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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1308

[Docket No. CPSC- 2016-0017**]**

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

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (Commission, or CPSC) is issuing a final rule that determines 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 will not require third party testing for compliance with the mandatory prohibitions on children's toys and child care articles containing phthalates.

DATES: The rule is effective on [insert date 30 days after publication in FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John W. Boja, Lead Compliance Officer, Regulatory Enforcement, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway Bethesda, MD 20814-4408; telephone: 301-504-7300; e-mail: jboja@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) amended the CPSA and 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." 15 U.S.C. 2063(d)(3)(B).

2. Prohibitions in Section 108 of the CPSIA

Section 108(a) of the CPSIA permanently prohibits the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any "children's toy or child care article" that contains concentrations of more than 0.1 percent of di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or butyl benzyl phthalate (BBP). 15 U.S.C. 2057c(a). Section 108(b)(1) prohibits on an interim basis (*i.e.*, until the Commission promulgates a final rule), the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of "any children's toy that

can be placed in a child's mouth" or "child care article" containing concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-*n*-octyl phthalate (DNOP). 15 U.S.C. 2057c(b)(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.

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." 15 U.S.C. 2057c(b)(2). 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 permanently prohibit children's toys and child care articles containing concentrations of more than 0.1 percent of DINP, and proposing to lift the interim statutory prohibitions with respect to DIDP and DnOP. In addition, the NPR proposed adding four new phthalates, DIBP, DPENP, DHEXP, and DCHP, to the list of phthalates that cannot exceed 0.1 percent concentration in accessible component parts of children's toys and child care articles. The Commission has not finalized its proposal on phthalates in children's toys and child care articles. As the determinations NPR noted, the research providing the basis for the determinations covers the six phthalates subject to the statutory prohibition, as well as the additional phthalates the Commission proposed to prohibit in children's toys and child care articles.

[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.

This determinations final rule lists only the six phthalates subject to the statutory prohibition. However, when the Commission issues a final rule for the specified prohibited phthalates in children's toys and child care articles, the Commission will revise the list of prohibited phthalates in children's toys and child care articles to reflect the phthalates prohibited in the final rule.

B. The Proposed Rule

On August 17, 2016, the Commission published an NPR in the *Federal Register*, which proposed determinations that polypropylene (PP), polyethylene (PE), high-impact polystyrene (HIPS), and acrylonitrile butadiene styrene (ABS), with specified additives, would not contain the specified phthalates prohibited in children's toys and child care articles. *See* 81 FR 54754. A determination means that third party testing of the specified plastics with specified additives is not required to demonstrate compliance with the phthalates prohibitions on children's toys and child care articles. The NPR describes the CPSC's contracts with Toxicology Excellence for Risk Assessment (TERA) to conduct research on phthalates and provide CPSC with two research reports on phthalates that are the primary basis for the determinations.

C. Comments on the NPR

CPSC received 11 comments on the NPR. Below, we summarize the key issues raised by the comments and provide responses.

1. General and Technical Comments

Some commenters express support for the proposed rule as a means to reduce third party testing costs.

Comment 1: A commenter asserts that the proposed rule erroneously listed a catalyst as an additive. The commenter notes that a catalyst is not an additive and should not have been listed as such in the proposed rule.

Response 1: The commenter is correct that a catalyst is not an additive, but rather, is used to accelerate chemical reactions, and therefore, is not intended to be an additive that provides a feature (*e.g.*, color, flame resistance) to a plastic. However, plastic manufacturing processes can leave small amounts of catalyst in the resultant resin. These unrecovered catalysts can be considered trace materials or nonfunctional additives. Consequently, the Commission has changed "catalyst," used in the text of the proposed rule, to "unrecovered catalyst" in the text of the final rule, to more precisely identify any catalysts that remain in the plastic resin after manufacture.

Comment 2: Commenters suggest several editorial changes to the Task 12 report and the preamble of the final rule. The commenters suggested the following changes, among others, to the preamble of the rule:

- Use "propylene" instead of "PP monomer";
- Use "ethylene" instead of "PE monomer";
- Note that many additives are not added to virgin PE, and not all additives will be included in most plastic used by manufacturers;
- No longer list benzene as a raw material for HIPS; and
- No longer state that Ziegler-Natta catalysts are not directly used in the production of HIPS.

The commenters' did not suggest changes to the codified text of the rule.

Response 2: The Task 12 report is a completed work product that TERA produced under contract to the CPSC, and is not subject to modification. However, because the proposed rule was based on information in this report, and in the Task 11 report, we appreciate the technical comments and corrections. To the extent that the NPR relied on imprecise terminology, the preamble to the final rule uses the commenters' suggested changes in terminology. The Commission notes that several of the suggested changes to the Task 12 report have no bearing on the rule, and as such, no changes to the preamble to the rule are necessary.

Comment 3: A commenter suggests that the CPSC should list all the different types of plastics that qualify for a determination by their Chemical Abstracts Service Registry Number (CASRN) because the lack of this type of helpful guidance may lead to uncertainty and confusion over which plastics qualify for a determination. The commenter adds that many plastics have different types, not all of which may qualify for a determination that third party testing is not required.

Response 3: The Task 11 and Task 12 reports used both specific CASRNs and common chemical names (*e.g.*, polyethylene, polypropylene, HIPS, and ABS). Therefore, CPSC considers that a CASRN or a common chemical name is acceptable for use as a plastic identifier because the contractor's research indicates that none of the terms for the plastics researched showed that these plastics contain the specified phthalates in concentrations greater than 0.1 percent.

Suppliers may use the common name and not the CASRN to identify the plastics sold to component part manufacturers or children's product manufacturers. Additionally,

a rule listing only CASRNs could be unnecessarily restrictive, excluding versions of the specified plastics that are equally expected always to comply with the phthalates content limits. Conceivably, a plastic resin plus a specific combination of these additives could be assigned a unique CASRN, and would be excluded from using the third party testing determinations, if the determinations were limited to a defined set of CASRNs.

2. Contamination Risk and Continued Testing

Comment 4: A commenter states that molded plastics may become contaminated with phthalates if the molding machine used phthalate-containing plastics and the molds were not cleaned before the new plastics were introduced. The commenter provides a theoretical example of polyvinyl chloride (PVC) production followed by production using one of the specified plastics. The commenter did not provide data regarding the possible levels of phthalate transfer.

Another commenter states that hard plastics are at high risk of contamination with phthalates. The commenter asserts that they have measured the commenter has measured "high" concentrations of phthalates on ABS plastic during laboratory testing. The commenter did not provide any data or other specific information.

Response 4: These commenters appear to describe contamination, not intentional use of the specified phthalates in the plastics that are the subject of the current determinations proceeding. Neither commenter provides information about manufacturing ABS or other plastics to contradict the findings in the Task 12 report. Thus, we are unable to evaluate the commenters' claim.

Comment 5: A commenter suggests that the CPSC should conduct or procure "unbiased testing on the relevant plastics" to assure that none of the prohibited phthalates is present

in the plastics. The commenter suggests that if CPSC does not conduct such testing, then the current third party testing requirements should be maintained.

Response 5: The Commission's determination that the specified plastics do not contain the specified phthalates at concentrations above 0.1 percent is based on data and information about raw materials and manufacturing processes that show that phthalates are not used to, or not present at, concentrations above 0.1 percent in the finished plastic. Staff has not conducted a study specifically to test products made with the specified plastics for the presence of the specified phthalates. However, staff's experience with testing and screening of plastic products supports the conclusion, based on the raw material and manufacturing process information that the specified plastics do not contain the specified phthalates.

The final rule is based on information about the use and production of phthalates and about the production of the specific plastics. Therefore, a testing study is not necessary. The information shows that phthalates are not used as plasticizers for the specified plastics and do not have other uses that would result in phthalate content in the plastics at levels exceeding the specified limit for children's toys and child care articles. Thus, the final rule is not based on manufacturers' choices or promises to use non-phthalate formulations, but rather, the rule is based on technical studies demonstrating that phthalates have no function or value in the specified plastics.

3. Exclude Other Materials from Required Third Party Testing

Comment 6: A commenter states that phthalates are incompatible with polyolefins, and that the phthalates' cost will restrict their use to materials "absolutely necessary to make certain materials flexible when this cannot be achieved by other means."

Response 6: We agree that the available information supports a determination that the polyolefins do not contain phthalates. The rule specifically includes determinations for the polyolefins, polyethylene, and polypropylene.

Comment 7: A commenter recommends that the Commission include rigid vinyl in future assessments of whether specified plastics can be determined not to contain the specified phthalates in concentrations above 0.1 percent. The commenter states that rigid vinyl typically has a hardness of 70 or higher as measured using the Shore D durometer test method.

Another commenter suggests that the final rule incorporate a provision that plastics meeting a hardness specification are exempt from third party testing requirements. According to the commenter, because rigid plastics' hardness would be compromised by the addition of phthalates, plastics with Shore A hardness of 90 or greater are unlikely to contain any prohibited phthalate in concentrations above 0.1 percent with a high degree of assurance.

Response 7: The hardness of a plastic is not sufficient to determine the plastic's compliance to the prohibitions in section 108 of the CPSIA. The Shore A and D hardness tests were never intended to be used as indicators of the presence of phthalates at low concentrations in plastics. As noted in Tab B of the staff's briefing package, otherwise rigid plastics can be noncompliant with the 0.1 percent content limit for the specified phthalates. *See https://www.cpsc.gov/s3fs-public/Plastics-Determinations-Final-Rule-August-16-2017.pdf?wF38T29pcl.Z5lMna6tu4Yo2HxWEZwb5.*

Plasticized polyvinyl chloride (PVC) typically contains phthalates in concentrations up to 40 percent or more. "Rigid" PVC has been shown to be

noncompliant to the content limit of 0.1 percent. Furthermore, PVC is often recycled into new PVC products. Recycling of PVC provides a path for plasticized PVC to be used in a new "rigid" product that is noncompliant with the prohibitions in section 108 of the CPSIA. The determinations in the final rule for materials that do not, and will not, contain the specified phthalates at concentrations exceeding 0.1 percent are based on information about raw materials and manufacturing processes. Physical characteristics about finished products are not sufficient information to indicate that a plastic complies with the prohibitions of section 108 of the CPSIA.

Comment 8: Two commenters request that the CPSC exclude other plastic materials from required third party testing. The commenters request that the Commission determine that the materials in the following list do not contain any prohibited phthalates in concentrations above 0.1 percent, and thus, are not subject to third party testing for certification purposes, preferably by issuing a rule to that effect. The commenters provide no additional data to support the assertions that the materials on the list do not contain any prohibited phthalates:

- 1,3,5-trioxane, copolymer with 1,3-dioxolane (acetal/polyoxymethylene (POM) copolymer)
- 2,5-Furandione polymer with 1-propene (maleic anhydride grafted PP)
- 2,5-Furandione polymer with ethane (maleic anhydride grafted PE)
- Acetal/polyoxymethylene (POM) homopolymer
- Acrylic (polymethylmethacrylate and polyacrylonitrile)

- Ionomers
- Liquid crystal polymers (hydroxybenzoic acid copolymers)
- Nylon/polyamide
- Olefin thermoplastic elastomers (such as EPDM)
- Polybutene
- Polybutylene terephthalate
- Polycarbonate
- Polyesters
- Polyethylene terephthalate
- Polylactic acid
- Polyphenylene sulfide
- Polystyrene, including crystal and general-purpose (GPPS), medium-impact (MIPS) and super-high-impact (SHIPS) grades
- Polytetramethylene glycol-dimethyl terephthalate-1,4-butanediol copolymer (polyester elastomer)
- Silicone rubber (pure)
- Styrene-butadiene copolymers

- Styrene-butadiene-styrene rubbers (SBS/SBR)
- Styrene-acrylonitrile copolymers (SAN)
- Vinylidene chloride/methyl acrylate copolymers
- CMYK Process Inks
- Butadiene-ethylene resins
- Butene-ethylene copolymers
- Ethylene copolymers
- Ethylene acrylic acid copolymers
- Ethylene-propylene copolymers
- Ethylene vinyl acetate copolymers
- Ethylene vinyl acetate vinyl alcohol copolymers
- Ethylene vinyl alcohol copolymers
- Propylene-ethylene copolymers.

One of these commenters specifically requests that the Commission extend the exclusion for high-impact polystyrene (HIPS) to crystal and general-purpose polystyrene (GPPS, or GPS), medium-impact polystyrene (MIPS), and super-high-impact polystyrene (SHIPS) grades.

Another commenter urges the CPSC to continue to review other plastics for exemptions from required third party testing for phthalate content. Finally, a commenter suggests that the Commission allow suppliers of novel resin and additive combinations to warrant that the materials comply with the requirements of the CPSIA to a high degree of assurance. The commenter suggests that a third party testing exception could be granted based on "demonstrated data."

Response 8: The commenters provided no information to support their claim that the plastics they listed do not contain phthalates as a part of their manufacture or as an additive. The Commission cannot make determinations without such information.

However, after submission of the NPR to the Commission, CPSC's contractor completed another report (the Task 16 report), which included information about the additional polystyrene-based plastics, GPPS, MIPS, and SHIPS, mentioned by the commenter. [3] The Task 16 report contains information regarding the potential for GPPS, MIPS, SHIPS, and other plastics to contain any of the specified phthalates.

Staff examined the Task 16 report and determined that GPPS, MIPS, SHIPS, and HIPS can be considered members of a family of polystyrene plastics. GPPS is the polystyrene component of HIPS, MIPS, and SHIPS, as described in the Task 12 and Task 16 reports. GPPS does not involve the use of phthalates in its manufacture, or as an additive. Because GPPS is brittle, polybutadiene rubber is added as a "shock absorber," to increase the impact resistance of the polystyrene-butadiene mixture. In the

[3] *Exposure Assessment: Potential for the Presence of Phthalates in Specified Materials at Concentrations Above 0.1 Percent*, Task Order 16, Contract Number CPSC-D-12-0001, August 8, 2016, Final Report. Prepared by: Toxicology Excellence for Risk Assessment (TERA) University of Cincinnati. Available at: https://www.cpsc.gov/s3fs-public/ThePotentialforPhthalatesinSelectedPlastics.pdf.

manufacturing of polybutadiene, Ziegler-Natta catalysts, which can include DBP, DIBP, and DEHP, are used, raising the possibility that these phthalate components of the catalysts could remain in the processed plastics. However, catalysts are washed from the polybutadiene, and the remaining phthalate concentrations are not likely to exceed the 0.1 percent limit.[4]

Medium-impact polystyrene consists of GPPS with about two to five percent butadiene added.[5] HIPS typically contains 6 to 12 percent butadiene.[6] The concentration of butadiene in SHIPS ranges from 40 to 60 percent.[7] All of these polystyrenes use the same materials as HIPS in their manufacture and use the same additives to achieve desired finished component part characteristics.

The Task 16 report largely referred to the information about HIPS summarized in the previous Task 12 report because of the lack of additional references for the specific polystyrene materials and the similarities among the various polystyrene materials described in the general references. No specific reference in the Task 16 report identified the use of phthalates in production of GPPS, MIPS, HIPS, or SHIPS for consumer products. Additional research by staff did not discover any more information, suggesting that phthalates may be used to produce these polystyrene-based materials.

[4] Borealis, A.G. 2014. Polypropylene Products: Borealis' Position on Phthalates in PP Catalysts. Vienna, Austria. Available at: http://www.borealisgroup.com/Global/Company/Sustainability/polypropylene-products.pdf.
[5] Sastri, Vinny R., (2013). *Plastics in Medical Devices: Properties, Requirements, and Applications*. William Andrew, publisher, ISBN 0323265634, 9780323265638. P 107.
[6] Ibid.
[7] Deanin, Rudolph D., Crugnola Aldo M. (1976). *Toughness and Brittleness of Plastics*. American Chemical Society, ISBN13: 9780841202214. eISBN: 9780841223356. P239.

Because the Task 12 and 16 reports and staff's research show that phthalates are not used in GPPS, MIPS, and SHIPS (except as a catalyst to make the butadiene component), and the final concentration of phthalates in the polystyrene-based materials are likely to be well below 0.1 percent, the Commission agrees with the commenter that these materials can be included in the determination, along with HIPS. The codified text of the final rule adds GPPS, MIPS, and SHIPS to HIPS and the accompanying additives.

Regarding the commenter's suggestion to allow suppliers of novel resin and additive combinations to warrant that the materials comply with the requirements of the CPSIA, section 14 of the CPSA does not allow warrants to substitute for required third party testing. The Commission could consider determinations regarding third party testing requirements for new plastics or other materials in the future, if sufficient data and other information show that third party testing is not required to assure compliance. Currently, the Commission lacks those data.

Comment 9: A commenter request that the Commission "publicly identify the many types of plastic materials that will not contain the restricted phthalates in excess of 0.1 percent and that can thus be excluded from third-party testing requirements." The commenter also suggests that the Commission consider identifying the very few types of plastic materials that may contain the specified phthalates, and presumably, restrict required third party testing to those materials only. The commenter asserts that either approach would "offer added certainty to both testing laboratories and customers, of critical importance due to the high cost of phthalates testing."

Response 9: In this rulemaking, the Commission identifies several specific plastics that do not contain the specified phthalates in concentrations greater than 0.1 percent, based

on information about raw materials, manufacturing processes, and other relevant factors. Any additional recommendations for determinations would similarly require data and other information to support a conclusion that the material does not, and will not, contain the specified phthalates. At this time, staff does not have evidence supporting additional plastics determinations, and therefore, the Commission cannot make determinations for additional plastics.

Furthermore, although we understand the typical uses of phthalates and generally the types of products that may contain phthalates in concentrations exceeding 0.1 percent, we do not agree that specifying a list of products and materials that would have to be tested (as opposed to specifying materials that do not require testing to demonstrate conformance with the standard) is practical, given the range of materials that may contain phthalates and the possibility of future development of novel uses for the specified phthalates.

4. Rule Contrary to CPSC 2009 Statement of Policy and Public Law 112-28

Comment 10: A commenter asserts that the proposed rule is contrary to section 108(c) of the CPSIA (as amended by Public Law 112-28). The commenter points to a sentence in the proposed rule at § 1308.2(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.

Section 108(c) of the CPSIA states:

> APPLICATION.—Effective on the date of enactment of this Act, subsections (a) and (b)(1) and any rule promulgated under subsection (b)(3) shall apply to any plasticized component part of a children's toy or

> child care article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates.

The commenter asserts that because this language limited required third party testing for phthalate content to accessible *plasticized* component parts, and to component parts that *may contain phthalates*, required third party testing is limited "to only component parts that have had a plasticizer added to it or to component parts that could contain phthalates." The commenter adds that required third party testing is therefore not required for component parts that have not been plasticized and materials that may not contain phthalates. The commenter states that the aforementioned sentence in the proposed rule creates a new scope by applying required phthalate testing to all plastics not specifically listed in the determinations.

The commenter suggests that the language in proposed § 1308.2(c) should state:

> 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 must still be comprised of compliant materials pursuant to section 108 of CPSIA, Public Law 110-314 as amended by H.R. 2714, Public Law 112-28.

The commenter asserts that this change to the language recommended above will reflect Congressional intent and be consistent with CPSC phthalate testing policy that has been effectively used by some companies to eliminate phthalate testing on materials known to be compliant.

Response 10: The commenter is correct that section 108(c) of the CPSIA applies to this rule and that compliance to section 108 of the CPSIA is limited to plasticized component parts and other materials that may contain phthalates. As noted in the NPR preamble, children's toys and child care articles are always required to comply with the

requirements of section 108 of the CPSIA, regardless of any exceptions to required third party testing under section 14 of the CPSA.

We acknowledge that § 1308.2(c) of the proposed rule could be interpreted as conflicting with section 108(c) of the CPSIA. Thus, we have revised § 1308.2(c) in the final rule to clarify that the rule concerns accessible component parts of children's toys and child care articles made from materials that are plasticized or may contain phthalates.

We are making this change because, if a manufacturer or importer (*i.e.*, a certifier) of a children's toy or child care article has accessible component parts that have been plasticized, or are composed of a material that may contain phthalates, third party testing is required to assure compliance to section 108 of the CPSIA. Examples of materials that may contain phthalates include, but are not limited to, plastics (for which a determination has not been made), inks, solvents, surface coatings, adhesives, and some rubberized materials.

Comment 11: Two commenters claim that the NPR reverses the Commission's 2009 *Statement of Policy*, which, according to the commenters, lists a number of plastic materials other than the four plastics in the NPR that are not subject to third party testing for certification purposes. Another commenter states that the proposed rule "appears to negate the flexibility afforded in the 2009 *Statement of Policy* document on phthalates." The commenter suggests that "the flexibility granted by the CPSC's *Statement of Policy* should be maintained." The commenter asserts that this flexibility allows suppliers with supply chain knowledge to use their discretion when determining which materials to subject to third party testing.

Response 11: The Commission's 2009 guidance document, *Statement of Policy: Testing of Component Parts With Respect To Section 108 of the Consumer Product Safety Improvement Act*,[8] was intended to provide general guidance. It listed a number of materials that *might not* require third party testing. In contrast, the determination rule specifies that third party testing is not required for specified plastics with accompanying additives. The determination does not remove flexibility, but provides a clear pathway for manufacturers to know that third party testing is not required if they use the specific plastics and additives listed in the determination.

5. Due Care and Certification

Comment 12: A commenter suggests that the Commission state whether a Certificate of Compliance (COC) is required for plastics for which a third party testing determination has been made. The commenter states that if a COC is required when third party testing is not necessary, additional due diligence would be needed to ensure that the plastic material qualifies for a determination. The commenter suggests adding to the final rule a "due care" provision, similar to the provision in 16 CFR part 1109 (the component part testing rule).[9] The commenter contends that the due care requirement should apply to the phthalates determinations because of the inherent complexity involved with properly identifying the specific plastics and additives that would be exempt from testing.

Another commenter states that importers often have limited knowledge of their products' materials and lack the evidence to demonstrate compliance without testing.

[8] https://cpsc.gov/s3fs-public/pdfs/blk_media_componenttestingpolicy.pdf.
[9] http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title16/16cfr1109_main_02.tpl, Section 1109.4 (g) states: "Due care means the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Due care does not permit willful ignorance."

The commenter suggests that manufacturers use an Attenuated Total Reflectance (ATR) sensor to identify materials that do not contain prohibited phthalates.

The commenter requested that the preamble clarify that manufacturers must use due diligence to ensure that their products only have plastics that are covered by the determination. The commenter states that screening tests, conducted on a first party basis, would reduce third party testing costs while ensuring compliance to the CPSIA.

Response 12: The final rule addresses third party testing requirements for specified plastics to assure compliance to section 108 of the CPSIA. Certification of products subject to a children's product safety rule is required, regardless of whether third party testing is required. A certifier or testing party must exercise due care to ensure that no action or inaction after testing, and before distribution in commerce, would affect compliance, including contamination or degradation, while a component part or finished product is in its custody. Thus, the component part testing rule establishes due care requirements for certifiers or testing parties. To repeat the requirements in this rule would be redundant and unnecessary.

Comment 13: A commenter suggests that the final rule clarify that when certifying parties are relying on third party testing determinations for certification purposes, laboratories do not have the responsibility for:

- Determining the type of plastic;
- Verifying that the plastic is what a supplier declares;
- Confirming that there has been no contamination; and

- Confirming there have been no material changes through supply chain traceability and production safeguards.

The commenter asserts that these responsibilities reside with the certifying party (domestic manufacturer or importer).

Response 13: We agree with the commenter that the manufacturer or importer of a children's product is responsible for the product's certification. Laboratories have limited responsibilities regarding certification issues. Unless a laboratory, on behalf of a manufacturer or importer, voluntarily chooses to be a children's product or component part certifier, the laboratory is not responsible for the compliance of a tested product to the applicable children's product safety rules. The manufacturer or importer is responsible for meeting the requirements of 16 CFR parts 1107 and 1109, which generally include the responsibilities listed by the commenter.

6. Research Does Not Demonstrate High Degree of Assurance

Comment 14: A commenter asserts that the research does not provide a high degree of assurance that the specified plastics do not contain any of the specified phthalates in concentrations above 0.1 percent because data are lacking on how phthalates are used, where they occur, and their migration. The commenter also expresses concern about phthalates in recycled materials.

The commenter provides as examples:

- The presence or concentration of the specified phthalates in polyethylene was not reported in TERA report.

- Other studies cited in the Task 12 report and patents for toys and child care products did not include information on the presence of phthalates in ABS."[10]
- Zeigler-Natta catalysts (which can contain the prohibited phthalates) could remain in high-impact polystyrene at a concentration of 0.0001 percent, but no test data had been supplied to support that claim.
- There is a lack of information on phthalates in recycled plastics; and
- Information on the possibility of a plastic's contamination with a specified phthalate is also lacking.

Response 14: CPSC disagrees with the assertion that data are lacking to support the determination. The available information identifies how and where phthalates are used, and also shows the chemicals and processes used to manufacture the specified plastics. Therefore, the Commission considers the available information provides support for the conclusion that the specified plastics do not contain phthalates at levels exceeding the specified limit for children's toys and child care articles.

We agree that few studies directly measured phthalate content in the specified plastics. However, we expected that such studies might be rare, given that the available information does not indicate that phthalates might be present.

We acknowledge that the literature on recycling is not as extensive as the data on phthalates and plastics manufacturing. Nonetheless, we consider all of the information about phthalates' use and occurrence to indicate that recycling could result in plastics that

[10] TERA Task 12 report, page 57.

contain traces of phthalates. We expect that residual levels would be well below the maximum-allowed concentration in children's toys and child care articles.

In work done by a contractor and presented in the Task 12 and 16 reports, the contractor was faced with "proving a negative," *i.e*., showing that phthalates are not present in the specified plastics. The contractor employed a tiered approach to research the specified plastics. This approach narrowed the field of possible sources and assisted in identifying information that was not available (data gaps) so that focused efforts could be directed in those areas. In the Task 12 report, from a "universe" of more than 109 million sources, the contractor screened 119,800 articles for relevant information on the four plastics and phthalates. The contractor states:

> Given the search strategy and its success at getting the other information, we can be confident that if there had been information on the phthalate content of the four plastics we would have found it. In fact, the consistent lack of information amongst the many places we searched, both secondary authoritative web and library sources and primary literature sources made us highly confident that there was very little information on the specified phthalates in the four plastics.[11]

In the Task 16 report, the contractor screened more than 179,000 sources for relevant information on the specified plastics and phthalates in a nonbiased manner that was representative of the world wide literature on this subject matter. As in the Task 12 report, the contractor states that its Task 16 report search strategy and its success at obtaining other information gives them confidence that, if there had been information on the phthalate content of the specified plastics, then they would have found it.

[11] Tera Task 12 report, page 55.

Thus, for the reasons discussed above, CPSC considers the Task 12 and 16 reports to provide a high degree of assurance that the specified plastics do not contain any prohibited phthalates in concentrations above 0.1 percent.

Comment 15: A commenter recommends that the Commission exercise "extreme caution and skepticism with unproved claims of compliance with CPSC requirements." The commenter expresses concern about unintentional or unknown factors that could result in the presence of phthalates. The commenter claims that many toys have disconnected and global supply chains, and that as a consequence, U.S. toy importers often rely on laboratory test results from foreign suppliers. The commenter cites the alleged failure of an importer to meet a state standard as evidence that CPSC should exercise caution and skepticism.

Response 15: The rule is primarily based on information in the TERA Task 11, 12, and 16 reports about use and production of phthalates, and about the production of specified plastics. The available information shows that phthalates are not used as plasticizers for the specified plastics, and are not otherwise found in the plastics at levels exceeding the specified limits for children's toys and child care articles. The determinations in this rule are not based on suppliers' assertions, manufacturer's laboratory test results, or other industry attestations. We consider the information in the TERA Task 12 and 16 reports, and the additional staff research, to be sufficient to make a determination with a high degree of assurance that the specified plastics are compliant with section 108 prohibitions without requiring third party testing.

Regarding the commenter's concerns about unintentional or unknown factors, we note that manufacturers and importers are required to have a high degree of assurance

that their products are compliant to the applicable children product safety rules. Furthermore, manufacturers and importers are responsible for exercising due care to ensure their children's products comply with the applicable children's product safety rules. 16 CFR 1109.5(b)(3).

Comment 16: A commenter states that the contractor (TERA) engaged by the CPSC to study phthalate use and investigate the presence of phthalates in four specified plastics may have a conflict of interest. The commenter notes TERA's past litigation support for regulated industries. The commenter asserts TERA's potential conflict of interest is exemplified in a 2016 paper sponsored by a chemical manufacturers' trade group.[12]

The commenter adds that TERA is a founding member of the Alliance for Risk Assessment (ARA). The ARA's Standing Panel includes the TERA founder, two industry consultants, employees of Dow Chemical and ExxonMobil, and two government employees. The commenter alleges that, in light of TERA's relationship with ExxonMobil, TERA's conclusions should be viewed with caution.

Response 16: We consider TERA to be an independent organization[13] that focuses on advancing the science of toxicology and risk assessment. We do not agree that work by TERA or individual TERA staff in scientific projects, workshops, or publications concerning industrial chemicals or products or that include chemical firms, industry employees, or trade organizations necessarily indicates unreliable performance or improper influence in CPSC contract work.

[12] *Approaches for describing and communicating overall uncertainty in toxicity characterizations: U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) as a case study.* The publication can be found at: https://www.ncbi.nlm.nih.gov/pubmed/26827183.
[13] Staff notes that after the contract work discussed here, TERA reorganized as the Risk Science Center at the University of Cincinnati: https://med.uc.edu/eh/centers/rsc.

As standard procedure, CPSC reviews potential conflicts of interest before awarding a contract or task order. We did not identify any conflicts for TERA related to the investigation of the production and use of phthalates or the production of the specified plastics.

We do not agree that the membership in ARA is evidence of a potential conflict of interest. Rather, we consider ARA to be a transparent, multi-stakeholder scientific collaboration to develop risk assessment information to advance public health activities. Furthermore, the commenter does not specify any projects by the ARA that suggest that the contracted TERA work is affected by potential conflicts of interest.

In summary, the commenter did not provide any specific information that shows that the reports produced by TERA under contract with CPSC have been affected by potential conflicts of interest. Nor did the commenter show that the reports contain inaccurate or misleading data or information.

7. Out of Scope Comments

We also received comments on issues such as random spot checking for certificates of compliance, developing a procedure for petitioning the Commission for determinations, identifying statistical averaging and margins of error under which products could still be considered compliant, allowing other techniques beyond materials determinations for lead content testing that could reduce third party testing costs, asking Congress for authority to implement commenter's suggestions, determinations for lead content, and the inclusion of supply chain controls when noncompliant products are found. This rulemaking is limited to determinations regarding phthalate content in

specified plastics. The aforementioned comments are outside the scope of this rulemaking.

D. Determinations for Specified Plastics with Certain Additives

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 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.

The determinations will only relieve the manufacturer's 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 from third party testing requirements. Additionally, the manufacturer must issue a certificate stating that the product complies with CPSC requirements.

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.[14] 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 used in children's toys and child care articles 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, 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

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

requirements of section 108 of the CPSIA can be assured without requiring third party testing. To reduce the third party testing burden on children's product certifiers while continuing to assure compliance, the CPSC has determined with a high degree of assurance that the 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. 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 makes 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, as 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 determinations will relieve the specified plastics and accompanying additives from the third party testing requirement of section 14 of the CPSA to support the required certification. However, the determinations would not apply to any other plastic or additives beyond those listed in the rule.

3. Description of the Final Rule

The rule creates a new part 1308 for "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics." The rule determines that the specified 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.

Section 1308.1 of the 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. This section is unchanged from the proposed rule. As discussed in section A.2 of the preamble, currently, the agency is 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. At the time of publication of this final rule in the *Federal Register*, the Commission has not issued a final rule in the phthalates rulemaking. Therefore, this determinations rule lists the phthalates that are statutorily prohibited from being in children's toys and child care articles under section 108 of the CPSIA.

Section 1308.2(a) of the rule establishes the Commission's determinations that the following seven plastics do not exceed the phthalates content limits with a "high degree of assurance" as that phrase is defined in 16 CFR part 1107. Section 1308.2(a) of the rule is being finalized as proposed, except for the following changes. The final rule:

- Adds "naphthenic oil" to the list of PP plasticizers in § 1308.2(a)(1)(i). Naphthenic oil is a nonphthalate plasticizer listed with paraffinic and mineral plasticizing oils in a Task 12 report reference and should have been included in the proposed rule but was inadvertently omitted;
- Adds the word "unrecovered" before "catalysts" in §§ 1308.2(a)(1)(iii), (a)(2)(iv), (a)(3)(i), (a)(4)(vii) of the final rule to clarify that this additive refers to small amounts of catalyst that may remain in a plastic resin after manufacture;
- Adds general purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), and super high-impact polystyrene (SHIPS) to § 1308.2(a)(3), to high-impact polystyrene (HIPS) that was listed in the proposed rule, to the list of materials that can be determined not to require third party testing in order to assure compliance with section 108 of the CPSIA. This change is made based on a commenter's suggestion and supporting information from the Task 16 report. These three plastics, along with HIPS, can be considered members of a family of polystyrene plastics manufactured with the same raw materials and processes. The potential additives for GPPS, MIPS, and SHIPS are the same as those for HIPS;
- Replaces the term "phosphate esters" in § 1308.2(a)(4)(i) with "hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), and oligomeric phosphate" to more precisely identify the ABS plasticizers listed. The

specific phosphate esters added were listed and discussed in the preamble of the NPR and the underlying staff briefing package, but were inadvertently left out of the codified text in the NPR; and

- Deletes "hydrocarbon solvents" from the list of additives for PP in § 1308.2(a)(1)(ii) and ABS in § 1308.2(a)(4)(ii) because hydrocarbon solvents are not additives but rather are used in the production of resin. The list of additives in §§ 1308.2(a)(1)(ii) and (a)(4)(ii) has been renumbered to reflect this change.

Section 1308.2(b) of the 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 this section, are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107. Section 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. This provision is unchanged from the proposed rule.

Section 1308.2(c) of the rule has been revised to add the phrase "that are plasticized or may contain phthalates" between "in paragraph (a) of this section" and "are required to be third party tested." The new language tracks the statutory language of section 108(c) of the CPSIA regarding component parts of children's toys or child care articles that are plasticized or may contain phthalates. If a manufacturer or importer (*i.e.*, a certifier) of a children's toy or child care article has accessible component parts that have been plasticized, or are composed of a material that may contain phthalates, third party testing is required to assure compliance to section 108 of the CPSIA. This change

has been made because the language of § 1308.2(c) of the proposed rule could be interpreted as conflicting with section 108(c) 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). The Commission proposed a 30-day effective date because the rule provides relief from existing testing requirements under the CPSIA. No comments were received regarding the effective date. The effective date for the rule is 30 days from the date of publication of the rule in in the *Federal Register*.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed and final rules on small entities, including small businesses. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis (FRFA) when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The FRFA must describe the impact of the rule on small entities. CPSC staff prepared a FRFA. *See* Tab C of staff's briefing package at https://www.cpsc.gov/s3fs-public/Plastics-Determinations-Final-Rule-August-16-2017.pdf?wF38T29pcl.Z5lMna6tu4Yo2HxWEZwb5. We provide a summary below.

The rule is intended to reduce the burden of third party testing on manufacturers of children's toys and child care articles consistent with assuring compliance with CPSC requirements under section 14 of the CPSA, as amended by section 2 of Public Law 112-28. The final rule would reduce the burden of third party testing on manufacturers and

importers of children's toys and child care articles by establishing determinations for certain plastics (PP, PE, GPPS, MIPS, HIPS, SHIPS, and ABS) and accompanying additives. Based on these determinations, the specified plastics with specified additives will not require third party testing for compliance with the mandatory prohibitions on children's toys and child care articles containing phthalates.

Although comprehensive estimates of the number of products that contain components made from the specified 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.[15] The same source also stated that low-density polyethylene, polystyrene, and acrylonitrile butadiene styrene, are each used in less than 10 percent of injection-molded toys.

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 specified plastics are used extensively in toys, staff believes a substantial number of small entities would be impacted positively by this regulation.

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 third party testing for phthalates is between approximately $125 and $350 per test, depending on where the testing is conducted and any discounts that might be applicable.[16] Because one product might have several component parts that

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

require testing, the cost to test a finished product for phthalate content may be substantially higher. To the extent that small entities have lower production volumes than larger entities, these determinations would be expected to have a disproportionately beneficial impact on small entities because the costs of the tests are distributed over fewer units. Additionally, some laboratories may offer their larger customers discounts that might not be available to small entities that need fewer third party tests. However, the benefit of making the determinations could be less than might be expected. For example, some manufacturers might have already substantially reduced their third party phthalate testing costs by using the component part testing under 16 CFR part 1109. Therefore, the marginal benefit that might be derived from making the determinations might be low. Some importers might not be certain of what materials are actually being used in each component part and might not be able to use the determinations without testing.

Under section 604 of the Regulatory Flexibility Act, a FRFA should include a "statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected." The final rule is itself, the result of CPSC's efforts to reduce third party testing costs consistent with assuring compliance with all applicable consumer product safety rules. Therefore, CPSC considered few alternatives, other than expanding the list of plastics for which determinations could be made. We note that the final rule includes determinations for three additional polystyrenes (GPPS, MIPS, and SHIPS) that were not included in the NPR.

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 amends title 16 of the Code of Federal Regulations by adding 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.

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, isooctyl tallate, paraffinic, naphthenic, and mineral plasticizing oils, and polyol;

(ii) Unrecovered catalysts;

(iii) Fillers;

(iv) Primary and secondary antioxidants;

(v) Neutralizing agents;

(vi) Antistatic agents;

(vii) Slip agents;

(viii) Metal deactivators;

(ix) Quenchers;

(x) UV stabilizers;

(xi) Nucleating agents;

(xii) Flame retardants;

(xiii) Blowing or foaming agents;

(xiv) Antiblocking agents;

(xv) Lubricants; or

(xvi) 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) Unrecovered 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) General purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), and super high-impact polystyrene (SHIPS) with any of the following additives:

(i) Unrecovered 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 hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, long chain fatty acid esters and aromatic sulfonamide;

(ii) Stabilizers;

(iii) Lubricants;

(iv) Antioxidants;

(v) Molecular weight regulators;

(vi) Initiators/unrecovered catalysts,

(vii) Activators;

(viii) Emulsifiers; or

(ix) 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 that are plasticized or may contain phthalates are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Dated: August 25, 2017

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Todd A. Stevenson, Secretary
Consumer Product Safety Commission

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