatings, solvents, inks, adhesives, and some rubberized materials). One application of phthalates in children's toys and child care articles is as a plasticizer, or softener for plastic component parts.[6] The addition of a plasticizer converts an otherwise rigid plastic into a more flexible form, such as in a child's rubber duck or a soft plastic doll. Because plastics can contain the prohibited phthalates, third party testing is required before

[5] https://www.federalregister.gov/articles/2014/12/30/2014-29967/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates.

[6] The Merriam-Webster online dictionary defines a plasticizer as "a chemical added especially to rubbers and resins to impart flexibility, workability, or stretchability."

a CPC can be issued for children's toys and child care articles with accessible plastic component parts.

Phthalates tests are among the most expensive chemical tests to conduct on a product, and each accessible component part subject to section 108 of the CPSIA must be tested.[7] However, some specific plastics might not use any of the prohibited phthalates as a plasticizer, or for any other purpose. For these specific plastics, compliance with the requirements of section 108 of the CPSIA can be assured without requiring third party testing. As a means to reduce the third party testing burden on children's product certifiers while continuing to ensure compliance, the U.S. Consumer Product Safety Commission ("CPSC", "Commission") could make a determination that such materials comply with the phthalate content requirements of section 108 of the CPSIA based on evidence that such materials will not contain the prohibited phthalates. Such a determination would mean that third party testing for compliance to the phthalate restrictions would not be required for certification purposes. Third party testing burden reductions can only occur if each phthalate's concentration is below 0.1 percent. Because laboratories typically run one test for all of the prohibited phthalates, no testing burden reduction is achieved if any one of the prohibited phthalates requires compliance testing.

# 2 Research Conducted

## 2.1 TERA Task 11 Report

The CPSC contracted with Toxicology Excellence for Risk Assessment ("TERA", "contractor")[8] to conduct a literature search on the production and use of 11 specified phthalates (hereafter "phthalates" or "the phthalates") in consumer products[9] ("Task 11 Report"). TERA's research focused on the following factors:

- The raw materials used in the production of the specified phthalates;
- The manufacturing processes used worldwide to produce the specified phthalates;
- Estimated annual production of the specified phthalates;
- Physical properties of the specified phthalates (*e.g.*, vapor pressure, flashpoint, water solubility, temperature at which chemical breakdown occurs);
- Applications for phthalates use in materials and consumer and nonconsumer products; and
- Other potential routes by which phthalates can be introduced into an otherwise phthalates-free material (*e.g.*, migration from packaging, recycling, reuse, product breakdown).

[7] Test costs for the content of all the prohibited phthalates have been reported to range from $125 to $350 depending upon where the tests are conducted and any discounts that might apply.

[8] http://www.tera.org/. TERA joined the Department of Environmental Health, at the University of Cincinnati's, College of Medicine on August 1, 2015.

[9] http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/TERAReportPhthalates.pdf. The task order for this report is CPSC-D-12-0001-0011.

The 11 phthalates researched by TERA match the phthalates addressed in the CHAP report. Table 3 lists the phthalates researched by TERA.

**Table 3: Phthalates Researched**

| Phthalate | CASRN |
|---|---|
| DEHP: di-(2-ethylhexyl) phthalate | 117-81-7 |
| DBP: dibutyl phthalate | 84-74-2 |
| BBP: benzyl butyl phthalate | 85-68-7 |
| DINP: diisononyl phthalate | 28553-12-0, 68515-48-0 |
| DIDP: diisodecyl phthalate | 26761-40-0, 68515-49-1 |
| DnOP: di-n-octyl phthalate | 117-84-0 |
| DIOP: diisooctyl phthalate | 27554-26-3 |
| DIBP: diisobutyl phthalate | 84-69-5 |
| DPENP: di-n-pentyl phthalate | 131-18-0 |
| DHEXP: di-n-hexyl phthalate | 84-75-3 |
| DCHP: dicyclohexyl phthalate | 84-61-7 |

TERA screened secondary sources and some of the available primary literature to identify information on the 6 factors for the 11 specified phthalates. TERA focused on finding concentration data, particularly those where the specified phthalate was present in materials at greater than 0.1 percent.

## 2.2 TERA Task 12 Report

Additionally, the CPSC contracted with TERA to conduct a literature search on whether specified plastics could be determined not to contain any of the 11 phthalates in concentrations above the CPSIA limit of 0.1 percent[10] ("Task 12 Report"). The plastics researched were:

- Polypropylene ("PP");
- Polyethylene ("PE");

[10] http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/ReportonPhthalatesinFourPlastics.pdf. The task order for this report is CPSC-D-12-0001-0012.

- High-impact polystyrene ("HIPS"); and
- Acrylonitrile butadiene styrene ("ABS").

TERA's research included the following factors:

- The raw materials used in the production of the specified plastics;
- The manufacturing processes used worldwide to produce the plastics;
- Typical applications for the specified plastics in consumer products, especially toys and child care articles, focusing on circumstances where the plastic could contain phthalates at concentrations greater than 0.1 percent;
- The potential use of recycled materials containing the specified phthalates in the production of the plastics; and
- The potential for phthalate contamination during packaging, storage, use, or other factors.

### 2.3 TERA Research Method

TERA used a tiered approach to identify sources for review from among the "universe" of available data. For the Task 12 Report, TERA's approach had five tiers. TERA's first tier identified sources relevant to the four plastics from among the information available for plastics in general. The second tier identified and studied secondary sources (*e.g.*, reviews, factsheets, regulatory documents or risk assessments) used in the Task 11 Report to identify relevant sources. The third tier identified books that could serve as authoritative secondary sources about the five factors for the four plastics and the presence or absence of the specified phthalates. The fourth tier used the second and third tier results to search the worldwide primary literature to locate relevant information on the four plastics and the five factors not found in the approaches used in the earlier tiers. The last tier consisted of specific, targeted searches to double check for information to fill in information gaps identified using the data derived from the other tiers.

For the Task 11 Report, TERA used the same approach with a three tier method.

The use of this tiered approach resulted in a comprehensive review of the available literature that is representative of the information available on the potential for the presence of any of the 11 phthalates in the 4 specified plastics.

## 3 CPSC Staff Analysis

CPSC staff reviewed the TERA Task 11 and Task 12 Reports, and investigated many of the reports' references to fully understand the reports' findings. Additionally CPSC staff conducted additional supplementary research on aspects of plastics manufacturing and use not covered by the TERA Task 11 and Task 12 Reports.

## 3.1 Polypropylene (PP):

The production of PP plastic uses a PP monomer, ethylene, and other monomers, a hydrocarbon solvent, catalysts, nucleating agents or fillers, and a number of other additives, depending on the type of PP and other manufacturing considerations. The additives can include:

- *Hydrocarbon solvents:* Examples of solvents used are hexane and heptane;
- *Catalysts*[11]: Catalysts used in producing PP are the Ziegler-Natta catalysts[12];
- *Nucleating agents*: Nucleating agents are additives that increase the crystallization of a plastic from a liquid solution. Examples of nucleating agents for PP include carboxylic acids, benzyl sorbitols, and salts of organic phosphates.
- *Fillers*: Fillers are added to plastics to enhance their performance (*e.g.*, impact resistance, shrink resistance), and reduce manufacturing costs. Examples of fillers used in PP include talc, calcium carbonate, and fiberglass;
- *Primary antioxidants*: Antioxidants inhibit oxidative deterioration of a material. Primary antioxidants donate hydrogen atoms to prevent free radical creation. Examples of primary antioxidants include hindered phenol, such as butylated hydroxytoluene, and hindered amine light stabilizers ;
- *Secondary antioxidants*: Secondary antioxidants prevent degradation by breaking down free radicals and hydroperoxides, and synergize with the primary antioxidants Examples of secondary antioxidants include phosphites and thioesters;
- *Neutralizing agents*: Neutralizing agents adjust the acidity of the chemicals during production, and can include calcium and zinc stearate, zeolites, calcium and zinc oxides, and metallic salts of lactic or benzoic acid;
- *Antistatic agents*: Antistatic agents reduce the buildup of static electricity, and can include cationic compounds, anionic compounds, and nonionic compounds;
- *Slip agents*: Slip agents are added to reduce a plastic surface's coefficient of friction. Examples of slip agents include modified fatty acid amides;
- *Metal deactivators*: Transition metals like copper and iron can accelerate plastic degradation. Metal deactivators, such as N,N'-dibenzaloxaldihydrazide, combine with the metal ions and prevent catalytic degradation of the plastic;
- *Quenchers*: Quenchers scavenge stray free radicals and decompose unwanted peroxides. Examples of quenchers are organic nickel complexes, nickel salts of thiocarbamate, and nickel complexes with alkylated phenol phosphonates,
- *UV stabilizers*: Ultraviolet ("UV") stabilizers are added to PP to protect the plastic from degradation in sunlight. Examples of UV stabilizers are hindered amine light stabilizers, carbon black, titanium dioxide, zinc oxide, derivatives of benzophenone, benzotriazoles, phenyl, aryl, or acrylic esters, formamidines, and oxanilides;
- *Flame retardants*: Examples of flame retardants include brominated flame retardants, cycloaliphatic chlorines; antimony trioxide, ferric oxide, zinc oxide, zinc borate,

[11] The Merriam-Webster online dictionary defines a catalyst as "a substance that causes or accelerates a chemical reaction without itself being affected." A catalyst is not consumed, altered, or incorporated into one of the reaction's products.

[12] A Ziegler–Natta catalyst, named after Karl Ziegler and Giulio Natta, is a class of catalyst used in the production of some plastics.

barium metaborates; phosphorus flame retardants, magnesium hydroxide, and aluminum hydroxide;

- *Colorants*: Colorants for plastics typically consist of dyes, in which the color-producing material is dissolved in a carrier medium, and pigments, in which very small particles of the color-producing material are suspended in the carrier medium. Examples of colorants used in PP include heavy metal-based oxides, sulfides, chromates, and other complexes, including cadmium, zinc, titanium, lead, molybdenum; and ultramines (sulfide-silicate complexes containing sodium and aluminum; azo pigments);
- *Antiblocking agents*: Antiblocking agents are used to prevent plastic films from sticking together through cold flow or static electricity. Examples of antiblocking agents include natural and manufactured waxes, metallic salts of fatty acids, silica compounds, and some polymers (*e.g.*, polyvinyl alcohol, polyamides, polyethylene, polysiloxanes, and fluoroplastics);
- *Lubricants*: Lubricants are used in PP (and other plastics) to lower the molten material's coefficient of viscosity and prevent the plastic from sticking to metal surfaces. The lubricants allow the plastic's hydrocarbon chains to slip past each other in the melt. Examples of lubricants include metal soaps, hydrocarbon waxes, polyethenes, amide waxes, fatty acids, and fatty alcohols, (*e.g.*, calcium or zinc stearates); and
- *Blowing or foaming agents*: Blowing and foaming agents create gas bubbles during molding, resulting in a foamed plastic. Examples of blowing and foaming agents include sodium bicarbonate, sodium borohydride, polycarbonic acid, citric acid, 4,4'oxybis(benzenesulfonyl hydrazide), azodicarbonamide, or para-toluenesulfonyl semicarbazide.

Of these raw materials and additives, the Ziegler-Natta catalysts may contain one or more of the prohibited phthalates. Ziegler-Natta catalysts are generally titanium-based catalyst systems in combination with an organoaluminum co-catalyst, and an internal donor (a molecule that contributes an electron to the chemical reaction), such as DBP, DIBP or DEHP. As described in the Task 12 Report, these catalysts may survive the plastic's polymerization process, and the phthalates may be present in the final plastic pellets, theoretically at concentrations of about 1 mg/kg (1 part per million, "ppm"). The Task 12 Report references an industry analysis (Borealis, 2014) in the context of European regulations that indicates that phthalate concentrations in PP do not exceed 0.15 mg/kg (0.15 ppm), and are often below the measurement threshold of the analytical method of 0.01 mg/kg (0.01 ppm).[13]

The Task 12 Report included a reference to a patent for modeling clay that would include PP and DBP (Yokoyama et al., 1978). The patent does not describe a PP plastic.

[13] Borealis, A. G. (2014). Polypropylene Products: Borealis' Position on Phthalates in PP Catalysts. Vienna, Austria. http://www.borealisgroup.com/Global/Company/Sustainability/polypropylene-products.pdf.

## 3.2 Polyethylene (PE):

PE is manufactured using PE monomers or certain copolymers or other monomers, initiators, promotors, catalysts and a number of additives. The additives can include:

- *Initiators*: Initiators help form the plastic macromolecules from the solution. Examples of PE initiators are benzoyl peroxide, azodi-isobutyronitrile, and oxygen;
- *Promoters*: Promoters in PE improve paint adhesion and resistance to some solvents. PE promoters include sodium and calcium (in metal or hydride form);
- *Catalysts*: Catalysts for PE include the Ziegler-Natta catalysts, triethylaluminum plus a metallic salt ($TiCl_4$), chromium oxides (mainly $CrO_3$), silica-alumina catalyst, molybdenum oxide, and metallocene catalysts (*e.g.*, zirconium, titanium);
- Fillers: silane and titanate coupling agents are used as fillers in PE;
- *Colorants*: PE colorants are often based on cobalt, cadmium, and manganese;
- *Flame retardants*: PE flame retardants include antimony trioxide, and halogenated substances;
- *Anti-blocking agents*: Fine silicas are an example of a PE antiblocking agent;
- *Slip agents*: PE slip agents include fatty amides such as oleamide and erucamide ;
- *Blowing agents*: PE blowing agents include 4,4'-oxybisbenzenesulfonohydrazine and azocarbonamide;
- *Cross-linking agents*: Cross-linking agents set up chemical bonds between the plastic macromolecules and assists in "curing" the plastic. Examples of cross-linking agents include dicumyl peroxide, and vinyl silanes;
- *Antioxidants*: PE antioxidants include 4-methyl-2,6-t-butyl phenol, 1,1,3-tris-(4-hydroxy-2-methyl-5-butylphenyl)butane, bis-[2-hydroxy-5-methyl-3-(1-methylcyclohexyl)phenyl]methane, and dilauryl-β,β'-thiodipropionate;
- *Plasticizers*[14]: Examples of plasticizers for PE include glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, EVA polymer, DOP[15];
- *Carbon black*; and
- *Antistatic agents*: PE antistatic agents include polyethylene glycol alkyl esters.

As with PP, PE catalysts include an internal donor, such as DBP, DIBP, or DEHP, although the phthalate concentration in the final plastic is generally well below 0.15 mg/kg (0.15 ppm).

[14] The Task 12 Report indicated that several prohibited phthalates are used as plasticizers in PE. CPSC staff reviewed the report's references for this information. As cited in the Task 12 Report, Bhunia et al. (2013) reported several phthalates used in food packaging plastic films, including PE, referencing Sablani and Rahman (2007). In the latter reference, staff did not find any support for the claimed uses of phthalates. In fact, in the section on plasticizers, Sablani and Rahman (2007) stated that most plasticizers are used in PVC and that as a result of studies on migration of plasticizers from food packaging, "…industry has replaced PVC with other polymers, **such as PE or regenerated cellulose not associated with plasticizers**." [emphasis added]

[15] The isomer of DOP was not specified. DOP can include DEHP.

One reference indicated that DOP can be used as a plasticizer in PE. Staff reviewed the cited references—Wypych (2012) as well as citations within this reference—and found that uses of DOP in PE are mentioned in patents for specialized materials with no known current consumer product application, or may be used in materials, such as pavement marking, which are not children's products. One cited patent described use of phthalates in a microporous film used as an internal separator for lithium ion batteries.

The Task 12 Report cited a patent for a material made with PE plastic and DBP for use as a surface for outdoor athletic track, basketball, volleyball, and playgrounds (Tian, 2013). CPSC staff found no information indicating that such a product has been manufactured and marketed for consumer use. Further, the applications for the material do not include children's toys or child care articles that are subject to the phthalate content restrictions.

## 3.3 High-impact polystyrene (HIPS):

HIPS is a plastic blend generally produced from styrene, polybutadiene rubber, benzene, and a number of other substances, including:

- *Catalysts*: The Ziegler-Natta catalysts
- *Internal lubricant*: Zinc stearate is a lubricant for HIPS;
- *Chain transfer/transition agent*: Chain transfer/transition agents regulate the length of the HIPS macromolecules. HIPS chain transfer/transition agents include tertdocecylmercaptan and liquid paraffin;
- *Stabilizer*: Tert-butylcatechol is a stabilizer for HIPS;
- *Diluent*: Diluents are used to reduce the concentration of a plastic as a means to reduce the plastic's viscosity and to modify its processing conditions. Examples of HIPS diluents include ethylbenzene, and toluene; and
- *Colorants*: HIPS colorants include azo dyes, anthraquinone dyes, perinone dyes, or xanthene dyes[16].
- *Other additives*: Additional materials used in the manufacture of HIPS include:
    - Aluminum chloride, ethyl chloride, hydrochloric acid;
    - Iron oxide, potassium oxide, chromium oxide; and
    - Bifunctional peroxides.

As with PP and PE, the polybutadiene used in HIPS production is made with the use of catalysts that include an internal donor, such as DBP, DIBP, or DEHP. Although no testing for phthalate content was located, because the use of phthalate in HIPS is as a catalyst, the concentration in the final product is expected to be well below 0.1 percent.

[16] The TERA Task 12 Report did not specify HIPS colorants. CPSC staff supplemented the Task 12 Report with additional research.

## 3.4 Acrylonitrile butadiene styrene (ABS):

ABS plastic is manufactured with specific monomers, hydrocarbon solvents and several additives. The raw materials used to make ABS include:

- *Monomers*: acrylonitrile, butadiene, and styrene, trans-1,4-butadiene, cis-1,4-butadiene, 1,2-butadiene; and
- *Hydrocarbon solvents*: hexane, heptane, and ethyl benzene;

Several additives are included in ABS to achieve various chemical and mechanical characteristics. The additives are:

- *Stabilizers against heat or light degradation*: Stabilizer examples include phenolic antioxidants, thiol-containing antioxidants, phosphites, thioesters, substituted benzophenones and benzotriazoles, and hindered amines;
- *Plasticizers*: ABS plasticizers include hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, long chain fatty acid esters, and aromatic sulfonamide;
- *Lubricants* ABS lubricants include metallic stearates, montan waxes or amide waxes[17];
- *Colorants*: ABS colorants include phthalocyanines, perylenes, cromophtals, titanium dioxide, carbon black, black iron oxide, ultramarine blue, red iron oxide, and aluminum flake[18];
- *Molecular weight regulator*: An example of an ABS molecular-weight regulator is *tert*-dodecyl mercaptan;
- *Initiators/catalysts*: ABS initiators and catalysts include potassium persulfate, sodium persulfate, oil-soluble initiators in a redox system (*e.g.*, cumene hydroperoxide, sodium pyrophosphate, dextrose, and iron (II) sulfate);
- *Activators*: Activators prepare the ABS surface for electroplating. The activators in ABS are often palladium and tin salts in an acid solution[19];
- *Emulsifiers*: Emulsifiers are chemicals that promote the mixing of hydrophilic and hydrophobic materials. ABS emulsifiers include salts of rosin, fatty sodium lauryl sulfate, and oleate;
- *Antioxidants*: Phenolic-based or phosphate-based antioxidants are used in the manufacture of ABS.

[17] The TERA Task 12 Report did not specify ABS lubricants. CPSC staff supplemented the Task 12 Report with additional research.
[18] The TERA Task 12 Report did not specify ABS colorants. CPSC staff supplemented the Task 12 Report with additional research.
[19] The TERA Task 12 Report did not specify ABS activators. CPSC staff supplemented the Task 12 Report with additional research.

## 3.5 Additional CPSC Staff Research

The TERA research did not include an examination of the colorants in polyethylene, high-impact polystyrene, or acrylonitrile butadiene styrene. The TERA research also did not include an examination of the lubricants, activators, and antioxidants that could be used in the production of ABS. CPSC staff conducted additional research into these component parts of the plastics. The research results are detailed in the memorandum *Additional CPSC Staff Research in Support of Recommendations for Determinations on Phthalates Testing in Specified Plastics*, which is found in Appendix A.

## 3.6 Potential Phthalate use in the Four Plastics

The Task 11 Report indicates that phthalates are used generally as plasticizers or softeners of certain plastics, primarily polyvinyl chloride ("PVC"), as solvents, and as components of inks, paints, adhesives, and sealants. Except for the general category of inks and colorants, the Task 11 Report did not indicate uses of the prohibited phthalates in any of the four plastics, in the raw materials, or in the types of additives that might be used in the four plastics.

The four plastics also may be used as ingredients in a variety of materials. For example, PP may be used in formulations for concrete, paints, and lubricating grease. These materials would not be considered to be PP plastic. PE, HIPS, ABS also may be used as additives in materials that would not be considered plastics.

The TERA Task 11 and Task 12 Reports indicate that the phthalates researched are not associated with the chemistry and applications of the plastics PP, PE, HIPS, or ABS. When these plastics are plasticized, materials other than the phthalates are used as plasticizers (*e.g.*, hydrocarbon processing oil, phosphate esters, long chain fatty acid esters, and aromatic sulfonamide for ABS). TERA found one reference[20] in which DnOP (also referred to as DOP) was used as a plasticizer for PE. However, the only application cited was a patent for a microporous plastic film used in the production of lithium-ion batteries. TERA's research included references prior to and after the enactment of the CPSIA, none of which indicated any phthalate use in the four plastics.

### 3.6.1 Studies in Which Phthalates were Detected

TERA's investigation of uses of the four plastics shows that all four are used to make plastic consumer products and component parts. None of these applications specifically include phthalates, although a few studies were located that indicated the presence of phthalates.

Several studies evaluated food, beverage, and cosmetics packaging made with PP, PE, and polystyrene ("PS") (Casajuana and Lacorte, 2003; Chang et al., 2015; Di Bella et al., 2014; Kawamura et al., 2000; Lee et al., 2011; Onghena et al., 2014; Thomas et al., 2014). These studies generally measured the migration of specified chemicals, including phthalates, from products purchased in retail stores. The references provided few or no details about all the

[20] Wypych, G. (2012). Handbook of Plasticizers (Second Edition). Toronto, Ontario, ChemTec Publishing.

materials used in the products, including whether other plastics were present, whether other component parts were present such as coatings, finishes, inks, or adhesives, or whether residues of the contained products were present.

The Task 12 Report also cited a Korean study of various products that reported low levels of phthalates in a toy car made with ABS (Song et al., 2012). The study provided no details about other materials used in the product, including whether other plastics were present, or whether other component parts were present such as coatings, finishes, inks, or adhesives.

The Task 12 Report's detailed description of the raw materials and manufacturing processes for PP, PE, PS, and ABS plastics showed that phthalates are not present after these plastics are produced. However, the Task 11 Report describes uses of phthalates in materials on these plastics, such as coatings, inks, and adhesives. Because consumer products purchased in stores likely consist of a number of different component parts, some of which may have contained phthalates, the studies described above should not be considered to be evidence that phthalates were used in the manufacture of the PP, PE, PS, or ABS plastic component parts of consumer products subject to the phthalate content restrictions.

### 3.6.2 Phthalates in Recycled Materials

All four plastics may be recycled and reprocessed into new products. However, degradation of the original plastics during the recycling process and mixing with other plastics or materials in the recycling stream can reduce the quality of the recovered plastic and limit further commercial uses. In some cases, recovered plastics are mixed with virgin plastics to improve the products' quality and utility. The Task 12 Report indicated that few studies were located for analysis of phthalates in recycled plastics. One study found no phthalates in recycled PP carpet (Greenpeace Research Laboratories et al. 2001). Two studies analyzed solid waste consisting of PP or PE (Camacho and Karlsson, 2000; Huber and Franz, 1997). One study reported detection of phthalates in recovered waste PP and PE material, but not in samples of virgin PP or PE plastic. The other study reported phthalates in recovered PE. The authors of the latter study suggested that the source of phthalates could have been the products that had been in contact with the plastic.

HIPS and ABS are generally used as rigid materials; available information does not indicate use of phthalates in such materials or associated with recycled HIPS or ABS.

Some studies indicated the potential for low, but detectable, levels of phthalates in plastics, such as PP or PE packaging, which contained or had been in contact with a phthalate-containing product. Products made with such materials could contain residual phthalates, although at levels well below the maximum allowed concentration in children's products.[21]

[21] The highest level recorded by Huber and Franz was 200 ppm for one sample of DBP. The other samples' concentrations ranged from 3.1 to 96.3 ppm.

## 3.7 Staff Conclusions on TERA Research

With the exception of the catalysts for polymerization, and certain, specific uses of phthalates in products without consumer product applications, neither of the TERA task reports, nor research by CPSC staff found that phthalates are used as a component part of the four plastics. In the case of the phthalate catalysts used in plastics manufacturing, the phthalate concentration in finished plastics is significantly below the maximum allowable concentration of 0.1 percent.

The two TERA task reports and the CPSC staff research show that very little information exists that indicates that manufactured PP, PE, HIPS, and ABS plastics could contain the researched phthalates. The research located references, including patents, for uncommon and specialized products, and products that generally do not have applications to children's toys and child care articles.

Staff found no evidence that phthalates are present at concentrations above 0.1 percent in any of the four plastics (either virgin or using recycled material) for consumer products, especially children's products.

# 4 Discussion

## 4.1 A High Degree of Assurance is Required to Issue a CPC

A *High Degree of Assurance* is defined in 16 C.F.R. § 1107.2 as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture." Section 1107.20(D) of the regulation states:

> A manufacturer cannot certify the children's product until the manufacturer establishes, with a high degree of assurance that the finished product does comply with all applicable children's product safety rules.

Thus, certifiers of children's products require a high degree of assurance that their product complies to the applicable children's product safety rules before they issue a Children's Product Certificate.

## 4.2 Third Party Testing

Materials determined not to require third party testing to assure compliance to the applicable children's product rules, must continue to comply with the requirements of those rules. Thus, a manufacturer or importer who certifies a children's toy or child care article, must assure the toy's or child care article's compliance. For example, if a manufacturer or importer is relying on a determination that a plastic does not contain any prohibited phthalate in concentrations above 0.1 percent, the manufacturer must ensure that the plastic is one on which a determination has been made, and is not another plastic material. Additionally, the manufacturer or importer must have a high degree of assurance that the children's toy or child care article has not been adulterated or contaminated to an extent that would render the children's toy or child care article noncompliant.

## 4.3 Required Compliance to the Phthalates Content Limit

For accessible component parts of children's toys and child care articles subject to section 108 of the CPSIA, compliance to the content limit of 0.1 percent for any prohibited phthalate is always required, irrespective of any testing exemptions. The presence of the phthalate does not have to be intended as a plasticizer for a material to require compliance. Prohibited phthalates used for any functional purpose, present as a trace material, or as a contaminant, must be in concentrations less than 0.1 percent for the material to be compliant.

## 4.4 CPSC Staff Conclusions

Considering the evidence relating to the factors researched in the Task 11 and Task 12 Reports, CPSC staff concludes, with a high degree of assurance, that none of the 11 phthalates researched are present in PE, PP, HIPS, and ABS. Additionally, none of the typical additives to the plastics (*e.g.*, fillers, blocking agents, quenchers, nucleating agents, plasticizers) result in a plastic with greater than 0.1 percent concentration of any of the 11 phthalates. The Task 11 report focused on the production and uses of phthalates. No application of the 11 phthalates for use in the 4 plastics was identified. The Task 12 report investigated five areas where phthalates could be introduced into one of the 4 plastics. Other than the aforementioned microporous PE film, no instance was found that resulted in a plastic with greater than 0.1 percent of any of the 11 phthalates.

Public Law 112-28 authorizes the Commission to issue regulations that the Commission determines "will reduce third party testing costs consistent with assuring compliance" with applicable CPSC requirements. Thus, to issue a determination, the Commission must have sufficient evidence to conclude that the material would consistently comply with the CPSC requirement so that third party testing is unnecessary to provide a high degree of assurance of compliance. Staff concludes that the Task 11 and Task 12 Reports provide a basis for the Commission to determine that accessible component parts of children's toys and child care articles made from the four plastics (polypropylene, polyethylene, high-impact polystyrene, and acrylonitrile butadiene styrene) do not contain any prohibited phthalate in concentrations above 0.1 percent.

# 5 Recommendations

CPSC staff recommends that the Commission determine that the following four plastics do not to contain the prohibited phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP) in concentrations above 0.1 percent, and thus, are not required to be third party tested to assure compliance with section 108 of the CPSIA, and any regulation promulgated by the Commission pursuant to section 108 of the CPSIA.

The agency is currently involved in rulemaking regarding the list of prohibited phthalates in section 108 of the CPSIA ("the phthalates rulemaking"). TERA's research covered all the phthalates prohibited in section 108 and those that the Commission proposed to prohibit in the phthalates rulemaking. If the Commission publishes a Final Rule on phthalates before publishing

a Final Rule on determinations subsequent to this proposed determination rule, the final determination rule could include whichever of the 11 phthalates the final phthalates rule prohibits.

For accessible component parts of toys and child care articles made of plastics on which a determination has been made, no adulteration or contamination of the plastic with a prohibited phthalate is allowed during the plastic's manufacture, transport, storage, or application into a children's toy or child care article.

## 5.1 Polypropylene

CPSC staff recommends that the Commission determine, with a high degree of assurance, that commercially available polypropylene be determined not to contain any of the 11 phthalates researched in concentrations above 0.1 percent. The recommendation is for polypropylene plastic, with any of the following additives:

- Hydrocarbon solvents;
- Nucleating agents;
- Fillers;
- Primary and secondary antioxidants;
- The following plasticizers: polybutenes, dioctyl sebacate, paraffinic oil, isooctyl tallate, naphthenic, paraffinic and mineral plasticizing oils, and polyol;
- Neutralizing agents;
- Antistatic agents;
- Slip agents;
- Metal deactivators;
- Quenchers and UV stabilizers;
- Flame retardants;
- Colorants;
- Antiblocking agents;
- Lubricants; or
- Blowing or foaming agents.

## 5.2 Polyethylene

CPSC staff recommends that the Commission determine, with a high degree of assurance, that commercially available polyethylene be determined not to contain any of the 11 phthalates researched in concentrations above 0.1 percent. This recommendation does not include polyethylene films. The recommendation is for polyethylene plastic, with any of the following additives:

- Initiators;
- Promoters;
- Fillers;

- Colorants;
- Flame retardants;
- Anti-blocking agents;
- Slip agents;
- Blowing agents;
- Cross-linking agents;
- Antioxidants;
- The following plasticizers: glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer;
- Carbon black; or
- Antistatic agents;

## 5.3 High-impact polystyrene

CPSC staff recommends that the Commission determine, with a high degree of assurance, that commercially available high-impact polystyrene be determined not to contain any of the 11 phthalates researched in concentrations above 0.1 percent. The recommendation is for high-impact polystyrene plastic, with any of the following additives:

- Catalysts;
- Internal lubricants;
- Chain transfer/transition agents;
- Stabilizers;
- Diluents; or
- Colorants.

## 5.4 Acrylonitrile Butadiene Styrene

CPSC staff recommends that the Commission determine, with a high degree of assurance, that commercially available, acrylonitrile butadiene styrene be determined not to contain any of the 11 phthalates researched in concentrations above 0.1 percent. The recommendation is for acrylonitrile butadiene styrene plastic, with any of the following additives:

- Stabilizers;
- The following plasticizers: phosphate esters, long chain fatty acid esters and aromatic sulfonamide;
- Lubricants;
- Colorants;
- Molecular weight regulators;
- Initiators/catalysts;
- Activators;
- Emulsifiers; or
- Antioxidants.

## 5.5 Recommended Effective Date

Because the proposed determinations for the four plastics would reduce the testing burden on certifiers of children's toys and child care articles, staff recommends an effective date 30 days from the final rule's publication in the *Federal Register*.

# 6 Impact on Manufacturers and Importers of Children's Toys and Childcare Articles

The draft proposed rule would reduce the burden on manufacturers and importers of children's toys and childcare articles by eliminating the requirement to third party test to assure that accessible PE, PP, ABS, and HIPS component parts do not contain any prohibited phthalate in concentrations above 0.1 percent. The cost of third party testing for phthalates is between about $125 and $350, depending upon where the testing is conducted and any discounts that might be applicable.[22] Because one product might have several component parts that require testing, the cost to test one product for phthalate content may be substantially higher. To the extent that small businesses have lower production volumes than larger businesses, these determinations would be expected to have a disproportionately beneficial impact on small businesses because the cost of the tests are spread over fewer units. Additionally, some laboratories may offer their larger customers discounts that might not be available to small businesses that need less third party testing.

Although the cost of third party phthalate testing is relatively high on a per test or per product basis, the total amount by which the third party testing costs would be reduced cannot be reliably estimated with the information available. For example, although the number of manufacturers of children's toys and childcare articles is available from the Bureau of the Census, the number of these manufacturers that actually use PE, PP, ABS, or HIPS in their products is not known. Likewise the number of children's toys and childcare articles that contain these plastics is also not known.

Although comprehensive estimates of the number of products that contain components made from the four plastics are not available, there is some evidence that these plastics are extensively used in children's toys. One source stated that polypropylene and high density polyethylene are used in 38 and 25 percent, respectively, of injection molded toys.[23] Low density polyethylene and ABS, are each used in less than 10 percent of the injection molded toys. Polystyrene may also be used in injection molded toys, but the source does not specify the proportion that is high-impact polystyrene.[24]

A determination that plastics used in toys and child care articles do not require third party testing is expected to be entirely beneficial to manufacturers and importers using those plastics in

[22] The cost estimates of third party phthalate testing are based on information provided both by consumer product manufacturers and by testing laboratories.
[23] Donald V. Rosato, Plastics End Use Applications, Springer, New York, (2011).
[24] Ibid.

accessible component parts. However, the benefit magnitude is uncertain. If children's product certifiers previously implemented techniques such as component part testing (as allowed in 16 C.F.R. part 1109), to spread the testing costs among a large volume of products, then the benefit might be less than otherwise expected. Importers who certify children's products might be unsure what plastics are being used in the toys and child care articles they import. Additional efforts, including testing, may be required to assure that a component part is composed of one of the four plastics.

Because of the uncertainty in which manufacturers use PE, PP, HIPS, or ABS and which toys or child care articles contain these plastics, coupled with the unquantified potential testing burden reduction, staff does not recommend the Commission certify at this time. However, staff has solicited comments in the notice of proposed rulemaking ("NPR") and will evaluate them in developing a draft Final Rule.

# 7 Options for Future Commission Action Regarding Determinations on the Four Specified Plastics

CPSC staff recommends issuing an NPR, regarding testing for any of the 11 phthalates in the four plastics, as described above.

The Commission could take one or more of the following actions:

- Issue the draft NPR to determine that the four specified plastics do not contain any of the eleven specified phthalates in concentrations above 0.1 percent. Thus manufacturers of children's toys and child care articles would not need to obtain third party tests for accessible component parts made of these plastics to assure compliance with section 108 of the CPSIA;
- Issue the draft NPR with changes, as directed by the Commission;
- Direct staff to develop other documentation, such as Manufacturer Guidance; or
- Other actions the Commission decides.

# 8 Conclusions

CPSC contracted with TERA to conduct a literature review of the potential presence of 11 phthalates in 4 specified plastics. TERA screened over 119,800 studies identified by their tiered search method, for relevance to the 11 phthalates and 4 plastics. TERA believes their method generated a sample that is representative of all the relevant studies available. CPSC staff reviewed the information provided in the contractor report and formulated recommendations for Commission consideration.

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# Appendix A: Additional CPSC Staff Research in Support of Recommendations for Determinations on Phthalates Testing in Specified Plastics

**UNITED STATES**
**CONSUMER PRODUCT SAFETY COMMISSION**
**BETHESDA, MD 20814**

**Memorandum**

Date: August 3, 2016

TO: George A. Borlase, Ph.D., P.E., Assistant Executive Director
Office of Hazard Identification and Reduction

FROM: Randy Butturini. P.E., SCPM, Lead General Engineer, Office of Hazard Identification and Reduction
Kristina Hatlelid, Ph.D, M.P.H., Toxicologist, Division of Toxicology & Risk Assessment, Office of Hazard Identification and Reduction

SUBJECT : **Additional CPSC Staff Research in Support of Recommendations for Determinations on Phthalates Testing in Specified Plastics**

# 1 Introduction

CPSC contracted with Toxicology Excellence for Risk Assessment ("TERA")[1] to conduct literature reviews on the manufacture and applications of 11 specified phthalates, and the potential for polyethylene ("PE"), polypropylene ("PP"), high-impact polystyrene ("HIPS"), and acrylonitrile butadiene styrene ("ABS") to contain those phthalates in concentrations above 0.1 percent. [2] Table 1 lists the specified phthalates.

[1] http://www.tera.org/. TERA joined the Department of Environmental Health, at the University of Cincinnati's, College of Medicine on August 1, 2015.
[2] http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/TERAReportPhthalates.pdf. The task order for this report is CPSC-D-12-0001-0011. http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/ReportonPhthalatesinFourPlastics.pdf. The task order for this report is CPSC-D-12-0001-0012.

**Table 1: Specified Phthalates**

| Phthalate | CASRN[3] |
|---|---|
| DEHP: di-(2-ethylhexyl) phthalate | 117-81-7 |
| DBP: dibutyl phthalate | 84-74-2 |
| BBP: benzyl butyl phthalate | 85-68-7 |
| DINP: diisononyl phthalate | 28553-12-0, 68515-48-0 |
| DIDP: diisodecyl phthalate | 26761-40-0, 68515-49-1 |
| DnOP: di-n-octyl phthalate | 117-84-0 |
| DIOP: diisooctyl phthalate | 27554-26-3 |
| DIBP: diisobutyl phthalate | 84-69-5 |
| DPENP: di-n-pentyl phthalate | 131-18-0 |
| DHEXP: di-n-hexyl phthalate | 84-75-3 |
| DCHP: dicyclohexyl phthalate | 84-61-7 |

TERA's research covered the raw materials used in the manufacture of the plastics, the manufacturing processes, and the potential for recycling or contamination to introduce any of the specified phthalates into the plastic. However, due to the time and resource constraints in the contract, TERA's research did not include some commonly used additives. This memorandum summarizes additional research conducted by CPSC staff to supplement TERA's findings concerning the specified phthalates in the four plastics.

## 2 Ziegler-Natta Catalysts

Residual catalysts in PP have an adverse effect on oxidation resistance, color, and light stability.[4] Removing excess catalyst, or deashing, is difficult and expensive. Thus, "high efficiency" Ziegler-Natta catalysts, which, in very low concentrations, accelerate the plastic polymerization, are typically used in PP manufacture. The remaining catalyst in the plastic is in concentrations of around 0.0003 percent (3 parts per million, or ppm). At this concentration, deashing is not necessary.

[3] CASRN stands for Chemical Abstract Service Registry Number. A CASRN number is a unique numerical identifier of a chemical substance.
[4] Plastics Technology Handbook, 4th Edition, Chanda, M., Roy, S. K., December 19, 2006, CRC Press, Boca Raton, Florida, ISBN: 9781420006360.

The TERA Task 12 report included a reference stating that, although Ziegler-Natta catalysts (used in the manufacture of PP and PE) may contain one or more of the prohibited phthalates, the concentration of any remaining phthalates in the finished plastic is well below the 0.1 percent limit of section 108 of the CPSIA.[5] A plastics compounder (a company that mixes a plastic with various additives to achieve desired physical, thermal, electrical or aesthetic characteristics of the plastic compound), in response to the European Chemicals Agency REACH regulation,[6] also states that any prohibited phthalates in its plastic compounds are at a maximum concentration of 0.0005 to 0.001 percent (5 to 10 ppm).[7] In a discussion of plastics and health effects, residual Ziegler-Natta catalysts are found in PP and PE plastics at concentrations below 0.01 percent (less than 100 ppm).[8] Residual phthalates in PP and PE have undesirable effects on the plastic quality and modern manufacturing methods use Ziegler-Natta catalysts in concentrations well below 0.1 percent concentrations.

# 3 Acrylonitrile Butadiene Styrene

## 3.1 Lubricants

Lubricants are used in ABS (and other plastics) to lower the molten material's coefficient of viscosity and prevent the plastic from sticking to metal surfaces during the molten plastic's flow in mold dies. The lubricants allow the plastic's hydrocarbon chains to slip past each other in the melt. Examples of lubricants include fatty acid esters (calcium stearate),[9] primary amides (*e.g.*, stearamide, oleamide, erucamide)[10] and secondary amides (*e.g.*, oleyl palmitamide or stearyl erucamide,[11] ethylene bis-stearamide[12]). None of the references lubricants for ABS stated that any phthalate was used as a lubricant or as a component part of a lubricant.

## 3.2 Activators

Activators are additives that prepare the ABS surface for electroplating. The activators in ABS are catalysts that make the surface conductive for the electroplating operation. Most commonly, the plastic surface is exposed to a solution of palladium chloride and stannous chloride (a tin salt) in hydrochloric acid.[13] Palladium ions remain on the plastic surface after activation, and aid the adhesion of the electroplating metal. A palladium-free method uses

[5] Borealis, A. G. (2014). Polypropylene Products: Borealis' Position on Phthalates in PP Catalysts. Vienna, Austria. http://www.borealisgroup.com/Global/Company/Sustainability/polypropylene-products.pdf.
[6] http://echa.europa.eu/regulations/reach.
[7] http://www.sirmax.it/sites/default/files/EU%20Directive%20-%20REACh%20prohibition%20of%20Phthalates%20-%20Declaration.pdf.
[8] *Plastics and Environmental Sustainability*, Andrady, A. L., March 23, 2015, Wiley, Hoboken, New Jersey, ISBN: 9781118312605.
[9] *Functional Additives for the Plastics Industry*, Peter Dufton, July 1998, Rapra Technology, Shrewsbury, Shropshire, Shawbury, SY4 4NR, UK. ISBN: 1-85957-145-X.
[10] *Additives for Plastics Handbook*, 2nd Edition, John Murphy, Elsevier, 2001, ISBN: 0080498612, 9780080498614.
[11] Ibid.
[12] http://www.chinamasterbatches.com/ethylene-bis-stearamide.html.
[13] Kuzmik, John J., "Plating on Plastics," Chapter 14, pp. 377-399 in "Electroless Plating: Fundamentals and Applications," Mallory, G.O. & Hajdu, J.B., editors, American Electroplaters and Surface Finishers Society, 1990.

transition metals (the metallic elements in the Periodic Table between scandium and copernicium) as metallic salts to activate the surface of ABS.[14] Phthalates are not used as activators because they cannot prepare the plastic surface to adhere to metallic electroplating ions.

## 3.3 Antioxidants

Antioxidants inhibit oxidative deterioration of a material. Plastics use antioxidants to avoid breaking their hydrocarbon chains due to reactions with atmospheric oxygen.[15] ABS antioxidants include phenols (*e.g.*, 2,2'-ethylidenebis(4,6-di-tert-butylphenol),[16] octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate[17] and thioesters, such as dilauryl thiodipropionate.[18] The antioxidants prevent oxygen atoms in radicals or hydroperoxides from breaking the ABS carbon chain by donating hydrogen atoms. Phthalates do not donate hydrogen atoms to act as a primary antioxidant in ABS plastic.

Secondary antioxidants neutralize the intermediate products in an oxidation reaction to prevent the free radicals from being created. Phthalates do not react with intermediate oxidation products and do not act as a secondary antioxidant.

## 3.4 Colorants

A very wide range of materials are used to color ABS. Some are metals or oxides, such as titanium dioxide,[19] or red iron oxide.[20] Other colorants are organic compounds such as azo pigments,[21] and azine dyes, perinone dyes, or quinolone dyes.[22] A patent describing a liquid colorant base for ABS includes a long list of chemicals currently used to color ABS.[23]

The colorants for ABS are contained in a liquid or solid carrier medium for mixing with the uncolored ABS plastic. Typical ABS colorant carriers include ethylene methyl acrylate,[24] Ethylene vinyl acetate ("EVA"), or low density polyethylene ("LDPE").[25] Modified polystyrene

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[14] Vijaykumar Ijeri, Komal Shah and Snehal Bane, "Chromium-free Etching and Palladium-free Plating of Plastics," NASF Surface Technology White Papers, 78 (12), 1 – 8, (September 2014).
[15] Gongsheng, Li, Xuhong, Guo , Wang, Na , Diancheng, Hao , Mingyao, Zhang , Huixuan, Zhang , Jun, Xu, "Performance and synergistic effect of phenolic and thio antioxidants in ABS graft copolymers," Frontiers of Chemical Science and Engineering, Volume 5, Issue 1, pp 26-34, March 2011.
[16] http://www.vanderbiltchemicals.com/product_categories/product_listing/category/app-acrylonitrile-butadiene-styrene-abs.
[17] http://www.resikem.com.ar/admin/archivos/tecnica/237/TDS_Irganox_1076.PDF.
[18] http://www.songwon.com/en/products/polymerstabilizers/thioesters.
[19] http://www.mddionline.com/article/selecting-proper-colorant-thermoplastics.
[20] http://www.earthpigments.com/red-iron-oxide-pigment/.
[21] Christensen, Ian N., *Developments in Colorants for Plastics*, (Rapra Review Reports), Jan 1, 2003, ISBN-13: 978-1859573730, ISBN-10: 1859573738.
[22] Yam, Kit L, editor, *The Wiley Encyclopedia of Packaging Technology*, 3rd Edition, January, 2010, ISBN: 978-0-470-54138-8.
[23] http://www.google.com.py/patents/US4639272.
[24] http://www.google.com/patents/EP0705875A1?cl=en.
[25] http://www.colortech.com/index.php/products-and-services/products/colortech-color-concentrates.

also can be used as a color carrier medium.[26] Dispersants are used in colorants to keep the pigmented materials from clumping and to spread the color uniformly through the plastic. Some dispersants used with ABS include magnesium stearate, calcium stearate and polar polyethylene wax.[27] Dispersants require a polarized "anchor" end to attach to the colored material, and a nonpolar "buffer" end to repel other colored molecules. Because phthalates lack these features, they would work poorly as a dispersant.[28]

None of the chemicals or oxides listed as colorants, carriers, or dispersants, included the addition of any phthalate.

## 4 Colorants in Polyethylene

Pure polyethylene can vary between transparent, a milky translucent, or opaque, depending on its initial processing. A variety of organic and inorganic materials are used to color this plastic. Among the organic colorants for PS are azo dyes, quinacridones, and phthalocynanines. The inorganic materials used to color PE include titanium dioxide, carbon black, iron oxide, cadmium sulfoselenide, cobalt aluminate, chrome (III) oxide, and aluminum flakes.[29] The carrier mediums for the color include synthetic waxes, made from a low molecular weight polypropylene,[30] and low density polyethylene plastic.[31]

None of the references examined for colors, carriers, or dispersants, use phthalates as a component part of a PE colorant.

## 5 Colorants in High-impact Polystyrene

High-impact polystyrene has a white, translucent appearance. Colorants are used to add a tint to the material or to create an opaque, colored component part. Azo dyes, anthraquinone dyes, perinone dyes, or xanthene dyes are used to color PS.[32,33,34]

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[26] http://www.chinamasterbatch.com/What_is_Masterbatch.html.

[27] http://www.hzquancai.com/en/newshow.asp?id=26&mnid=202&classname=%D0%C2%CE%C5%B6%AF%CC%AC&uppage=/en/news.asp.

[28] https://books.google.com/books?id=5USu6SvIk70C&pg=PA435&lpg=PA435&dq=colorant+dispersant+plastics&source=bl&ots=DHcNJmSr19&sig=9UO6s7R6-VOK-SBKZwdsT8xiXuw&hl=en&sa=X&ved=0ahUKEwist-Otuf_LAhWFJB4KHWWkC-EQ6AEITjAJ#v=onepage&q=colorant%20dispersant%20plastics&f=false

[29] Michael Tolinski, *Additives for Polyolefins: Getting the Most out of Polypropylene, Polyethylene and TPO*, 2nd edition, Elsevier Science, March 17, 2015, ISBN-13:9780323371773.

[30] *Additives for Plastics Handbook*, 2nd Edition, Murphy, J. November 22, 2001, Elsevier Science, Amsterdam, The Netherlands, ISBN: 9781856173704.

[31] http://www.chinamasterbatch.com/What_is_Masterbatch.html.

[32] Yam.

[33] Joseph C. Salamone, editor, *Concise Polymeric Materials Encyclopedia*, CRC Press, August 28, 1998, ISBN 9780849322266.

Similar to ABS, HIPS color carrier mediums include EVA, LDPE, and modified polystyrene. Typical dispersants include the same dispersants used for ABS (magnesium stearate, calcium stearate and polyethylene wax). One supplier promotes polyethylene wax as a colorant dispersant for PP, PE, ABS, and HIPS.[35]

None of the references examined for colors, carriers, or dispersants indicated the use of phthalates as a component part of a HIPS colorant.

[34] Herman F. Mark, *Concise Encyclopedia of Polymer Science and Technology*, 3rd edition, Wiley-Interscience, 3 edition, February 9, 2007, ISBN-10: 0470073691, ISBN-13: 978-0470073698

35 http://www.poly-masterbatches.com/manufacturers-suppliers-clariant-pe-wax-for-masterbatch-dispersant-color-p74158.html#.VwuRPk32bL8.

# Appendix B: Initial Regulatory Flexibility Analysis

**UNITED STATES**
**CONSUMER PRODUCT SAFETY COMMISSION**
**BETHESDA, MD 20814**

**Memorandum**

Date: August 3, 2016

TO: George A. Borlase, Ph.D., P.E., Assistant Executive Director
Office of Hazard Identification and Reduction

FROM: Robert Franklin
Directorate for Economic Analysis

SUBJECT : **Determinations that Certain Plastics Will Not Contain Prohibited Phthalates: Initial Regulatory Flexibility Analysis**

## Background

The Commission is considering a draft proposed rule that would establish determinations that four specific plastics will not contain any prohibited phthalates in concentrations greater than 0.1 percent. If the Commission makes these determinations, manufacturers of children's toys and child care articles will not have to obtain third party tests for accessible component parts made of these plastics in order to certify that the component parts do not contain prohibited phthalates in excess of allowable levels. The four plastics for which the determinations would be made are polyethylene, polypropylene, high-impact polystyrene, and acrylonitrile butadiene styrene. Based on an extensive literature review seeking information on the raw materials used in the manufacture of the specified plastics, the worldwide manufacturing practices of the plastics, the typical applications, and the potential for exposure to the specified phthalates through the use of recycled materials or due to contamination, CPSC staff has concluded that there is a high degree of assurance that these four plastics will not contain any of the prohibited phthalates in concentrations above 0.1 percent. Therefore, third party testing is not necessary to assure that children's toys and child care articles with component parts made from these plastics do not contain the prohibited phthalates. The draft proposed rule is one result of the Commission's ongoing efforts to find opportunities to reduce the cost of third party testing requirements that are consistent with assuring compliance with the applicable children's product safety rules.

Whenever an agency is required to publish a proposed rule, the Regulatory Flexibility Act (5 U.S.C. §§ 601 – 612) requires that the agency prepare an initial regulatory flexibility analysis ("IRFA") that describes the impact that the rule would have on small businesses and other entities, unless the agency certifies that the rule will not have significant economic impact on a substantial number of small entities. The initial regulatory flexibility analysis must contain:

(1) a description of why action by the agency is being considered;

(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
(5) an identification to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

The IRFA also must describe any significant alternatives to the proposed rule which would accomplish the stated statutory objectives and minimize any significant economic impact of the proposed rule on small entities.

According to the Small Business Administration's Office of Advocacy,

> "Congress considered the term 'significant' to be neutral with respect to whether the impact is beneficial or harmful to small businesses. Therefore, agencies need to consider both beneficial and adverse impacts in an analysis…Moreover early drafts of the RFA used the term 'significant adverse' impact, but the final bill used only the term 'significant impact'.[1]

The SBA guidance may seem counterintuitive in that burden reduction, although beneficial, could still be found to have a significant economic impact on a substantial number of small businesses. The SBA guidance states, "…an agency cannot certify a proposed rule if the economic impact will be significant but positive."[2]

This report provides the initial regulatory flexibility analysis of the draft proposed rule.

**Objectives and Legal Basis of the Draft Proposed Rule**

The objective of the draft proposed rule is to reduce the burden of third party testing on manufacturers of children's toys and childcare articles consistent with assuring compliance with CPSC requirements. The legal basis is section 2 of Public Law 112-28.

**Small Entities to Which the Draft Proposed Rule Would Apply**

The draft proposed rule would apply to small entities that manufacture or import children's toys or child care articles that contain accessible polyethylene, polypropylene, high impact polystyrene, or acrylonitrile butadiene styrene component parts. Toy manufacturers are classified in North American Industry Classification System ("NAICS") category 33993 (Doll, Toy, and

[1] SBA Office of Advocacy "A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act", May 2012, p. 23
[2] Id. p.20

Game Manufacturing). According to the U.S. Bureau of the Census, in 2012 there were 559 toy manufacturers in the United States, of which 552 had fewer than 500 employees and would be considered small entities according to the Small Business Administration ("SBA") criteria.[3] Of the small manufacturers, 326 had fewer than 5 employees.

Toy importers may be either wholesale merchants or retailers. The draft proposed rule would not apply to toy wholesalers or retailers if they obtain their merchandise from domestic manufacturers or importers and do not import toys or childcare articles themselves. Toy wholesalers are classified in NAICS category 42392 (Toy and Hobby Goods and Supplies Merchant Wholesalers). According to the U.S. Bureau of the Census, there were 2,096 firms in this category.[4] Of these, 2,021 had fewer than 100 employees and would be considered small businesses according to SBA criteria. Toy retailers are classified in NAICS category 45112 (Hobby, Toy, and Game Stores). There could be about 5,800 toy retailers that would meet the SBA criteria to be considered a small entity.[5] Although importers are responsible for the certification of the children's products that they import, they may rely upon third party testing performed by their foreign suppliers for purposes of certification. The number of small toy wholesales or retailers that import toys, as opposed to obtaining their product from domestic sources is not known. Also unknown is the number of small importers that must obtain or pay for the third party testing of their products. CPSC staff welcomes public comments that would provide information on how making the determinations may benefit or in other ways impact small importers.

The phthalate regulations also apply to manufacturers and importers of child care articles. Child care articles include many types of products for which the CPSC has recently promulgated or proposed new or amended mandatory safety standards. These include toddler beds, full size and non-full size cribs, bassinets and cradles, bedside sleepers, high chairs, hook-on-chairs, and booster seats. Other child care articles include sleepwear and crib or cradle bumpers. In its ongoing market research, CPSC staff has identified 364 suppliers of these products that would be considered small according to criteria established by the SBA. Additionally, there could be other child care articles, not listed above, for which CPSC has not yet developed a mandatory or proposed standard, but which nevertheless are covered by the phthalate requirements.

Child care articles would also include products such as pacifiers and bottle nipples. Manufacturers of these products are classified in NAICS category 326299 ("All other rubber product manufacturing"). There are 617 firms classified in this NAICS code of which 573 are

[3] 2012 County Business Patterns.
[4] 2012 County Business Patterns
[5] The SBA considers a toy retailer (NAICS 45112) to be a small entity if its annual sales are less than $27.5 million. According to the U.S. Bureau of the Census, in 2007, the average receipts for toy manufacturers with more than 500 employees was almost $500 million. The average receipts for the next largest category for which summary data was published, toy retailers with at least 100 but fewer than 500 employees were about $12 million. There were 5,864 firms in this NAICS category, of which 5,839 had fewer than 500 employees. (U.S. Census Bureau, Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2007.)

considered to be small.[6] However, this NAICS category includes many other products and most of these firms probably do not manufacture child care articles.

Although, as discussed above, while the number of small companies that supply children's toys or child care articles to the U.S. market might be close to 10,000, the number that actually supply products with accessible polyethylene, polypropylene, high impact polystyrene, or acrylonitrile, butadiene styrene component parts is not known. Also not known is the number of children's toys and child care articles that contain these plastics. In order to develop comprehensive estimates of the number of products that contain these plastics and the number of firms that supply the products it would probably be necessary to survey a representative sample of toy and child care article suppliers to solicit information on their use of the four plastics or to collect a representative sample of children's toys and child care articles and analyze the accessible components to determine which ones contained one or more of the four plastics.

While comprehensive estimates of the number of children's toys and child care articles that contain components made from the four plastics are not available, there is some evidence that these plastics are extensively used in children's toys. One source stated that polypropylene and high density polyethylene are used in 38 and 25 percent, respectively, of injection molded toys. Low density polyethylene and acrylonitrile butadiene styrene, are each used in less than 10 percent of the injection molded toys. Polystyrene may also be used in injection molded toys, but the source does not specify the proportion that is high impact polystyrene.[7]

Based on the number of domestic toy manufacturers that are classified as small businesses by the U.S. Bureau of the Census and evidence that the four plastics are extensively used in toys, staff believes a substantial number of small entities would be impacted by this proposed regulation.

**Reporting, Recordkeeping and Other Compliance Requirements and Impact on Small Businesses**

CPSC staff is recommending that the Commission propose to make determinations that there is a high degree of assurance that four specific plastics will not contain any prohibited phthalates at concentrations above 0.1 percent. If the Commission promulgates a rule making the determinations, manufacturers, importers, and private labelers of children's toys and child care articles that have accessible components that consist of these plastics will not have to obtain third party tests to certify that the components do not contain the prohibited phthalates in concentrations above 0.1 percent. The four specific plastics for which the determinations could be made are:

- Polypropylene, including the following plasticizers: polybutenes, dioctyl sebacate, paraffinic oil, isooctyl tallate, mineral plasticizing oils, and polyol, and any of the following additives; hydrocarbon solvents, catalysts, fillers, primary and secondary antioxidants, neutralizing agents, antistatic agents, slip agents, metal deactivators,

[6] U.S. Bureau of the Census, "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2011," 2011 County Business Patterns.
[7] Donald V. Rosato, Plastics End Use Applications, Springer, New York, (2011).

quenchers, UV stabilizers, nucleating agents, flame retardants, colorants, antiblocking agents, lubricants, or blowing or foaming agents that may be added to the plastic;

- Polyethylene, including the following plasticizers: glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer, and any of the following additives: initiators, promoters, catalysts, fillers, colorants, flame retardants, anti-blocking agents, slip agents, blowing agents, cross-linking agents, antioxidants, carbon black; or antistatic agents; that may be added to the plastic;
- High-impact polystyrene, including catalysts, internal lubricants, chain transfer/transition agents, stabilizers, diluents, colorants, aluminum chloride, ethyl chloride, hydrochloric acid, iron oxide, potassium oxide, chromium oxide, or bifunctional peroxides that may be added to the plastic; and
- Acrylonitrile butadiene styrene, including the following plasticizers: phosphate esters, long chain fatty acid esters and aromatic sulfonamide, and any of the following additives: hydrocarbon solvents, stabilizers, lubricants, colorants, molecular weight regulators, initiators/catalysts, activators, emulsifiers, or antioxidants that might be added to the plastic.

The draft proposed rule would not impose any reporting, recordkeeping, or other compliance requirements on small entities. In fact, because the draft proposed rule would eliminate a testing requirement, there would be a small reduction in some of the recordkeeping burden under 16 C.F.R. part 1107 and 16 C.F.R. part 1109 because manufacturers would no longer have to maintain records of third party phthalate tests for the component parts manufactured from these four plastics.

The impact of the determinations on small businesses would be to reduce the burden of third party testing for phthalate content and would be expected to be entirely beneficial. The cost of phthalate testing is relatively high: between about $125 and $350 per component, depending upon where the testing is conducted and any discounts that are applicable. Because one product might have multiple components that require testing, the cost of testing a single product for phthalates could exceed $1,000 in some cases. Moreover, more than one sample might have to be tested to provide a high degree of assurance of compliance with phthalate requirements during a year. To the extent that small businesses have lower production or sales volumes than larger businesses, these determinations would be expected to have a disproportionately beneficial impact on small businesses. This beneficial impact is because the costs of the testing are spread over fewer units; and the benefit of the Commission making the determinations would be greater on a per unit basis for small businesses. Additionally, some testing laboratories may offer their larger customers discounts that might not be available to small businesses that need less third party testing. Given the relatively high cost of phthalate testing and evidence that these plastics may be extensively used in children's toys and childcare articles, making the determinations could potentially significantly benefit a substantial number of firms.

On the other hand, there are reasons to believe that the benefit of the making the determinations could be less than might be expected. For example, some manufacturers might have been able to substantially reduce their third party phthalate testing costs by using

component part testing as allowed by 16 CFR 1109, so the marginal benefit that might be derived from making the determinations might be low. The volume of children's toys or childcare articles that contain PE, PP, HIPS, or ABS that are manufactured or imported might be substantially higher than average and therefore, the testing costs per unit might be low compared to the revenue per unit. Some importers might not be certain of what materials are actually being used in each component. Therefore, these importers might have to undertake testing to determine the material from which components are made before they can decide that third party testing for phthalate content is not required. Doing so would reduce the beneficial impact of the Commission making the determinations.

Based on staff's research, staff cannot rule out the possibility that the burden reduction from this proposed determination rule could result in testing cost reductions that exceed 1 percent of the gross revenues for a substantial number of toy manufacturers or importers. However, staff does not have enough information on testing costs and revenues to provide a better quantitative estimate of burden reduction.

CPSC staff welcomes public comments on the potential impact of the draft proposed rule on small entities. Comments are especially welcome on the following topics:

- The extent to which PE, PP, HIPS, or ABS are used in children's toys and childcare articles, especially those manufactured or imported by small firms,
- The potential reduction in third party testing costs that might be provided by the Commission making the determinations, including the extent to which component part testing is already being used,
- Any situations or conditions in the draft proposed rule that would make it difficult to make use of the determinations to reduce third party testing costs, and finally
- Although the CPSC staff expects that the impact of the draft proposed rule will be entirely beneficial, any potential negative impacts of the draft proposed rule.

**Federal Rules Which May Duplicate, Overlap or Conflict with the Draft Proposed Rule**

We have not identified any Federal rules that duplicate or conflict with the draft proposed rule.

**Alternatives Considered to Reduce the Burden on Small Entities**

Under section 603( c) of the Regulatory Flexibility Act, an initial regulatory flexibility analysis should "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities." The draft proposed rule is itself the result of efforts of the CPSC to reduce third party testing costs consistent with assuring compliance with all applicable consumer product safety rules. Because the proposed rule is itself intended to reduce the cost of third party testing on small businesses and will not impose any additional burden, the staff did not consider other alternatives to this specific draft proposed rule that would reduce the burden of this rule on small businesses.