



January 20, 2016

**Comments from Earthjustice, Natural Resources Defense Council and Washington Toxics Coalition on Problem Formulation and Data Needs Assessment for the Brominated Phthalates Flame Retardant Cluster**, Docket ID: EPA-HQ-OPPT-2014-0491

The following comments are submitted by Earthjustice, Natural Resources Defense Council (“NRDC”) and Washington Toxics Coalition on the U.S. Environmental Protection Agency’s (“EPA” or “the Agency”) August 2015 Toxic Substances Control Act (“TSCA”) Work Plan Chemical Problem Formulation and Data Needs Assessment for the Brominated Phthalates Cluster (“BPC”) of flame retardants (“Data Needs Assessment”). Earthjustice submits these comments on behalf of NRDC and Washington Toxics Coalition. NRDC and Washington Toxics Coalition submit these comments on behalf of their millions of members and online activists. Earthjustice, NRDC, and Washington Toxics Coalition have no financial interest in the chemicals or products that are the subject of these comments.

We commend EPA for undertaking an evaluation of the brominated phthalate flame retardant chemical cluster. EPA added these chemicals to its Work Plan because it expects that these chemicals, which are used extensively in consumer products, are persistent, bioaccumulative, and potentially hazardous to human health and the environment.<sup>1</sup> These comments address the following documents prepared by EPA on the BPC flame retardant chemicals:

- **TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment Brominated Phthalates Cluster Flame Retardants** (EPA document 740-Q1-4004, referred to as the “Data Needs Assessment” in our comments)
- **TSCA Work Plan Chemical Technical Supplement – Physicochemical Properties and Environmental Fate of the Brominated Phthalates Cluster (BPC) Chemicals** (EPA document 740-Q1-4001, referred to as the “Physicochemical Properties and Environmental Fate Supplement” in our comments)
- **TSCA Work Plan Chemical Technical Supplement – Hazard Assessment of the Brominated Phthalates Cluster (BPC) Chemicals** (EPA document 740-Q1-4003, referred to as the “Hazard Assessment Supplement” in our comments)
- **TSCA Work Plan Chemical Technical Supplement - Use and Exposure of the Brominated Phthalates Cluster (BPC) Chemicals** (EPA document 740-Q1-5001, referred to as the “Use and Exposure Supplement” in our comments).

## **BACKGROUND AND INTRODUCTION**

There is strong evidence that the BPC flame retardants may pose unreasonable risks. EPA ignored legal requirements to issue a data call-in for TBB and TBPH and initiate a test rule (or explain why it is not doing so), and improperly relied on confidential business information claims to conceal health and safety information about these chemicals from the public. EPA furthermore improperly

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<sup>1</sup> Data Needs Assessment at 9.

delayed ruling on, and then denied, our request for an extension of the comment period that was only necessary because these documents, which should have been in the public domain, were inaccessible.

### **There Is Strong Evidence that the BPC Flame Retardants May Pose Unreasonable Risks**

There is good reason to be concerned that the BPC flame retardants pose unreasonable risks to human health and the environment. Toxicity testing links BPC chemicals to hormone disruption and DNA damage.<sup>2,3,4</sup> The types of health effects caused by Firemaster 550 in animal tests are serious and significant-- early puberty, excessive weight gain, and decreased performance in behavioral tests.<sup>5</sup> EPA's Design for the Environment Program ("DfE") designated benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester (CAS 183658- 27-7) ("TBB") as highly persistent based on the expected persistence of the parent compound in soil as well as the persistence of degradation products. There is also evidence for bioaccumulation of TBB and its metabolite tetrabromobenzoic acid (TBBA). DfE gave TBB a high hazard designation for bioaccumulation based on detections in multiple species, including mollusks, fish, birds, seals, polar bears, and finless porpoises.<sup>6,7</sup> TBB has been found in human breast milk and serum, and its metabolite tetrabromobenzoic acid (TBBA) is present in the urine of adults and children.<sup>8,9</sup>

TBB and 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester (CAS 26040-51-7) ("TBPH") are omnipresent in the environment. They have been frequently observed in the atmosphere, and the sum of the two compounds is estimated to be doubling in concentration every year in urban areas and every 1.6 years in rural areas.<sup>10</sup> TBB and TBPH have been detected in

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<sup>2</sup> Berr, J., HM Stapleton, and CL Mitchelmore, Accumulation and DNA damage in fathead minnows (*Pimephales promelas*) exposed to 2 brominated flame-retardant mixtures, Firemaster® 550 and Firemaster® BZ-54. *Environmental Toxicology and Chemistry* 2010, 29, (3), 722-729.

<sup>3</sup> Patisaul, H.; Roberts, S.; Mabrey, N.; McCaffrey, K.; Gear, R.; Braun, J.; Belcher, S.; Stapleton, H., Accumulation and endocrine disrupting effects of the flame retardant mixture Firemaster®550 in rats: an exploratory assessment. *J Biochem Molecular Toxicology* 2013, 27, (2), 124-136.

<sup>4</sup> La Guardia, M.; Hale, R.; Harvey, E.; Mainor, T.; Ciparis, S., In Situ accumulation of HBCD, PBDEs, and several alternative flame retardants in the bivalve (*Corbicula fluminea*) and gastropod (*Elimia proxima*). *Environ. Sci. Technol.* 2012, 46, 5798-5805.

<sup>5</sup> Patisaul, H.; Roberts, S.; Mabrey, N.; McCaffrey, K.; Gear, R.; Braun, J.; Belcher, S.; Stapleton, H., Accumulation and endocrine disrupting effects of the flame retardant mixture Firemaster®550 in rats: an exploratory assessment. *J Biochem Molecular Toxicology* 2013, 27, (2), 124-136.

<sup>6</sup> La Guardia, M.; Hale, R.; Harvey, E.; Mainor, T.; Ciparis, S., In Situ accumulation of HBCD, PBDEs, and several alternative flame retardants in the bivalve (*Corbicula fluminea*) and gastropod (*Elimia proxima*). *Environ. Sci. Technol.* 2012, 46, 5798-5805.

<sup>7</sup> Zhu, B.; Lai, N.; Wai, T.-C.; Chan, L.; Lam, J.; Lam, P., Changes of accumulation profiles from PBDEs to brominated and chlorinated alternatives in marine mammals from the South China Sea. *Env Int* 2014, 66, 65-70

<sup>8</sup> Zhou, S.; Buchar, A.; Siddique, S.; Takser, L.; Abdelouahab, N.; Zhu, J., Measurements of selected brominated flame retardants in nursing women: implications for human exposure. *Environ Sci Technol* 2014, 48, 8873-8880

<sup>9</sup> Butt, C.; Congleton, J.; Hoffman, K.; Fang, M.; Stapleton, H., Metabolites of organophosphate flame retardants and 2-ethylhexyl tetrabromobenzoate in urine from paired mothers and toddlers. *Environ Sci Technol* 2014, 48, (17), 10432-8.

<sup>10</sup> Ma, Y.; Venier, M.; Hites, R., 2-Ethylhexyl tetrabromobenzoate and bis(2-ethylhexyl) tetrabromophthalate flame retardants in the Great Lakes atmosphere. *Environ. Sci. Technol.* 2012, 46, (1), 204-8.

recent indoor air sampling of U.S. homes.<sup>11</sup> They have also been found in air samples in the Arctic, far from point sources, which indicates long-range transport.<sup>12</sup> TBB and TBPH have also been measured in surface water, with frequent detections in the Great Lakes, and in laundry water, which suggests a consumer product source.<sup>13</sup>

### **EPA Ignored Legal Requirements to Issue a Test Rule and Data Call-in for TBB and TBPH**

Despite the importance of EPA's effort to characterize the risks posed by the BPC chemicals, the Data Needs Assessment, and the process used to develop it, are deeply flawed. EPA bears responsibility for the significant data gaps that it claims prevent it from moving forward with this risk assessment, because the Agency appears to have ignored the November 2011 recommendation of the Interagency Testing Committee ("ITC") that EPA give "priority consideration" to issuing a TSCA section 4(e) test rule for TBB and TBPH.<sup>14</sup> By failing to either initiate a test rule rulemaking within 12 months of the ITC recommendation or publish an explanation for not doing so, EPA has violated a mandatory duty under TSCA section 4(e). This violation has denied EPA, other federal agencies, and the public important information about the toxicity of chemicals used extensively in consumer products.

Not only has EPA violated TSCA by failing to give priority consideration to adopting a test rule for TBB and TBPH, it also appears to have violated its own regulations by not adding TBB or TBPH to the list of chemicals subject to a TSCA section 8(d) data call-in, which its regulations require once ITC has recommended testing.<sup>15</sup> As a result, EPA has failed to seek from the chemical manufacturers the health and safety studies for TBB and TBPH to which it is legally entitled.

### **EPA Has Improperly Relied on CBI to Conceal Health and Safety Information about TBB and TBPH from the Public**

Equally concerning, both for the BPC risk assessment and for future TSCA risk assessments, is that the Data Needs Assessment reveals multiple ways in which EPA has unlawfully approved a chemical manufacturer's effort to hide critical health and safety information about the BPC chemicals under the guise of "Confidential Business Information" ("CBI").

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<sup>11</sup> Schreder ED, La Guardia MJ, Uding N. Inhalation exposure to chlorinated organophosphate and other flame retardants: respirable vs. inhalable intake. Beijing, China: International Symposium on Flame Retardants (BFR) 2015; 2015.

<sup>12</sup> Salamova A, Hermanson MH, Hites RA. Organophosphate and Halogenated Flame Retardants in Atmospheric Particles from a European Arctic Site. *Environ Sci Technol* [Internet]. 2014 Jun [cited 2014 Jun 16];48(11):6133-40. Available from: <http://pubs.acs.org/doi/abs/10.1021/es500911d>

<sup>13</sup> La Guardia, M.; Hale, R.; Harvey, E.; Mainor, T.; Ciparis, S., In Situ accumulation of HBCD, PBDEs, and several alternative flame retardants in the bivalve (*Corbicula fluminea*) and gastropod (*Elimia proxima*). *Environ. Sci. Technol.* 2012, 46, 5798-5805; also Schreder, E.; La Guardia, M., Flame retardant transfers from U.S. households (dust and laundry wastewater) to the aquatic environment. *Environ Sci Technol* 2014, 48, 11575-11583.

<sup>14</sup> See Sixty-Ninth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments, 77 Fed. Reg. 30,856 (May 23, 2012).

<sup>15</sup> See 40 C.F.R. § 790.20(b).

We are particularly troubled that EPA allowed the flame retardant manufacturer Chemtura to assert that more than a dozen health and safety studies relating to BPC chemicals, which Chemtura submitted to the EPA in 2012, are CBI.<sup>16</sup> TSCA flatly prohibits the use of CBI claims to withhold health and safety studies from the public.<sup>17</sup> Yet EPA did not question Chemtura's CBI claim, despite the clear language of TSCA section 14 and the Agency's own policy, adopted in 2010 (two years before the Chemtura submission), that it will "begin a general practice of reviewing confidentiality claims for chemical identities in health and safety studies."<sup>18</sup>

In addition, when the Data Needs Assessment was released in August 2015, EPA improperly referred to two of the chemicals in the BPC cluster as "Confidential A" and "Confidential B" without any generic identification and without providing an accession number, denying the public information about these chemicals to which they are entitled under EPA's own TSCA regulations.<sup>19</sup>

On December 9, 2015, one week before the close of the public comment period, and only in response to repeated requests from another public interest organization, EPA released generic identifiers and accession numbers for these chemicals.<sup>20</sup> With this information, we determined that a TSCA Section 5(e) consent order is in effect for "Confidential A" and we made a special request to EPA to obtain a copy of the consent order. We received a "sanitized" version of the consent order on December 22, 2015, nearly a week after the close of the comment period on December 16, 2015. A copy of that consent order, dated January 13, 2009, is attached hereto as Exhibit B. The consent order indicates that Confidential A is intended for use in consumer products (though the precise use is claimed to be CBI), and that there are concerns for liver and kidney toxicity and possible carcinogenicity, as well as concerns that the chemical is persistent, bioaccumulative, and toxic. The consent order states that Confidential A "will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance." None of EPA's concerns about Confidential A are reflected in the Data Needs Assessment or the Technical Supplement documents.

In sum, EPA violated TSCA by failing to take required actions in response to the ITC recommendation, including failing to issue a data call-in for TBB and TBPH. This has allowed chemical manufacturers to keep existing health and safety studies out of the public domain, and has delayed new testing on TBB and TBPH by several years. In addition, EPA's actions have effectively concealed from the public health and safety studies for TBB and TBPH that are in the Agency's possession, as well as the consent order for Confidential A (reflecting EPA's serious concerns about exposures and toxicity).

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<sup>16</sup> See Letter from Nancy McIntyre, Chemtura, to EPA OPPT Docket Control Office (Aug. 27, 2012) (enclosing a "CD containing CONFIDENTIAL studies" and attaching a non-CBI list of the studies, which makes clear that at least some of them are health and safety studies), a copy of which is attached as Exhibit A.

<sup>17</sup> See 15 U.S.C. § 2613(b).

<sup>18</sup> Claims of Confidentiality of Certain Chemical Identities Contained in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act, 75 Fed. Reg. 29,754 (May 27, 2010).

<sup>19</sup> See 40 C.F.R. §§ 720.85(b), 720.90(d).

<sup>20</sup> EPA-HQ-OPPT-2014-0491-0009, PMN number associated with two substances identified as Confidential A and Confidential B in the Brominated Phthalates Cluster Flame Retardants Data Needs Assessment: Docket EPA-HQ-OPPT-2014-0491, available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2014-0491-0009>.

**EPA Improperly Delayed Ruling on, and then Denied, Our Request for an Extension of the Comment Period That Was Only Necessary Because Documents that Should Have Been in the Public Domain Were Inaccessible.**

We raised concerns with EPA about the improperly designated CBI studies and the lack of access to the consent order for “Confidential A” on December 11, 2015. At the same time, we sought an extension of the public comment period on the Data Needs Assessment until the studies improperly designated as confidential and other non-public materials relating to the risks presented by these chemicals were made available. The Agency did not finally respond to our request until January 12, 2016, several weeks after the official comment period expired on December 16, 2015. The Agency spoke to us by phone several times after the extension request was submitted, alerting us to how we could locate summaries of some of the Chemtura-designated-CBI studies in the public domain, and also released the sanitized consent order. However, none of the full health and safety studies of BPC chemicals conducted by Chemtura are in the public domain and for several of the studies, even summaries are not available.

EPA’s delay in responding to, and ultimate denial of, our extension request has ensured that the existing studies and consent order could not be discussed in public comments submitted during the official comment period. While EPA has advised us that it will read the comments we are submitting today, and will place the comments into the official docket on Regulations.gov, it has declined our request to confirm that these comments, which were delayed because the Agency did not comply with TSCA or its own regulations and policies, will be accorded the same weight and consideration as comments submitted during the official comment period.

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Our concerns about the Data Needs Assessment are summarized here and discussed in detail below.

- 1. Confidential business information (“CBI”) is inappropriately used to conceal critical information from the public.**
- 2. EPA should immediately issue a Section 8(d) Data Call-in and Section 4 Test Rules for TBB and TBPH.**
- 3. A systematic review process should be used to conduct a comprehensive literature search and document evidence before the Office of Pollution Prevention and Toxics (“OPPT”) draws conclusions about the available data and their adequacy.**
- 4. OPPT should make clear whether they reviewed original studies or summaries, and original studies should be made available. Studies underlying a number of the hazard conclusions are not publicly available and there are problematic interpretations of hazard data.**
- 5. The hazard endpoints of liver toxicity and carcinogenicity should be included as critical data needs.**
- 6. OPPT erroneously interprets a lack of testing as evidence that chemicals are not present. Such issues must be flagged as important data gaps that need to be filled.**
- 7. Degradation and toxic combustion products of these flame retardants should be considered.**
- 8. Electronics must be considered as uses and sources of exposure for both TBB and TBPH.**
- 9. Data indicate that TBPH release from PVC occurs and this must be included in the assessment.**

**10. BPC chemicals are used in mixtures and people will be co-exposed to these chemicals. OPPT must account for the risks presented by such mixtures, and should evaluate whether data are sufficient to move forward with assessment of the mixtures.**

**DETAILED COMMENTS**

**1. Confidential business information (“CBI”) is inappropriately used to conceal critical information from the public.**

As we mentioned at the outset of these comments, we are very concerned about the extensive invocation of “CBI” in the Data Needs Assessment to withhold important information about the BPC chemicals, to conceal health and safety studies relied on by EPA in developing the Data Needs Assessment, and even to obscure the identity of chemicals that are included in the BPC.

For a CBI claim to be valid, it must comply with requirements of TSCA section 14(a), which allows information to be designated CBI only if it meets:

- the criteria for the Freedom of Information Act’s (FOIA’s) trade secret/CBI exemption<sup>21</sup> and
- EPA’s CBI criteria, including that the “business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business’s competitive position.”<sup>22</sup>

TSCA section 14(a) cannot be used to prohibit the disclosure of “any health and safety study” or “any data reported to, or otherwise obtained by, the Administrator from a health and safety study.”<sup>23</sup> TSCA defines the term “health and safety study” very broadly as including: “any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.”<sup>24</sup>

As discussed in the Background and Introduction above, we are deeply concerned that EPA allowed Chemtura to assert that health and safety studies they submitted in 2012 are CBI, in contravention of TSCA section 14(b) and EPA’s own policy. EPA must ensure that this error is corrected as soon as possible. Because these studies were relied on by EPA in preparing the Data Needs Assessment, they should be made publicly available. EPA has inaccurately advised us that the studies are already in the public domain and are cited in the Australian Government National Industrial Chemicals Notification and Assessment Scheme (NICNAS) assessment.<sup>25</sup> Our review indicates that the NICNAS assessment provides only study summaries, some of which set forth inaccurate interpretations of the study data. It is unclear who wrote the study summaries (NICNAS or the

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<sup>21</sup> 15 U.S.C. § 2613(a); *see also* 5 U.S.C. § 552(b)(4).

<sup>22</sup> 40 C.F.R. § 2.208(e)(1).

<sup>23</sup> 15 U.S.C. § 2613(b). The only exception to the rule that health and safety studies cannot be CBI is that “any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture” can be claimed as CBI. *Id.*

<sup>24</sup> 15 U.S.C. § 2602(6).

<sup>25</sup> National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Full Public Report, Firemaster BZ-54 File No. STD/649 (November 11, 2004), *available at* [https://www.nicnas.gov.au/data/assets/pdf\\_file/0004/9418/NA649FR.pdf](https://www.nicnas.gov.au/data/assets/pdf_file/0004/9418/NA649FR.pdf)

chemical manufacturer/ testing lab). Furthermore, at least four of the Chemtura 2012 health and safety studies are not cited or summarized in the NICNAS assessment.<sup>26</sup> At a minimum, these studies should be placed in the docket.

In other respects, too, the Data Needs Assessment itself improperly withholds information from the public under the guise that it is CBI. For example, EPA asserts that the uses of “Confidential A” and “Confidential B,” as well as information about the general population and consumer exposures to “Confidential A” and “Confidential B” are CBI.<sup>27</sup> We disagree. Information about exposures falls within the definition of a “health and safety study” and cannot be claimed as CBI. We ask that EPA either revise the Data Needs Assessment to include this information or place it on the docket so it is in the public domain.

Unreasonable claims of CBI are even applied to the manufacturer’s identity. In Table 1-2 of the Use and Exposure Supplement, three manufacturers of TBPH are identified: Teknor Apex, Unitex and “CBI.” Perhaps “CBI” refers to Chemtura, but how can it be CBI that Chemtura manufactures TBPH when, as stated on page 5 of the Use and Exposure Supplement, this information appears on Chemtura’s own website? EPA should immediately clarify whether Chemtura submitted a 2012 CDR report for TBPH, and if so it should insist that the CBI designation be removed since this information is in the public domain. If Chemtura did not submit a CDR report, then that would constitute a violation of 15 U.S.C. § 2614(3), and EPA should move forward with penalties as prescribed by 15 U.S.C. § 2615. In any event, since EPA acknowledges that Chemtura manufactures TBPH, it should amend the Use and Exposure Supplement to add the production volume, or it should explain why Chemtura has a valid claim that its production volume for TBPH is CBI.

Furthermore, the Data Needs Assessment asserts that production volumes for TBB, “Confidential B,” TBPA-diol (mixed esters) are CBI.<sup>28</sup> Again, we disagree. What explanations have the manufacturers provided to show that revealing this information would cause “substantial harm to the business’s competitive position”? This inappropriate invocation of CBI is particularly concerning since EPA claims it cannot rely on some data claimed as CBI, which will hamper its ability to accurately assess exposures and determine risk. We ask that EPA reconsider the appropriateness of the assertion that this information is CBI.

Finally, the Data Needs Assessment cryptically asserts that “[s]ome [c]onfidential data may be applicable to the data gaps for the non-CBI cluster members.”<sup>29</sup> We ask that EPA explain what kind of “confidential data” it is referring to and on what basis it is CBI. If this data is exposure data, or other types of health and safety information, it cannot be considered CBI and EPA should revise the Data Needs Assessment to include this information, or place it in the docket so it is in the public domain. In any event, in the interest of transparency, EPA should explain what kind of data it is withholding and why it is CBI.

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<sup>26</sup> These are: Porous Pot Biodegradability, Migration Protocol, 2-generation reproductive toxicity, prenatal developmental toxicity.

<sup>27</sup> Data Needs Assessment at 26.

<sup>28</sup> Data Needs Assessment at 18-19, Table 2-1.

<sup>29</sup> Data Needs Assessment at 27, n. 8.

## 2. EPA Should Immediately Issue Section 4 Test Rules and a Section 8(d) Data Call-in for TBB and TBPH

It is painfully ironic that EPA cites a lack of health and safety data for TBB and TBPH, because EPA has been under a legal obligation since 2012 to obtain additional data but has failed to take the required actions. In 2012, the ITC added TBB and TBPH to the TSCA section 4(e) Priority List,<sup>30</sup> meaning that it recommended that EPA “should give priority consideration for the promulgation of a [TSCA test] rule under [section 4(a)].”<sup>31</sup> Under TSCA section 4(e), within 12 months after a chemical substance is added to the Priority List, “the Administrator *shall* with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) of this section or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.”<sup>32</sup> As far as we can determine, EPA has not fulfilled this mandatory obligation because it has neither initiated a rulemaking proceeding to adopt a test rule, nor published notice in the Federal Register explaining its decision not to do so. In the words of a federal court addressing a similar circumstance, “EPA's decision to withhold final promulgation of test rules thus subverts the essence of the statutory scheme.”<sup>33</sup> We urge EPA to cease “subvert[ing] the essence” of the testing scheme established by Congress, and to move expeditiously to comply with TSCA section 4(e) with respect to TBB and TBPH.<sup>34</sup>

EPA should also act swiftly to comply with its own regulation that requires a Section 8(d) data call-in for all chemicals on the ITC Priority List. Under 40 C.F.R. § 790.20(b), once a chemical has been added to the ITC Priority List, EPA's regulations require it to:

(2) . . . publish a Federal Register document adding all ITC-recommended chemicals to the automatic reporting provisions of its rules under sections 8(a) and 8(d) of TSCA (40 CFR parts 712 and 716).

(3) ... hold a public “focus meeting” to discuss the ITC's testing recommendations and obtain comments and information from interested parties.

(4) ... evaluate submissions received under TSCA sections 8(a) and 8(d) reporting requirements, comments filed on the ITC's recommendations, and other information and data compiled by the Agency.

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<sup>30</sup> 77 Fed. Reg. 30,856 (May 23, 2012).

<sup>31</sup> 15 U.S.C. § 2603(e).

<sup>32</sup> 15 U.S.C. § 2603(e)(1)(B) (emphasis added).

<sup>33</sup> *Natural Resources Defense Council, Inc. v. U.S. E.P.A.*, 595 F. Supp. 1255, 1270 (S.D.N.Y. 1984).

<sup>34</sup> There should be no doubt that TBB and TBPH meet the criteria for a section 4 test rule. Under TSCA section 4(a), testing may be required either due to potential risk or high exposure. EPA has already found that TBB meets the Section 4(a) “may present” criteria for risk and TBPH meets the criteria for high exposure. *See* Data Needs Assessment at 7 (“EPA/OPPT found that ... the data ... are sufficient to support a determination that TBB may present an unreasonable risk in certain scenarios”); *id.* at 11-12 (“Monitoring data show that [TBPH and TBB] are present not only in environments where chemicals are expected (homes, aircrafts, cars and office buildings), but also in environments where anthropogenic chemicals are not expected (natural environment and wildlife) raising concerns about exposure to these chemicals”); *id.* at 18 (TBPH is a high production volume chemical).

(5) ... make a preliminary staff determination of the need for testing and, where testing appears warranted, will tentatively select the studies to be performed.

(6) ... hold a public meeting to announce its preliminary testing determinations.

As far as we can determine, EPA has taken none of these steps. We strongly urge EPA to move forward with “publish[ing] a Federal Register document adding [TBB and TBPH] to the automatic reporting provisions of its rules under section[] . . . 8(d) of TSCA.”<sup>35</sup> Once the data call-in is issued, manufacturers of TBB and TBPH will have a relatively short window of time in which to submit to EPA “(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to [TBB and TBPH] at any time, (B) known to such person, or (C) reasonably ascertainable by such person; and (2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.”<sup>36</sup> This information will help EPA to:

- conduct a needed systematic review (as discussed in section 3 below);
- obtain and make public original studies where it now relies on summaries (some of which are inaccurate) (as discussed in section 4 below);
- determine the scope of the test rule it should issue for TBB and TBPH in light of their designation on the Priority List (as discussed in this section above)
- determine whether it has adequate information to conduct risk assessments of the commercial mixtures Firemaster BZ-54 and Firemaster 550 (as discussed in section 10 below) ; and
- determine whether it has adequate information to conduct risk assessments of TBB, TBPH, and other BPC chemicals.

### **3. A systematic review process should be used to conduct a comprehensive literature search and document evidence before OPPT draws conclusions about the available data and their adequacy.**

A risk assessment is only as robust as the hazard and exposure data upon which it relies. Unfortunately, OPPT has not explained or clearly documented the process used for researching and reporting hazard and exposure data to support this data needs assessment. It appears that the Data Needs Assessment is based on a literature review that does not utilize a systematic approach to search for and compile evidence. Consequently, as we discuss in more detail below, EPA’s list of References (Data Needs Assessment at 47-51) omits many published studies that address exposure to and hazards of chemicals in the BPC. Indeed, the References list includes no exposure or hazard studies of chemicals in the BPC published after 2013, though these chemicals have been the subject of many studies conducted since then.

Before OPPT concludes that available data are inadequate to proceed with a risk assessment of the BPC, it must undertake a systematic review to identify all relevant information including *in vivo* toxicological data, *in vitro* cellular and mechanistic data, *in silico* computational information, and data from sampling of environmental matrices and biota.

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<sup>35</sup> 40 C.F.R. § 790.20(b)(2).

<sup>36</sup> 15 U.S.C. § 2607(d).

Systematic review methods for chemical assessments have been developed and implemented through various case studies by the National Toxicology Program (NTP) Office of Health Assessment and Translation (OHAT), the EPA Integrated Risk Information System (IRIS) program, the University of California San Francisco, and others.<sup>37,38,39,40,41</sup> The National Research Council recently commended the IRIS program on its development of systematic review methods for chemical evaluations.<sup>42</sup> A systematic review is a critical first step because in the absence of such a process, OPPT's determination that it lacks data sufficient to conduct a risk assessment could be erroneous. At a minimum, OPPT's catalogue of missing data may be inaccurate.

A transparent, systematic review of the evidence should begin with a protocol which clearly outlines up-front the study question to be addressed in the assessment, as well as the process for searching, screening, selecting, evaluating, and interpreting the body of scientific literature available. This protocol would increase transparency of both the methods and the process of the assessment, serve as a foundation for stakeholders to follow the assessment and provide constructive feedback, as well as allow for a better opportunity to engage subject matter experts. It also would minimize bias in evidence integration by ensuring that decisions regarding how the evidence will be treated are made prior to seeing the data, so that the inclusion and interpretation of studies are consistent and do not change depending on the study findings.<sup>43</sup>

#### *Comprehensive literature search*

We urge OPPT to conduct, as soon as possible, a systematic review that includes a documented and comprehensive literature search to gather relevant information from the published, unpublished,

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<sup>37</sup> Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. Systematic review and evidence integration for literature-based environmental health science assessments. *Environ Health Perspect* [Internet]. 2014 Jul [cited 2015 Sep 7];122(7):711–8, available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4080517&tool=pmcentrez&rendertype=abstract>

<sup>38</sup> Thayer KA, Wolfe MS, Rooney AA, Boyles AL, Bucher JR, Birnbaum LS. Intersection of systematic review methodology with the NIH reproducibility initiative. *Environ Health Perspect* [Internet]. 2014 Jul [cited 2015 Sep 7];122(7):A176–7, available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4080520&tool=pmcentrez&rendertype=abstract>

<sup>39</sup> Birnbaum LS, Thayer KA, Bucher JR, Wolfe MS. Implementing systematic review at the National Toxicology Program: status and next steps. *Environ Health Perspect* [Internet]. 2013 Apr [cited 2015 Oct 10];121(4):A108–9. available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3620750&tool=pmcentrez&rendertype=abstract>

<sup>40</sup> Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. *Environ Health Perspect* [Internet]. 2014 Oct [cited 2015 Sep 7];122(10):1007–14, available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4181919&tool=pmcentrez&rendertype=abstract>

<sup>41</sup> US EPA. Toxicological Review of Inorganic Arsenic: IRIS External Draft for Peer Review. 2010.

<sup>42</sup> National Research Council, Review of EPA's Integrated Risk Information System (IRIS) Process [Internet]. Washington, D.C.; 2014 [cited 2015 Oct 10], <http://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process>

<sup>43</sup> The National Academy of Sciences. Review of the formaldehyde assessment in the National Toxicology Program 12th report on carcinogens [Internet]. Washington, D.C.; 2014 [cited 2014 Oct 17]. Available from: [http://www.nap.edu/catalog.php?record\\_id=18725](http://www.nap.edu/catalog.php?record_id=18725)

and “grey” literature (publicly available government reports, etc.). By ‘documented’, we mean that the methodology used to conduct the search (i.e., search terms, which databases were searched, etc.) should be recorded and made publicly available. The systematic review should include literature regarding both commercial mixtures containing BPC chemicals and the individual chemicals.

#### *Documentation*

Upon completion of the comprehensive literature search, it is vital for OPPT to document the results of the search in a way that stakeholders can easily evaluate, and to provide the public access to the body of evidence that OPPT will rely on for the risk assessment. For instance, EPA IRIS is utilizing the HERO (Health and Environmental Research Online) database to store all references that are used in their assessments. OPPT should also utilize HERO or something similar to transparently document the body of literature that it uses to come to final conclusions. As it stands, the referenced literature is split across 4 separate documents (the Data Needs Assessment and 3 technical supplements), making it difficult for commenters to assess which literature was relied upon. As discussed in more detail below, documentation should include whether OPPT is relying on a robust summary of a study or utilizing the full study. To the extent that it is relying on a robust summary, OPPT should indicate who prepared that summary.

#### *Evaluation of evidence*

OPPT’s documentation should include a description of the criteria for study selection. Without information on OPPT’s literature search, or inclusion and exclusion criteria, it is impossible to know how and why OPPT selected the studies it chose to include in the BPC documents.

OPPT’s documentation should also include its criteria for rating study bias, as well as for identifying and potentially excluding very low-quality studies.<sup>44</sup> Evaluation of study bias (internal validity) is a critical step in evaluating the quality of studies. Other agencies and organizations have developed tools specifically designed to evaluate the internal validity of animal toxicology and observational human studies related to environmental health questions.<sup>45,46,47,48</sup>

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<sup>44</sup> For example, the NTP systematic review framework identifies aspects that would lead to downgrading the confidence rating for studies, including: risk of bias, unexplained inconsistency, indirectness in the relationship between a measured outcome and a health effect, imprecision, and publication bias serious enough to significantly decrease confidence in the body of evidence.

<sup>45</sup> Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. Systematic review and evidence integration for literature-based environmental health science assessments. *Environ Health Perspect* [Internet]. 2014 Jul [cited 2015 Sep 7];122(7):711–8, available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4080517&tool=pmcentrez&rendertype=abstract>

<sup>46</sup> Birnbaum LS, Thayer KA, Bucher JR, Wolfe MS. Implementing systematic review at the National Toxicology Program: status and next steps. *Environ Health Perspect* [Internet]. 2013 Apr [cited 2015 Oct 10];121(4):A108–9. available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3620750&tool=pmcentrez&rendertype=abstract>

<sup>47</sup> Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. *Environ Health Perspect* [Internet]. 2014 Oct [cited 2015 Sep 7];122(10):1007–14, available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4181919&tool=pmcentrez&rendertype=abstract>

<sup>48</sup> US EPA. Toxicological Review of Inorganic Arsenic: IRIS External Draft for Peer Review. 2010.

We recommend that OPPT align with NTP by adopting their systematic review process and criteria, which have already undergone significant inter-agency and public review and are currently being successfully implemented for chemical assessments. Developing systematic review methodology would ensure that the Agency had indeed identified and appropriately evaluated all the relevant data before drawing conclusions about data adequacy and data gaps.

**4. OPPT should make clear whether it reviewed original studies or summaries, and original studies should be made available. Studies underlying a number of the hazard conclusions are not available and there are problematic interpretations of hazard data.**

Some of the hazard data on Firemaster BZ-54 presented in Table 1-3 of the Hazard Assessment Supplement refers to NICNAS (2004). The rest of the BZ-54 studies in the table are tagged with a superscript “14” for which there is no corresponding footnote, so the source is unclear.

In either case, the original studies are not available for review because the NICNAS document contains study summaries rather than the original studies. We were unable to review the original studies because Chemtura inappropriately claims that they are CBI (as we detailed above). It is unclear whether OPPT obtained the original studies and reviewed them to draw conclusions, or whether OPPT based conclusions on the NICNAS study summaries. It is also unclear who wrote the study summaries in the NICNAS document.

If summaries will be relied upon, OPPT staff should prepare the summaries themselves, or validate the accuracy and completeness of existing summaries by comparison to the original, full studies. As we describe above, such studies cannot be claimed as CBI and the full studies should be made publicly available upon request. If OPPT cannot access the original, full study, then that should be made clear in the assessment document and OPPT should identify who prepared the summary and account for potential biases based on funding source.

We are concerned because there are inaccurate interpretations of the test data in the study summaries presented by NICNAS and it is unclear the extent to which OPPT relied on these summaries. For example, guideline protocols often specify both male and female study groups because it is well known that males and females may display sexually dimorphic responses. Yet the study summary on page 17 of the NICNAS document completely discounts a clear, statistically significant sexually dimorphic response: “Differences in haematology parameters although statistically significant when compared with the control group were not considered as treatment related because the changes were confined to high dose females only and/or the values were within the historical control data.” The NICNAS summary also discounts these effects because they do not show classic dose-response (effects seen in high-dose group only). However, nonmonotonic dose-effect functions are common in toxicity studies, especially when endocrine pathways are involved.<sup>49,50,51</sup> The National Academies reviewed EPA’s approach to nonmonotonic effects and

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<sup>49</sup> Birnbaum LS. Environmental Chemicals: Evaluating Low-Dose Effects. *Environ Health Perspect* [Internet]. 2012 Mar 14;120(4):a143–4. Available from: <http://ehp.niehs.nih.gov/1205179>

<sup>50</sup> Zoeller RT, Vandenberg LN. Assessing dose–response relationships for endocrine disrupting chemicals (EDCs): a focus on non-monotonicity. *Environ Heal* [Internet]. 2015 Dec [cited 2015 May 18];14(1). Available from: <http://www.ehjournal.net/content/14/1/42>

<sup>51</sup> Vandenberg LN. Non-Monotonic Dose Responses in Studies of Endocrine Disrupting Chemicals: Bisphenol A as a Case Study. *Dose-Response* [Internet]. 2013 Oct [cited 2015 Jan 26];12(2):259–76. Available from:

concluded that the Agency does not have a consistent framework for addressing such effects under current risk-assessment guidelines.<sup>52</sup> TBPH presents known endocrine disruption potential as observed in Springer (2012) and because of its structural similarity to the endocrine disrupting phthalate DEHP.<sup>53</sup>

## **5. The hazard endpoints of liver toxicity and carcinogenicity should be included as critical data needs.**

OPPT's dismissal of liver toxicity and potential carcinogenicity concerns<sup>54</sup> is extremely surprising given the data indicating adverse liver effects from the Springer (2012) study, and the fact that there are no carcinogenicity data. OPPT's reasoning is that the data from Springer provide some evidence of PPAR $\alpha$  activation, which is a mechanism not relevant to humans and thus there is lower concern for liver toxicity or carcinogenicity. This is faulty for two major reasons:

- A. It is contrary to EPA's own policy document *Proposed OPPTS Science Policy: PPAR $\alpha$ -Mediated Hepatocarcinogenesis in Rodents and Relevance to Human Health Risk Assessments*.<sup>55</sup>

This document states that it must be clearly established that a PPAR $\alpha$  mechanism of action (MOA) is the *only* contributing mechanism, and that other MOAs do not contribute significantly, before effects can be considered not relevant to humans. There is no such clear establishment here. In fact, there is only one study investigating the mechanism of liver toxicity at all.

- B. Numerous studies indicate that PPAR $\alpha$  is not the only mechanism important in DEHP liver carcinogenesis, and thus that rodent carcinogenesis studies are relevant to humans.<sup>56,57</sup>

The metabolite of TBPH shows liver toxicity effects similar to DEHP and thus may indicate similar risks for liver carcinogenesis. This should be an area flagged for further study, rather than set aside as low concern.

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<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4036398/>

<sup>52</sup> The National Academies. Review of the Environmental Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response Relationships as they Apply to Endocrine Disruptors (2014). Available: <http://www.nap.edu/catalog/18608/review-of-the-environmental-protection-agencys-state-of-the-science-evaluation-of-nonmonotonic-dose-response-relationships-as-they-apply-to-endocrine-disruptors>

<sup>53</sup> Springer, C. et al., 2012. Rodent Thyroid, Liver, and Fetal Testis Toxicity of the Monoester Metabolite of Bis-(2-ethylhexyl) Tetrabromophthalate (TBPH), a Novel Brominated Flame Retardant Present in Indoor Dust. *Environmental Health Perspectives*, 120(12), pp.1711-9.

<sup>54</sup> Hazard Assessment Supplement at 16-17.

<sup>55</sup> Available at

<http://archive.epa.gov/scipoly/sap/meetings/web/pdf/peroxisomeproliferatorsciencepolicypaper.pdf>

<sup>56</sup> Rusyn, I. & Corton, J.C., Mechanistic considerations for human relevance of cancer hazard of di(2-ethylhexyl) phthalate. *Mutation research*, 750(2), pp.141-58.

<sup>57</sup> Guyton, K.Z. et al., 2009. A Reexamination of the PPAR- $\alpha$  Activation Mode of Action as a Basis for Assessing Human Cancer Risks of Environmental Contaminants. *Environmental Health Perspectives*, 117(11), pp.1664-72.

**6. OPPT erroneously interprets a lack of testing as evidence that chemicals are not present. Such issues must be flagged as important data gaps that need to be filled.**

Throughout the Data Needs Assessment document, the problematic phrases “no evidence of...” and “there is no evidence” are used. These phrases are misleading because they can be interpreted to mean that studies tested for a substance and did not find it. It could also be interpreted to mean that no studies have yet looked at the subject in question. For every instance where this phrase is used in the Data Needs Assessment, we believe it is the latter meaning (no one has studied the question), and thus every use of “no evidence” should be replaced by “It is unknown whether...”

- A. “No evidence of environmental exposure to the other brominated phthalate cluster (BPC) members has been found.” (Data Needs Assessment at 12) *To our knowledge, no studies have tested for other BPC members. This sentence should read “It is unknown whether there are environmental exposures to other BPC members because no studies have tested for these compounds.”*
- B. “There is no evidence to suggest that release of BPC members from landfills occurs or that they are present in leachate under normal conditions.” (Data Needs Assessment at 18) *Again, to our knowledge, none of the previous studies on landfill leachate tested for TBB or TBPH. Previous studies have been focused on PBDEs and HBCD. A recent study that was published subsequent to OPPT’s release of this document found that TBB was the most abundant flame retardant in leachate.<sup>58</sup>*
- C. “EPA/OPPT has found no evidence that these cluster chemicals are present in the environment suggesting that exposure to these cluster chemicals is either unlikely or below detection levels.” (Data Needs Assessment at 21) *This is not an accurate interpretation. To our knowledge, no one has tested for TBPA-diol, therefore exposures are unknown. The sentence should read “It is unknown whether these cluster chemicals are present in the environment because no studies have tested for them.”*

These areas (environmental testing for BPC members besides TBB and TBPH, testing for BPC chemicals in landfill leachate) are large data gaps where further research is needed. OPPT should add these to its list of data needs. Decisions about the importance of collecting data on hazard, exposure or both should not be made based on limited or uncertain exposure information or speculation.

**7. Degradation and toxic combustion products of these flame retardants should be considered.**

These BPC flame retardants, like other flame retardants, form toxic by-products under thermal stress. The NICNAS 2004 assessment of Firemaster BZ-54 (at 24) describes the formation of significant levels of the highly toxic by-products polybrominated dibenzo-p-dioxins (PBDDs) and polybrominated dibenzofurans (PBDFs) upon incineration. The formation of these toxic by-products under thermal stress is especially relevant to e-waste recycling, given that electronics appear to be major uses of TBPH and TBB. OPPT’s assertion that landfill incinerators would destroy

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<sup>58</sup> Olukunle, O.I. & Okonkwo, O.J., 2015. Concentration of novel brominated flame retardants and HBCD in leachates and sediments from selected municipal solid waste landfill sites in Gauteng Province, South Africa. *Waste Management*, 43, pp.300–306.

these chemicals<sup>59</sup> at high temperatures is unsupported. The consent order for Confidential A (at v) states “There are also carcinogenicity concerns for the potential formation of brominated [ ] during combustion in municipal incinerators of disposed consumer products containing the PMN substance. The Agency has also determined that the degradation (either metabolic or environmental) products of the PMN substance [ ] may cause liver toxicity.” The modified consent order for TBB states “There was also concern for the potential formation of brominated dibenzodioxins and dibenzofurans during combustion in municipal incinerators of disposed consumer plastics containing the PMN substance...The incineration study demonstrated the formation of dioxins and furans at low temperatures, but at higher temperature, complete destruction is expected.” OPPT does not present data showing that the chemicals would in fact be destroyed without production of toxic by-products at higher temperatures, or that incinerators at a typical landfill actually operate at such temperatures.

There is no proposal to consider the exposures of communities located near plants or of certain workers, like those employed in incineration or e-waste recycling, to toxic combustion by-products and degradation products. These are unique exposure routes that could result in some very high levels of exposure for workers and neighboring communities; ignoring these exposure scenarios may exclude significant sources of exposure and potential health impacts.

## **8. Electronics must be considered as uses and sources of exposure for both TBB and TBPH.**

On page 15 of the Data Needs Assessment, OPPT states:

The major use identified for all cluster members is as a flame retardant (FR) in polyurethane foams (PUF) and PUF products. The other uses identified are considered minor in comparison to the amount of chemical used in PUF. Therefore, the manufacture of the brominated phthalates cluster members for use in PUF and PUF products is the focus of this assessment.

This does not make sense because several lines of evidence, including EPA’s own data, indicate that electronics are a major use and source of exposure for TBB and TBPH.

- A. The production volume and use reporting data for TBPH presented in OPPT’s Technical Supplement indicate that 5 million pounds is used in electronics, at least 50% of the total production volume in 2012. This is not a ‘minor use’.

Two companies (Teknor and Unitex) report using 100% of their TBPH production volume for electronics (“Electrical and electronic products, electrical equipment, appliance and component manufacturing”).<sup>60</sup> These same companies report about 5 million pounds of production volume in 2010.<sup>61</sup> Since these companies report that 100% of their production volumes go to electronics, it stands to reason that about 5 million pounds of TBPH is going into electronics. The total national production volume in 2012 is reported as 1-10 million pounds/ year.<sup>62</sup> At the maximum production

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<sup>59</sup> Data Needs Assessment at 18.

<sup>60</sup> Use and Exposure Supplement at 9, Table 1-5.

<sup>61</sup> Use and Exposure Supplement at 6, Table 1-2.

<sup>62</sup> Use and Exposure Supplement at 6, Table 1-2.

volume of 10 million pounds, that means that at least 50% of the production volume of TBPH is going into electronics. This is certainly not a 'minor use' as OPPT claims.

B. Based on peer-reviewed studies, TBB is used extensively in electronics with TBPH.

OPPT does not present any use data for TBB, though it is reported in the CDR database (see Exhibit C hereto). The CDR data needs to be added to OPPT's document. According to EPA's ChemView database, the uses for TBB are reported as furniture (90%) and building/ construction materials (10%).

Electronics need to be evaluated as an important use of TBB not reported in CDR. Abbasi et al. found TBB associated with a majority of all electronics they tested by product wiping: large household appliances (57%), small household appliances (64%), personal computers (100%), audio/video equipment (79%), CRT TVs (50%) and flat screen TVs (64%).<sup>63</sup> The fact that almost all A/V equipment and all computers appeared to contain TBB is especially notable. The data from the Abbasi study finding TBPH extensively associated with hard plastics directly contradicts the statement that "Generally, hard plastics contain 'reactive', rather than 'additive' brominated phthalates."<sup>64</sup> This statement needs to be reevaluated in light of this evidence.

The Abbasi findings are supported by a number of other studies indicating that TBB and TBPH are used in electronics. Tests of food at e-waste sites find increased concentrations of TBB and TBPH, sometimes by orders of magnitude above the levels at non- e-waste sites.<sup>65</sup> The levels of TBB and TBPH in sediment are correlated with the locations of electronics manufacturing facilities and with the locations of e-waste facilities.<sup>66, 67</sup>

C. Electronics are a source of human exposure to TBB and TBPH

Abbasi et al. also found a correlation between concentrations of TBB and TBPH in product wipes and concentrations in dust, suggesting that electronics are sources of the TBB and TBPH found in dust.<sup>68</sup> Studies have shown that electronics emit significant amounts of other additive brominated flame retardants (HBCD and PBDEs) that are semi-volatile organic chemicals (SVOCs) like TBB and TBPH.<sup>69,70</sup>

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<sup>63</sup> Abbasi, G. et al., 2016. Product screening for sources of halogenated flame retardants in Canadian house and office dust. *Science of The Total Environment*, 545-546, pp.299-307.

<sup>64</sup> Data Needs Assessment at 16.

<sup>65</sup> Labunska, I. et al., 2015. Human dietary intake of organohalogen contaminants at e-waste recycling sites in Eastern China. *Environment International*, 74, pp.209-220.

<sup>66</sup> Liu, H.-H. et al., 2014. Occurrence of Halogenated Flame Retardants in Sediment off an Urbanized Coastal Zone: Association with Urbanization and Industrialization. *Environmental Science & Technology*, 48(15), pp.8465-8473.

<sup>67</sup> La Guardia, M.J., Hale, R.C. & Newman, B., 2013. Brominated Flame-Retardants in Sub-Saharan Africa: Burdens in Inland and Coastal Sediments in the eThekweni Metropolitan Municipality, South Africa. *Environmental Science & Technology*, 47(17), pp.9643-9650.

<sup>68</sup> Abbasi, G. et al., 2016. Product screening for sources of halogenated flame retardants in Canadian house and office dust. *Science of The Total Environment*, 545-546, pp.299-307.

<sup>69</sup> Harrad, S., Abdallah, M.A.E. & Covaci, A., 2009. Causes of variability in concentrations and diastereomer patterns of hexabromocyclododecanes in indoor dust. *Environment International*, 35(3), pp.573-579.

In addition to contact with contaminated dust, direct contact with flame-retarded products may serve as an important pathway of human exposure.<sup>71</sup> Contact with electronics, especially computers (which people may contact for 8 hours a day or more), should be evaluated as a source of exposure.

#### **9. Data indicate that TBPH release from PVC occurs and this must be included in the assessment.**

OPPT states on page 21 of the Data Needs Assessment: “EPA/OPPT recognizes that FR have been associated with use in polyvinylchloride (PVC) which is present in many consumer goods (e.g. children’s toys, shower curtains, etc.). In addition, TBPH use was reported in the EPA/OPPT IUR data for decades before the Firemaster®550 or Firemaster®BZ-54 products were used in foam; however, no TBPH releases were observed. Stapleton et al., (Stapleton et al., 2008a) were not looking for TBPH/TBB when an unknown brominated flame retardant was observed that they identified as the Firemaster®550 components, suggesting that if TBPH had previously been present in dust from non-foam uses, it would likely have been found in earlier sampling.”

This reasoning is faulty because TBPH was observed in earlier sampling. Indeed, in the very paper cited by OPPT (Stapleton 2008), the researchers detected TBPH in NIST Standard Reference Material 2585, (house dust collected in the mid-to-late 1990s).<sup>72</sup> This indicates that TBPH did migrate out of other products long before the Firemaster mixtures were in use.

These findings are consistent with all the evidence we have on the behavior of SVOC chemicals used additively in polymer matrices, like TBPH in PVC. It is well known that SVOCs partition out of their original source in the indoor environment over time.<sup>73</sup> The migration of DEHP plasticizer (a structural analog of TBPH) from vinyl flooring is well characterized, and contrary to the statement on page 12 of the Use and Exposure Supplement (“Typical polyvinyl chloride (PVC) emits its ester plasticizers when strongly heated, and these plasticizers are flammable”), such releases occur at typical room temperatures, not just at high temperatures.<sup>74,75</sup>

Other studies published prior to 2008 did not observe TBPH in dust or the environment because they were not looking for it. Dr. Stapleton’s results show that the chemical was in fact in dust before the year 2000. As EPA notes, “Emissions from a single product or article may be small. However, combined emissions from all sources within various indoor microenvironments, residences,

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<sup>70</sup> Li, Y. et al., 2015. Characterizing distribution, sources, and potential health risk of polybrominated diphenyl ethers (PBDEs) in office environment. *Environmental Pollution*, 198, pp.25–31.

<sup>71</sup> Stapleton, H.M. et al., 2014. Flame retardant associations between children’s handwipes and house dust. *Chemosphere*, 116, pp.54–60.

<sup>72</sup> Stapleton, H.M. et al., 2008. Alternate and New Brominated Flame Retardants Detected in U.S. House Dust. *Environmental Science & Technology*, 42(18), pp.6910–6916.

<sup>73</sup> Weschler, C.J. & Nazaroff, W.W., 2008. Semivolatile organic compounds in indoor environments. *Atmospheric Environment*, 42(40), pp.9018–9040.

<sup>74</sup> Clausen, P.A. et al., 2012. Influence of Temperature on the Emission of Di-(2-ethylhexyl)phthalate (DEHP) from PVC Flooring in the Emission Cell FLEC. *Environmental Science & Technology*, 46(2), pp.909–915.

<sup>75</sup> Xu, Y., Cohen Hubal, E.A. & Little, J.C., 2010. Predicting Residential Exposure to Phthalate Plasticizer Emitted from Vinyl Flooring: Sensitivity, Uncertainty, and Implications for Biomonitoring. *Environmental Health Perspectives*, 118(2), pp.253–258.

schools, public and commercial buildings, cars, trains, airplanes, may be significant.”<sup>76</sup> Thus it is critical that PVC and any other materials in which TBPH is used additively be evaluated as sources of release and exposure.

**10. BPC chemicals are used in mixtures and people will be co-exposed to these chemicals. OPPT must account for the risks presented by such mixtures, and should evaluate whether data are sufficient to move forward with assessment of the mixtures.**

The independent literature includes research on both individual BPC members as well as the commercial mixtures. *In vitro* tests indicate that both TBB and TBPH affect sex hormone production and activity, creating a potential for additive or synergistic effects.<sup>77,78</sup> We are concerned about the results of testing of the Firemaster 550 formulation in which exposed animals experienced early puberty, excessive weight gain, and decreased performance in behavioral tests.<sup>79</sup> Independent researchers have also examined the genotoxicity of the Firemaster 550 and BZ-54 mixtures because of the molecular similarity of TBB and TBPH to the phthalate DEHP, previously identified as genotoxic. Fathead minnows exposed to Firemaster 550 and BZ-54 mixtures showed more DNA damage than controls.<sup>80</sup>

The Data Needs Assessment states on page 7 that “EPA/OPPT found that while the data for Firemaster@BZ-54 are sufficient to support a determination that TBB may present an unreasonable risk in certain scenarios, this review identified critical data gaps...” OPPT indicates that it needs more information on the individual chemicals TBB and TBPH to proceed, but not how it intends to use the information it has on the toxicity of the mixtures. Often, the lack of information on the toxicological effects of a chemical mixture is a major challenge in accounting for the real world risks faced by people every day (i.e. exposure not to one chemical at a time, but many chemicals at once). But here, OPPT has significantly more data on the effects of the TBB/ TBPH mixtures Firemaster BZ-54 and Firemaster 550 than on the individual chemicals. The mixtures are relevant for real-world occupational and consumer exposures. The indoor monitoring data in the Use and Exposure Supplement show that both TBB and TBPH are present in indoor air and dust. The available studies of the mixture, including ones that OPPT has not referenced in its assessment documents, show endocrine disruption and developmental toxicity, and these effects must be accounted for in OPPT’s risk assessments. In describing the importance of implementing cumulative risk assessment, the National Academies noted that “First, even if the regulatory decision of interest were related to strategies to address a single chemical with a single route of exposure, consideration of other compounds and other factors may be necessary to inform the decision. Ignoring numerous agents or stressors that affect the same toxic process as the chemical of interest and omitting background

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<sup>76</sup> Use and Exposure Supplement pg. 23

<sup>77</sup> Saunders, D.; Higley, E.; Hecker, M.; Mankidy, R.; Giesy, J., *In vitro* endocrine disruption and TCDD-like effects of three novel brominated flame retardants: TBPH, TBB & TBCO. *Toxicol Lett* 2013, 223, 252-259.

<sup>78</sup> Patisaul, H.; Roberts, S.; Mabrey, N.; McCaffrey, K.; Gear, R.; Braun, J.; Belcher, S.; Stapleton, H., Accumulation and endocrine disrupting effects of the flame retardant mixture Firemaster@550 in rats: an exploratory assessment. *J Biochem Molecular Toxicology* 2013, 27, (2), 124-136.

<sup>79</sup> *Id.*

<sup>80</sup> Berr, J., HM Stapleton, and CL Mitchelmore, Accumulation and DNA damage in fathead minnows (*Pimephales promelas*) exposed to 2 brominated flame-retardant mixtures, Firemaster® 550 and Firemaster® BZ-54. *Environmental Toxicology and Chemistry* 2010, 29, (3), 722-729.

processes could lead to risk assessments that, for example, assume population thresholds in circumstances when such thresholds may not exist.”<sup>81</sup>

The serious hazards and potential for widespread exposures elevate the need to proceed with assessment of the mixtures. In parallel, OPPT should pursue assessment of the individual chemicals in order to avoid potential regrettable substitutions. The information on toxicity and exposure of the Firemaster mixtures should be used to inform the individual chemical assessments, as well as all the other ongoing flame retardant risk assessments (i.e., chlorinated phosphate esters, cyclic aliphatic bromides, and TBBPA and related chemicals). The risks presented by exposure to the mixtures must be accounted for in the other assessments, as these exposures are ongoing and occurring at the same time as exposures to other flame retardant chemicals in the general population.

EPA will obtain more data from doing a comprehensive systematic review, the data call in, and test rules. Any of these activities may provide OPPT with sufficient data on the chemical mixtures to proceed with risk assessments, if it does not already have sufficient data. OPPT should keep careful tabs on the status of critical data gaps and initiate the risk assessment as soon as possible.

There is precedent for EPA to regulate inconsistent mixtures: for example, commercial PCB mixtures were highly variable, both in terms of the particular chemicals contained and the ratios of those chemicals.<sup>82</sup> The fact that the ratios of chemicals in commercial Firemaster mixtures might vary does not in any way preclude OPPT from proceeding with assessment of the mixture and regulation based on that assessment.

## **CONCLUSION**

The known toxicity and widespread presence of these flame retardant chemicals in the air and dust of our homes and in the products we use every day elevate the importance of conducting a risk assessment for the BPC flame retardants as soon as possible, and of regulating uses of chemicals that pose unreasonable risks. In light of the urgency of this work, EPA’s actions and inactions with respect to the BPC flame retardants are deeply troubling. Its unlawful failure to take any action in response to the 2012 ITC recommendation that EPA order testing of TBB and TBPH, and subsequent failure to issue the required data call-in for TBB and TBPH, has allowed chemical manufacturers to keep existing health and safety studies out of the public domain, and has delayed new testing on TBB and TBPH by several years. In addition, EPA’s actions have effectively concealed from the public both health and safety studies for TBB and TBPH that are in the Agency’s possession and the consent order for Confidential A (reflecting EPA’s serious concerns about exposures and toxicity). During this delay, millions of Americans were exposed to these chemicals and may have suffered health impacts as a result, with young children at the highest risk.

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<sup>81</sup> National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009. at 214

<sup>82</sup> US EPA. Aroclor and Other PCB Mixtures. Available at <http://www3.epa.gov/epawaste/hazard/tsd/pcbs/pubs/aroclor.htm>

These missteps, as well as the others detailed above, need to be corrected as soon as possible. EPA should create and enforce internal policies and processes for the proper conduct of TSCA risk assessments, in order to ensure that the mistakes in the work to date on the BPC flame retardants are not repeated.

Thank you for the opportunity to present these comments. We would be happy to discuss them with you at your convenience.

Sincerely,

Handwritten signatures of Eve Gartner and Veena Singla.Handwritten signature of Erika Schreder.

Eve Gartner  
Staff Attorney  
Earthjustice

Veena Singla  
Staff Scientist  
Natural Resources Defense Council

Erika Schreder  
Science Director  
Washington Toxics Coalition

# **Exhibit A**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**Posting an FDMS Docket without a Federal Register Notice**

**MEMORANDUM**

**SUBJECT:** PMN number associated with two substances identified as Confidential A and Confidential B in the Brominated Phthalates Cluster Flame Retardants Data Needs Assessment: Docket EPA-HQ-OPPT-2014-0491

**FROM:** Maria Szilagyi, *Szilagyi 12/7/15*  
Toxicologist  
Risk Assessment Division (RAD)  
Office of Pollution Prevention and Toxics

**THRU:** Tala Henry, Ph.D., *Henry*  
Director  
RAD, Office of Pollution Prevention and Toxics

This memorandum authorizes the release of the PMN number associated with two substances denoted Confidential A and Confidential B in the Brominated Phthalates Cluster (BPC) TSCA Work Plan Data Needs Assessment.

Two substances were denoted Confidential A and Confidential B due to the potential release of Confidential Business Information (CBI) by association with other members of the BPC. Both of these substances were submitted to EPA under TSCA Section 5. In response to a request for the release of the PMN case number and generic name, EPA contacted the submitters to discuss the release of this information. Upon review, the submitters conceded that there was no longer a CBI linkage issue with respect to the uses of the TSCA Section 5 case number and generic name in the BPC data needs assessment. Therefore, the following information is released to the public:

Confidential A: PMN Case Number: P-04-0404      Generic Name: Tetrabromophthalate diol diester  
Confidential B: PMN Case Number: P-96-0965      Generic Name: Brominated phthalate diol

Additional information on the BPC TSCA Work Plan Data Needs Assessment can be found in the Docket at EPA-HQ-OPPT-2014-0491 and on the EPA website at: <http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-problem-formulation-and-data>

EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be CBI or otherwise protected through

<http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an 'anonymous access' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Should you have any questions regarding this memorandum, please contact Eric Schultz at (202) 566-1883, or via email at [schultz.eric@epa.gov](mailto:schultz.eric@epa.gov).

cc: Stanley Barone, Ph.D., OPPT/RAD  
Alva Daniels, OPPT/RAD  
Nhan Nguyen, OPPT/RAD  
Scott Sherlock, OPPT/EAD

# **Exhibit B**



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Attachment C - Consent Order for Contract Manufacturer

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P04-404 submitted by [ ] ("the Company"), to take effect upon expiration of the PMN review period.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

- (a) submit to EPA certain toxicity testing in two tiers, at least 14 weeks before manufacturing or importing a total of [ ] and [ ] kilograms, respectively, of the PMN substance;
- (b) label containers of the PMN substance and provide Material Safety Data Sheets (MSDSs) and worker training in accordance with the provisions of the Hazard Communication Program section;
- (c) distribute the PMN substance only to a person who agrees to follow the same restrictions applicable to the company (except the toxicity testing requirements) and to not further distribute the PMN substance until after it has been completely reacted, cured, or incorporated into a [ ];

- (d) not release the PMN substance into the waters of the United States; and
- (e) maintain certain records.

A Consent Order for Contract Manufacturer is attached to extend these requirements to the Contract Manufacturer.

### III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): Company name; chemical identity; trade identification; production volume; manufacturing, processing and use information.

Chemical Identity:

Specific: [

]

Generic: Tetrabromophthalate Diol Diester

Use:

Specific: [ ]

Generic: Flame Retardant

Maximum 12-Month Production Volume: [ ]

Test Data Submitted with PMN: None.

#### IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

##### Human Health Effects Summary:

Absorption: Absorption of low molecular weight fraction is expected to be poor via all routes of exposure (dermal, inhalation, and GI tract).

Toxicological Endpoints of Concerns: For the low molecular weight (LMW) components of the PMN substance, there are concerns for liver and kidney toxicity, and for potential to be persistent, bioaccumulative, and toxic (PBT). The Agency estimates that these LMW components of the PMN substance may persist in the environment more than six months, may have a bioaccumulation factor of greater than or equal to 1000, and be potentially toxic over long periods of time. There are also carcinogenicity concerns for the potential formation of brominated [ ] during combustion in municipal incinerators of disposed consumer products containing the PMN substance. The Agency has also determined that the degradation (either metabolic or environmental) products of the PMN substance [ ] may cause liver toxicity.

Basis: Kidney and liver toxicity and PBT concerns are based on test data on structurally similar halogenated esters. (See EPA's Policy Statement on New Chemical PBTs at 64 FR 60194, Nov. 4, 1999, and [www.epa.gov/oppt/newchems/pbtpolicy.htm](http://www.epa.gov/oppt/newchems/pbtpolicy.htm).) Based on available test data on halogenated [ ], the Agency has determined that those chemical substances are probable human carcinogens and may cause toxic effects in aquatic and terrestrial organisms.

Risk to Occupational Workers:

Inhalation exposures are expected to be negligible and, due to low absorption potential and the expectation that the Company will utilize dermal protective equipment, dermal exposures are not expected to pose an unreasonable risk to workers.

Risk to Consumers:

Formulations containing the PMN substance will be used in consumer goods. The Agency has not determined that resulting exposures may present an unreasonable risk to human health. However, based on the PBT potential of the LMW components of the PMN substance, the potential toxicity of the intact PMN substance, and the potential toxicity of the tetrabromophthalate degradation product, EPA does find that there may be significant (or substantial) human exposure to the substance.

Environmental Effects Summary:

Concerns: Chronic toxicity to aquatic organisms. EPA predicts a concern concentration of 3.0 parts per billion (ppb) of the LMW components of the PMN substance.

Basis: Data on halogenated esters structurally similar to the LMW components of parent PMN substance. See <http://www.epa.gov/oppt/newchems/chemcat.htm> ("Esters") for further information.

Exposure and Environmental Release and Risk Summary:

	Manufacture	Process/ Use
# Sites	[ ]	[ ]
Workers (#/site)	[ ]	[ ]

Exposure (days/year)	[ ]	[ ]
Dermal Exposure (mg/day)	up to 1,764	up to 1,764
Inhalation Exposure (mg/day)	negligible	negligible
Drinking Water Exposure (mg/kg/day)	none	$1 \times 10^{-6}$ (average daily dose)
Releases (days/year)	NA	1
Release to Water (kg/site/day)	not expected <sup>1</sup>	1.28 <sup>2</sup>
Surface Water Concentration (ppb)	NA	89
Days Exceeding Aquatic Toxicity Concern Concentration	NA	1

In the absence of regulation, additional releases to surface waters and PBT concerns associated with the PMN substance may present an unreasonable risk to the environment.

#### V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

A. EPA is unable to determine the potential for adverse effects from exposure of humans and aquatic organisms to the LMW components of the PMN substance and potential breakdown products of the PMN substance. Further EPA is unable to determine the potential for human

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<sup>1</sup>Reactor cleaned with solvent, which is recycled into the next batch. Worst case 580 kg/yr of PMN substance disposed of via incineration.

<sup>2</sup>In lieu of releases to water, these releases from cleaning residuals from dedicated shipping containers could go to landfill (32 kg/yr) or incineration (160 kg/yr)

health and environmental effects from by-products potentially formed during incineration of [ ] containing the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance.

B. In light of the potential risk of environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, and the Agency's conclusion that issuing the Order will not result in any significant loss of benefits to society, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to the environment.

C. In light of the estimated production volume of, and human exposure to, the PMN substance, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance.

## VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section. The Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN

substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

CONSENT ORDER

I. TERMS OF MANUFACTURE, IMPORT, PROCESSING,  
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL  
PENDING SUBMISSION AND EVALUATION  
OF INFORMATION

[ ] (“the Company”) is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substance [ ], diacetate] (P04-404) (“the PMN substance”) in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA’s review of, and regulatory action based on, that information, except under the following conditions:

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment, which is required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 68 Federal Register 33129 (June 3, 2003).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

1. The date when the study is scheduled to commence;
2. The name and address of the laboratory which will conduct the study; and
3. The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.
4. The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted at the time the study is initiated. Before starting to conduct any study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing or importing, or causing another person to manufacture or import, the PMN substance beyond the following aggregate manufacture and import volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

<u>Production Limit</u>	<u>Study</u>	<u>Guideline</u>
Tier 1: [ ]	Algal Toxicity Test	OPPTS 850.5400
	Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids	OPPTS 850.1010
	Fish Acute Toxicity Test	OPPTS 850.1075
	Either: 1) Shake-flask Die-away Test, or 2) Aerobic and Anaerobic Transformation in Aquatic Sediments, or an equivalent test (including identification of breakdown products)	OPPTS 835.3170, OECD 308
	Either: 1) Fish BCF; or 2) Bioconcentration: Flow-through Fish Test; or an equivalent test. (Measured BCF (bioconcentration factor) should be based on 100 percent active ingredient and measured concentration(s))	OPPTS 850.1730 OECD 305
	Incineration Simulation Study	Consult with the Agency for protocol
	Porous Pot (sewage treatment simulation)	OPPTS 835.3220

Tier 2: [	]	Migration Study from final foam products	Consult with the Agency for protocol
		Two Generation Reproduction Study: rats, oral route, modified with complementary blood chemistry and histopathology from the 90-day oral study protocol	OPPTS 870.3800, combined with OPPTS 870.3100
		Developmental Toxicity Study: rats, oral route	OPPTS 870.3700

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting", "Data and Reporting", and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data. (1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph

(e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data. (1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk. (1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part IV. of this Consent Order.

#### HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees,

and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

(b) Labeling. (1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (g) of this section or by the Company, for the PMN substance.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately relabeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to

control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(c) Material Safety Data Sheets. (1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

- (i) The requirements of this section.
- (ii) Any operations in the work area where the PMN substance is present.
- (iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (g) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and

other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low Concentrations in Mixtures. If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent by weight or volume, or 0.1 percent by weight or volume if paragraph (g) of this section identifies cancer as a potential human health hazard of the PMN substance. However, this exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) internal organ effects.

(2) Human hazard precautionary statements. When using this substance:

(i) avoid skin contact.

(ii) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) do not release to water.

(5) The human and environmental hazard and precautionary statement contained on a label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

### MANUFACTURING

(a) The Company shall not cause, encourage, or suggest the manufacture and/or import of the PMN substance by any other person outside the Company, except a Contract Manufacturer as described in paragraph (b).

(b) Notwithstanding paragraph (a), the Company may cause a "Contract Manufacturer" outside the Company to manufacture and/or import the PMN substance according to the following conditions:

(1) The Contract Manufacturer must be under contract to the Company to manufacture or import the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture or import.

(3) If, at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import of the PMN substance, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(A) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer.

(B) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(C) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for

Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substance, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture or import the PMN substance only upon written notification from the Agency.

(c)(1) Sunset Following SNUR. Paragraph (a) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraph (a) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and paragraph (a) expires in accordance with subparagraph (c)(1), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations.

(3) Subparagraph (c)(1) shall not negate the effect of any fully executed Consent Order for Contract Manufacturer entered into under subparagraph (b)(2).

DISTRIBUTION

(a) Distribution Requirements. Except as provided in paragraph (b), the Company shall distribute the PMN substance outside the Company, including for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Not further distribute the PMN substance to any other person, including for disposal, until after the PMN substance has been completely reacted, cured, or incorporated into a [ ].

(2) Comply with the same requirements and restrictions, if any, required of the Company in the Hazard Communication Program section of this Order.

(3) Comply with the same environmental release restrictions, if any, required of the Company in the Release to Water section of this Order.

(b) Temporary Transport and Storage. Notwithstanding paragraph (a), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers (labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order) provided the following two conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to a person who has given the Company the written agreement required by paragraph (a).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN

substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (a).

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section or, after paragraph (a)(1) expires in accordance with subparagraph (d)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (c)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to

comply with any of the conditions specified in paragraph (a) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(d) Sunset Following SNUR. (1) Paragraph (a)(1) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraph (a)(1) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (a)(1) of this Distribution section expires in accordance with subparagraph (d)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (a)(1), such notice may substitute for the written agreement required in the introductory clause of paragraph (a); so

that, if the Company provides such notice to the persons to whom it distributes the PMN substance, then the Company is not required to obtain from such persons the written agreement specified in paragraph (a).

### RELEASE TO WATER

The Company is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from manufacturing, processing, or use into the waters of the United States.

### II. RECORD-KEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Records documenting the aggregate manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(2) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(3) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(4) Copies of labels required under the Hazard Communication Program section of this Order;

(5) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(6) Records documenting compliance with any applicable manufacturing and distribution restrictions in the Manufacturing and Distribution sections of this Order;

(7) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(8) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(9) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured, imported, processed or used.

(b) Applicability. The provisions of this Record-keeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Company. The "collection of information" required in this TSCA 5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012**.

### III. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and is not required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent

Order and the "Notice of Transfer" document which is incorporated by reference as Attachment C to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405M), 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date and time of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date and time of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date and time of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used,

distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured and imported

by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

#### IV. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health or environmental effects of, human exposure to, or environmental release of, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

V. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order, or modifications made thereto, in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Wardner G. Penberthy, Acting Director  
Chemical Control Division  
Office of Pollution Prevention and Toxics

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name:

Title:

Company: [ ]

## ATTACHMENT A

### DEFINITIONS

*[Note: The attached Order may not contain some of the terms defined below.]*

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective

clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER OF TOXIC SUBSTANCES CONTROL ACT  
SECTION 5(e) CONSENT ORDER

[ \_\_\_\_\_ ]  
Company (Transferor)

P04-404  
PMN Number

1. Transfer of Manufacture Rights. Effective on \_\_\_\_\_, the Company did sell or otherwise transfer to \_\_\_\_\_, ("Successor in Interest") the rights and liabilities associated with manufacture of the above- referenced chemical substance, which was the subject of a premanufacture notice (PMN) and is governed by a Consent Order issued by the U.S. Environmental Protection Agency (EPA) under the authority of 5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. 2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

3. Confidential Business Information. The Successor in Interest hereby:

\_\_\_ reasserts,  
\_\_\_ relinquishes, or  
\_\_\_ modifies

all Confidential Business Information (CBI) claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT SECTION 5(e) CONSENT ORDER  
NOTICE OF TRANSFER (continued)

\_\_\_\_\_  
Company (Transferor)

P04-404  
PMN Number

\_\_\_\_\_  
Signature of Authorized Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Authorized Official

\_\_\_\_\_  
Title of Authorized Official

\_\_\_\_\_  
Successor in Interest

\_\_\_\_\_  
Signature of Authorized Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Authorized Official

\_\_\_\_\_  
Title of Authorized Official

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, Zip Code

\_\_\_\_\_  
Successor's Technical Contact

\_\_\_\_\_  
Address

\_\_\_\_\_  
City, State, Zip Code

\_\_\_\_\_  
Phone



CONSENT ORDER

I. TERMS OF MANUFACTURE, IMPORT, PROCESSING,  
DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL  
PENDING SUBMISSION AND EVALUATION  
OF INFORMATION

[ ] ("the Contract Manufacturer") has entered into a contract with [ ] ("the Company") to manufacture or import exclusively for the Company the chemical substance [ ] (P04-404) ("the PMN substance").

As a condition of manufacturing or importing the PMN substance for the Company, the Contract Manufacturer is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substance for any non-exempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on that information except under the following conditions:

TESTING

The Contract Manufacturer is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in the Testing section of the Consent Order for the Company:

<u>Production Limit</u>		<u>Guideline</u>
Tier 1:		
[	1) Shake-flask Die-away Test, or	
	2) Aerobic and Anaerobic Transformation in Aquatic Sediments, or	OPPTS 850.5400 OPPTS 850.1010 OPPTS 850.1075
	an equivalent test (including identification of breakdown products)	OPPTS 835.3170,
	Either:	OECD 308
	1) Fish BCF; or	
	2) Bioconcentration: Flow-through Fish Test; or an equivalent test. (Measured BCF (bioconcentration factor) should be based on 100	OPPTS 850.1730 OECD 305

Study

Algal Toxicity  
Acute Daphnid Toxicity  
Fish Acute Toxicity

Either:

percent active ingredient  
and measured  
concentration(s))

Porous Pot (sewage  
treatment simulation)

OPPTS 835.3220

Tier 2: [	]	Migration Study from final foam products	Consult with the Agency for protocol
		Two Generation Reproduction Study: rats, oral route, modified with complementary blood chemistry and histopathology from the 90-day oral study protocol	OPPTS 870.3800, combined with OPPTS 870.3100
		Developmental Toxicity Study: rats, oral route	OPPTS 870.3700

#### HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Contract Manufacturer shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Contract Manufacturer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Contract Manufacturer may rely

on an existing hazard communication program, including an existing program established under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Contract Manufacturer or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Contract Manufacturer is required either by another Order issued under section 5(e) of TSCA or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Contract Manufacturer will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Contract Manufacturer will use to inform contractors of the presence of the PMN substance in the Contract Manufacturer's workplace and of the provisions of this Order if employees of the contractor work in the Contract Manufacturer's workplace and are reasonably likely to be exposed to the PMN substance while in the Contract Manufacturer's workplace.

(b) Labeling. (1) The Contract Manufacturer shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (g) of this section or by the Contract Manufacturer, for the PMN substance.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Contract Manufacturer, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Contract Manufacturer, for the PMN substance.

(ii) The Contract Manufacturer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Contract Manufacturer need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Contract Manufacturer shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Contract Manufacturer unless the container is immediately relabeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Contract Manufacturer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Contract Manufacturer, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the Contract Manufacturer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Contract Manufacturer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Contract Manufacturer must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(c) Material Safety Data Sheets. (1) The Contract Manufacturer must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Contract Manufacturer, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Contract Manufacturer, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Contract Manufacturer.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Contract Manufacturer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Contract Manufacturer, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Contract Manufacturer.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Contract Manufacturer or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Contract Manufacturer must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Contract Manufacturer may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Contract Manufacturer must ensure that persons receiving the PMN substance from the Contract Manufacturer are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Contract Manufacturer may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Contract Manufacturer must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Contract Manufacturer must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as monitoring conducted by the Contract Manufacturer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (g) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Contract Manufacturer has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Contract Manufacturer under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low Concentrations in Mixtures. If the PMN substance is present in the work area only as a mixture, the Contract Manufacturer is exempt from the provisions of this section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent by weight or volume, or 0.1 percent by weight or volume if paragraph (g) of this section identifies cancer as a potential human health hazard of the PMN substance. However, this exemption does not apply if

the Contract Manufacturer has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing Hazard Communication Program. The Contract Manufacturer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

- (1) Human health hazard statements. This substance may cause:
  - (i) internal organ effects.
- (2) Human hazard precautionary statements. When using this substance:
  - (i) avoid skin contact.
  - (ii) use skin protection.
- (3) Environmental hazard statements. This substance may be:
  - (i) toxic to fish.
  - (ii) toxic to aquatic organisms.
- (4) Environmental hazard precautionary statements. Notice to users:
  - (i) do not release to water.

(5) The human and environmental hazard and precautionary statement contained on a label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

### MANUFACTURING

(a)(1) The Contract Manufacturer shall not cause, encourage, or suggest the manufacture and/or import of the PMN substance by any other person, except the Contract Manufacturer.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Contract Manufacturer shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations.

DISTRIBUTION

(a) Distribution Requirements. The Contract Manufacturer shall distribute the PMN substance only to the Company.

(b)(1) Sunset Following SNUR. Paragraph (a) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is so notified, paragraph (a) of this Distribution section shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and paragraph (a) of this Distribution section expires in accordance with subparagraph (b)(1), the Contract Manufacturer shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations.

(c) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Contract Manufacturer obtains knowledge that a recipient of the PMN substance has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Contract

Manufacturer shall cease supplying the substance to that recipient, unless the Contract Manufacturer is able to document each of the following:

(1) That the Contract Manufacturer has, within 5 working days, notified the recipient in writing that the recipient has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Contract Manufacturer received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (b)(2) of this Distribution section, the Contract Manufacturer obtains knowledge that the recipient has again engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Contract Manufacturer shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

#### DISPOSAL

Whenever the Contract Manufacturer disposes of the PMN substance by incineration, the incinerator must operate at temperatures equal to or greater than 800 degrees Celsius (+/- 100 degrees) with a 2 second minimum residence time.

RELEASE TO WATER

The Contract Manufacturer is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from manufacturing, processing, or use into the waters of the United States.

II. RECORD-KEEPING

(a) Records. The Contract Manufacturer shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Records documenting the aggregate manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(2) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Contract Manufacturer directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(3) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(4) Copies of labels required under the Hazard Communication Program section of this Order;

(5) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(6) Records documenting compliance with any applicable manufacturing and distribution restrictions in the Manufacturing and Distribution sections of this Order;

(7) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(8) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(9) The Contract Manufacturer shall keep a copy of this Order at each of its sites where the PMN substance is manufactured, imported, processed or used.

(10) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Contract Manufacturer and is not reasonably ascertainable by the Contract Manufacturer, the Contract Manufacturer must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

(b) Applicability. The provisions of this Record-keeping Section are applicable only to the Contract Manufacturer, if applicable, and not the Contract Manufacturer's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Contract Manufacturer is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Contract Manufacturer.

The "collection of information" required in this TSCA 5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012**.

#### IV. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Contract Manufacturer may petition EPA at any time, based upon new information on the health or environmental effects of, human exposure to, or environmental release of, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Contract Manufacturer may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA

determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

V. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Contract Manufacturer waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order, or modifications made thereto, in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does not constitute an admission by the Contract Manufacturer as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Contract Manufacturer may have under TSCA.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Jim Willis, Director  
Chemical Control Division  
Office of Pollution Prevention and Toxics

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name:

Title:

Contract Manufacturer: [

]

## ATTACHMENT A

### DEFINITIONS

*[Note: The attached Order may not contain some of the terms defined below.]*

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

# **Exhibit C**

|  
[Chemical Data Reporting](#)

- **Chemical Name** : Benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester
- **Chemical Identifier** : 183658-27-7
- **Use** : Commercial;

**Company Name:** CBI

**Site Name:** CBI

**Site Location:** CBI

**Manufacturing Information:**

- Activity (Manufacturing or Import) : MANUFACTURED
- Manufactured volume : CBI
- Imported production volume : 0
- 2011 production volume : CBI
- 2010 production volume : CBI
- Volume exported? : CBI
- Volume used on site? : 0
- Number of workers likely exposed? : 500 - 999
- Was the chemical recycled? : NO
- Physical forms : Liquid

**Processing and Use Information:**

**Industrial Processing and Use:**

- Type of process or use : Processing-incorporation into formulation, mixture, or reaction product
- Industrial sectors : Construction
- Industrial function category : Flame retardants
- Percent production volume : 10
- Number of sites : < 10
- Number of industrial workers likely exposed : 100 - 499

**Industrial Processing and Use:**

- Type of process or use : Processing-incorporation into formulation, mixture, or reaction product
- Industrial sectors : Furniture and Related Product Manufacturing
- Industrial function category : Flame retardants
- Percent production volume : 90
- Number of sites : < 10
- Number of industrial workers likely exposed : 100 - 499

**Commercial Use:**

- Product category : Furniture and Furnishings not covered elsewhere
- Consumer or commercial use : Commercial
- Used in product intended for children? : No
- Percent production volume : 90
- Maximum concentration : Not Known or Reasonably Ascertainable

- Number of commercial workers likely exposed : Not Known or Reasonably Ascertainable

**Commercial Use:**

- Product category : Building/Construction Materials not covered elsewhere
- Consumer or commercial use : Commercial
- Used in product intended for children? : No
- Percent production volume : 10
- Maximum concentration : Not Known or Reasonably Ascertainable
- Number of commercial workers likely exposed : Not Known or Reasonably Ascertainable