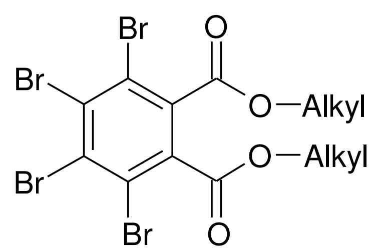
United States
Environmental Protection Agency

EPA Document# 740-Q1-4004
August 2015
Office of Chemical Safety and
Pollution Prevention

TSCA Work Plan Chemical
Problem Formulation and Data Needs Assessment

Brominated Phthalates Cluster
Flame Retardants



CASRN	NAME
26040-51-7	1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester
183658-27-7	Benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester
20566-35-2	1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester
77098-07-8	1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, mixed esters with diethylene glycol and propylene glycol
7415-86-3	1,2-Benzenedicarboxylic acid, 1,2-bis(2,3-dibromopropyl) ester
*	Confidential A
*	Confidential B

* Confidential Business Information

August 2015

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This report was developed by the United States Environmental Protection Agency (US EPA), Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT). The Work Plan Data Needs Assessment for the brominated phthalates cluster was prepared based on currently available data. Mention of trade names does not constitute endorsement by the EPA.

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Portions of this document and the technical supplements were prepared for EPA/OPPT by Abt Associates, the Syracuse Research Corporation (SRC) and Versar.

Docket

Please visit the public docket (Docket: EPA-HQ-OPPT-2014-0491) to view supporting information.

ABBREVIATIONS

BFR	Brominated Flame Retardant
BPC	Brominated Phthalates Cluster
CASRN	Chemical Abstract Service Registry Number
CBI	Confidential Business Information
CDR	Chemical Data Reporting
CPSC	Consumer Product Safety Commission
DEHP	bis (2-ethylhexyl) phthalate
DNA	Data Needs Assessment
EC	European Commission
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EU	European Union
FR	Flame Retardant
HPV	High Production Volume
IUR	Inventory Update Reporting Rule
kg	Kilogram(s)
K_{ow}	Octanol:Water partition coefficient
lb	Pound
LOEL	Lowest Observed Effect Level
Log K_{ow}	Logarithmic octanol:water partition coefficient
mg	Milligram
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No-observed-adverse-effect level
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBDE	Polybrominated Diphenyl Ether
PentaBDE	Pentabrominated diphenyl ether
PFA	Polyurethane Foam Association
PUF	Polyurethane foams (in recognition of the variety of polyurethane foam formulations)
PVC	Polyvinylchloride
REACH	Registration, evaluation, authorisation and restriction of chemicals
SVOCs	Semi-volatile organic chemicals
TBB	Benzoic acid, 2, 3, 4, 5-tetrabromo-, 2-ethylhexyl ester
TBPH	1, 2-Benzenedicarboxylic acid, 3, 4, 5, 6-tetrabromo-, 1, 2-bis (2-ethylhexyl) ester
TBPA-Diol	Generic designator that is used for 1, 2-Benzenedicarboxylic acid, 3, 4, 5, 6-tetrabromo-, 1-[2-(2-hydroxyethoxy) ethyl] 2-(2-hydroxypropyl) ester

TBPA-Diol (mixed esters)

Generic designator that is used for 3,4,5,6 tetrabromo-1, 2-benzene dicarboxylic acid, mixed esters with diethylene glycol and propylene glycol

TCEP	Tris (2-chloroethyl) phosphate
TSCA	Toxic Substances Control Act
US	United States

EXECUTIVE SUMMARY

As part of EPA's comprehensive approach to enhance the Agency's management of existing chemicals, EPA/OPPT identified a work plan of chemicals for further assessment under the Toxic Substances Control Act (TSCA) in March 2012. Chemical risk assessments will be conducted if, as a result of scoping and problem formulation, there are exposures of concern, identified hazards and sufficient data for quantitative analysis. If an assessment identifies unreasonable risks to humans or the environment, EPA will pursue risk reduction. This document presents the data needs assessment for the brominated phthalates cluster as part of the TSCA Work Plan.

EPA/OPPT has identified a cluster of cyclic aliphatic bromide flame retardant chemicals, including 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester (**TBPH**; CASRN 26040-51-7); benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester (**TBB**; CASRN 183658-27-7); 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester (**TBPA-Diol**; CASRN 20566-35-2); 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, mixed esters with diethylene glycol and propylene glycol [**TBPA-Diol (mixed esters)**; CASRN 77098-07-8] and 1,2-benzenedicarboxylic acid, 1,2-bis(2,3-dibromopropyl) ester (CASRN 7415-86-3). In addition there are two other chemicals in the cluster whose name and structure are considered confidential, designated, Confidential A and Confidential B. These chemicals have similar physical and chemical properties and environmental fate characteristics two of these chemicals, **TBPH** and **TBB**[1] have been selected as the index chemicals for this cluster. Uses for 1,2-benzenedicarboxylic acid, 1,2-bis(2,3-dibromopropyl) ester (CASRN 7415-86-3) have not been identified: the remaining identified members of the cluster are used as flame retardants in polyurethane foams (PUF). The toxicological hazard profile for this cluster of chemicals is incomplete.

The conclusions from Problem Formulation, as illustrated in the Conceptual Model and described by Assessment Questions, indicate that the toxicological profile and exposure profile for this cluster of chemicals is incomplete and inadequate to develop a TSCA work plan risk assessment. 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 and uncertainties related to exposure and hazard which preclude EPA/OPPT from moving forward with an assessment for any of the chemicals in the Brominated Phthalates Cluster.

During problem formulation, EPA/OPPT identified available fate, exposure and hazard data, and characterized potential exposures, receptors and effects. Data adequacy were determined following published EPA/OPPT criteria[2]. EPA/OPPT reviewed the public literature (nominally to

[1] **TBPH** and **TBB** have been identified as components for Firemaster®550 and Firemaster®BZ-54 for which data are being generated in the open literature

[2] Generally followed guidance outlined for the High Production Volume Challenge Program at: http://www.epa.gov/chemrtk/pubs/general/datadfin.htm and http://www.epa.gov/champ/pubs/hpv/Methodology%20for%20HBP%20under%20ChAMP_March%202009.pdf And EPA Risk Assessment Guidance at: http://www.epa.gov/raf/

August 2013) and its own files (public and confidential) to explore the sources, pathways, receptors and effects for consideration in the assessment and identified areas of data limitation, data uncertainty and critical missing data elements necessary to conduct the assessment. EPA/OPPT developed a conceptual model and an analysis plan as a result of problem formulation.

Likely sources and pathways considered for analysis include use of BPC members as flame retardants in polyurethane foams (PUF) and PUF products found in commercial and residential environments. Monitoring studies have reported the occurrence of **TBPH** and **TBB** in various media including sludge, sediment, indoor dust and biota. Frequent detection of **TBPH** and **TBB** in these media provides evidence of release and transport of **TBPH** and **TBB** into the environment and suggests an increasing potential for exposure. Some data show exposures to **TBPH** and **TBB** to remote species (e.g. seals and sea birds) indicating the occurrence of global release and transport. The source of the chemicals is unknown. There is no evidence of environmental exposure to the other BPC members reported in the literature. No information on potential worker exposure or release to the environment during BPC chemical manufacture, PUF manufacture or PUF processing is available. However, monitoring data suggest that worker exposure to BPC chemicals during the use of PUF containing products occurs.

EPA/OPPT developed a conceptual model to outline the assessment strategy for the PBC chemicals. Using available tools and approaches, EPA/OPPT identified the relevant TSCA use of **TBPH** and **TBB** as flame retardants in PUF and PUF products found in residential and commercial environments. EPA/OPPT determined that the major source of exposure to **TBPH** and **TBB** for human health and the environment was via **TBPH** and **TBB** in dust and/or **TBPH** and **TBB** in dust generated during the manufacture and processing of **TBPH** and **TBB** and the processing and use of products containing **TBPH** and **TBB. TBPH** and **TBB** have been detected in house dust. In addition, there is evidence that a diverse array of commercial and household PUF-containing articles containing **TPBH** and **TBB** can be broken down (i.e. via mechanical or physical wearing, or chemical degradation), thus contributing to dust/microplastic particles. During routine cleaning operations, it is thought that these microparticles derived from PUF and PUF products can be washed away into the sewerage systems where these particles containing BPC chemicals can adhere to wastewater treatment plant sludge or make their way into the outdoor environment by transportation through the air and/or washed down the drains (or storm drains) to enter waterways.

Due to the prevalence of PUF and PUF products in commercial and residential settings, EPA/OPPT focused the exposure scenarios on PUF manufacture and use of PUF products, and the use of PUF and PUF products by workers and consumers in commercial and residential environments. The monitoring of **TBPH** and **TBB** in dust is considered a good indicator for the evaluation of human exposure to PUF and PUF-containing products.

As a result of this problem formulation, EPA/OPPT is releasing a Data Needs Assessment for the Brominated Phthalates Cluster to guide the collection of additional data and information to fill the critical data gaps and reduce uncertainties identified during problem formulation. As the information is collected, EPA will continue to evaluate the adequacy of the database to conduct a risk assessment that can inform decision making.

1 INTRODUCTION

As a part of EPA's comprehensive approach to enhance the Agency's management of existing chemicals, in March 2012 EPA identified a work plan of chemicals for further assessment under the Toxic Substances Control Act (TSCA)[3]. After gathering input from stakeholders, EPA developed criteria used for identifying chemicals for further assessment[4]. The criteria focused on chemicals that meet one or more of the following factors: (1) potentially of concern to children's health (for example, because of reproductive or developmental effects); (2) neurotoxic effects; (3) persistent, bioaccumulative, and toxic (PBT); (3) probable or known carcinogens; (4) used in children's products; or (5) detected in biomonitoring programs. Using this methodology, EPA/OPPT identified a TSCA Work Plan of chemicals as candidates for risk assessment in the next several years. In the prioritization process, the brominated phthalates cluster (BPC), was identified for assessment based on available data for the two index chemicals **TBPH** and **TBB**. The cluster members are expected to be persistent, bioaccumulative and potentially hazardous to human health (developmental toxicity) and the environment (acute and chronic toxicity).

EPA/OPPT is performing risk assessments on chemicals in the work plan. If an assessment identifies unacceptable risks to humans or the environment, EPA/OPPT will pursue risk management. The target audience for this risk assessment is primarily EPA risk managers; however, it may also be of interest to the broader risk assessment community as well as US stakeholders interested in the brominated phthalates cluster. The information presented in the risk assessment may be of assistance to other federal, state and local agencies as well as to members of the general public who are interested in the risks of the brominated phthalates cluster.

The initial steps in EPA/OPPT's risk assessment development process, which is distinct from the initial prioritization exercise, includes scoping and problem formulation. During these steps EPA/OPPT reviews currently available data and information, including but not limited to, assessments conducted by others (e.g., authorities in other countries), published or readily available reports and published scientific literature. During scoping and problem formulation the more robust review of the factors influencing initial prioritization may result in refinement – either addition/expansion or removal/contraction – of specific hazard or exposure concerns previously identified in the prioritization methodology.

This document includes the results of scoping and problem formulation for the brominated phthalates cluster. In the initial prioritization and scoping stages EPA/OPPT determined which

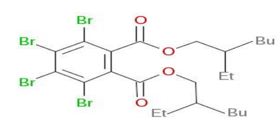
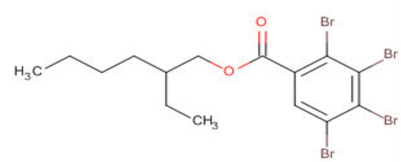
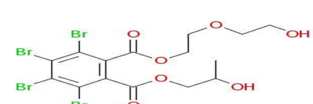
[3] http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html
[4] http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf

chemical(s) would be included and what uses would be considered in the assessment. During problem formulation, EPA/OPPT identified available exposure and hazard data, and characterized potential exposures, receptors and effects. EPA/OPPT developed a conceptual model (Section 2.6.1) and analysis plan (Section 2.6.2) as a result of problem formulation.

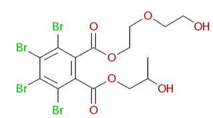
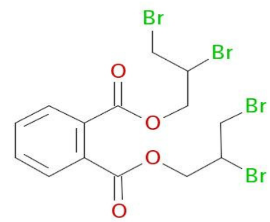
1.1 Scope of the Assessment

The members of the Brominated Phthalates Cluster (BPC) are depicted in Table 1-1. **Confidential A** and **Confidential B** are referenced throughout the assessment and where appropriate, information that is not deemed confidential is included or cited as Confidential Business Information (CBI). The BPC chemicals have several structural features in common: multiple bromine atoms, typically attached to the aromatic ring; the 1, 2-benzenedicarboxylate moiety (phthalate structure)[5] and they are alkyl esters. These common features form the basis of these chemicals being clustered and assessed together. In addition, the overarching use of these chemicals is as flame retardants (FR) in a variety of products with polyurethane foams (PUF) being the major use and focus of this assessment.

Table 1-1: Members of the Brominated Phthalates Cluster

CASRN	NAME	STRUCTURE
26040-51-7	**TBPH**: 1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester	
183658-27-7	**TBB**: Benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester	
20566-35-2	**TBPA-Diol**: 1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester	

[5] The cluster member 2-ethylhexyl tetrabromobenzoate (**TBB**), CASRN [183658-27-7] is missing one of the phthalate carboxylate esters but is included in this cluster since the commercial product Firemaster®550 also contains the **TBB** / **TBPH** phthalate mixture. This structural anomaly should not affect the inclusion of this chemical since phthalates often decarboxylate during metabolism and biodegradation. (Kleerebezem, 1999)

CASRN	NAME	STRUCTURE
77098-07-8	**TBPA Diol (mixed esters)**: 3,4,5,6 tetrabromo-1,2-benzene dicarboxylic acid, mixed esters with diethylene glycol and propylene glycol	 Representative Structure
7415-86-3	**Bromo Alkyl Ester**: 1,2-Benzenedicarboxylic acid, 1,2-bis(2,3-dibromopropyl) ester	
CONFIDENTIAL A	*	*
CONFIDENTIAL B	*	*

*Confidential Business Information

1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester (**TBPH**; CASRN 26040-51-7) and benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester (**TBB**; CASRN 183658-27-7) are used as additives in product formulations (e.g. Firemaster®550). 1, 2-Benzenedicarboxylic acid, 1, 2-bis (2, 3-dibromopropyl) ester (**Bromo Alkyl Ester;** CASRN 7415-86-3) is also used as an additive but hasn't been introduced into commerce in quantities that trigger reporting under IUR/CDR (Inventory Update Reporting/Chemical Data Reporting). 1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester (**TBPA-Diol**; CASRN 20566-35-2) and 1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, mixed esters with diethylene glycol and propylene glycol [**TBPA-Diol (mixed esters)**; CASRN 77098-07-8] are primarily used as reactives in product formulations and are incorporated into the polyurethane backbone via a covalent bond. Only one of the two confidential cluster members was reported in CDR. The stated use was claimed as CBI.

All chemicals in the cluster are listed on the TSCA Inventory. All chemicals, except for **Bromo Alkyl Ester** (CASRN 7415-86-3) and **Confidential A**, are all found in commerce at volumes greater than one million pounds. The exact production volume of **TBB** and **Confidential B** are considered CBI and the information cannot be shared publicly.

Monitoring data show that 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester (**TBPH**) and benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester (**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. Furthermore, the **TBPH/TBB** ratio found in the environment is different from that found in the manufactured commercial product (Davis et al., 2012; Stapleton et al., 2008a). No evidence of environmental exposure to the other brominated phthalate cluster (BPC) members has been found.

Using available tools and approaches, EPA/OPPT identified the relevant TSCA use of **TBPH** and **TBB** as flame retardants in PUF and PUF products found in residential and commercial environments. EPA/OPPT determined that the major source of exposure to **TBPH** and **TBB** for human health and the environment was via **TBPH** and **TBB** in dust and/or **TBPH** and **TBB** in dust generated during the manufacture and processing of **TBPH** and **TBB** and the processing and use of products containing **TBPH** and **TBB. TBPH** and **TBB** have been detected in house dust. In addition, there is evidence that a diverse array of commercial and household PUF-containing articles containing **TPBH** and **TBB** can be broken down (i.e. via mechanical or physical wearing, or chemical degradation), thus contributing to dust/microplastic particles. During routine cleaning operations, it is thought that these microparticles derived from PUF and PUF products can be washed away into the sewerage systems where these particles containing BPC chemicals can adhere to wastewater treatment plant sludge or make their way into the outdoor environment by transportation through the air and/or washed down the drains (or storm drains) to enter waterways.

Due to the prevalence of PUF and PUF products in commercial and residential settings, EPA/OPPT focused the exposure scenarios on PUF manufacture and use of PUF products, and the use of PUF and PUF products by workers and consumers in commercial and residential environments. The monitoring of **TBPH** and **TBB** in dust is considered a good indicator for the evaluation of human exposure to PUF and PUF-containing products.

TBPH and **TBB** have been detected in dust samples in commercial and domestic indoor environments suggesting that the monitoring of **TBPH** and **TBB** in dust is considered a good model for the evaluation of human exposure to PUF and PUF containing products. The source of **TBPH** and **TBB** in the outdoor environment is not known and so potential releases to the environment from PUF manufacturing and processing are also being assessed. PBDE research for foam products as a source of FR has been well documented and is the basis of EPA/OPPT's current focus on the BPC chemicals in dust and specifically PUF. Hale demonstrated that FR-treated polyurethane foams were a source of PBDE exposure up the food chain (Hale et al., 2002). In addition, **TBPH/TBB** were shown to increase in air samples as the market switched from PBDE to BPC in foam (Ma et al., 2012). FR [TCEP] concentrations in dust were directly associated with FR content in foam baby products as opposed to other FR containing products (Marklund et al., 2005).

EPA/OPPT found limited hazard data for assessing the human health and environmental effects endpoints. In addition, only limited data are available for the commercial products (e.g. Firemaster®550 and Firemaster®BZ-54) which show potential toxicity to human health and the environment and whose effects are difficult to attribute to a particular BPC chemical without additional information. Further, data on the commercial products from non-guideline studies indicate that toxicity observed for phthalates alone may not be the same for the structurally similar brominated phthalates. Available data from environmental studies were not considered reliable as these provided conflicting results. Consequently, EPA/OPPT determined that the available data for the BPC index chemicals, **TBPH** and **TBB,** are inadequate to characterize hazard or exposure for the purposes of risk assessment.

1.1 Regulatory and Assessment History

All chemicals in the cluster are listed on the TSCA Inventory. All chemicals, except for **Bromo Alkyl Ester** (CASRN 7415-86-3) and **Confidential A**, are all found in commerce at volumes greater than one million pounds. The exact production volume of **TBB** and **Confidential B** are considered CBI and the information cannot be shared publicly.

EPA/OPPT reviewed the public literature (nominally to August 2013) and its own files (public and confidential) in the preparation of this assessment. Data adequacy was determined following published EPA/OPPT criteria[6]. Internationally, **TBPH** has been registered for use in the European Union (EU) and Canada is gathering information for preparing a screening-level assessment. Canada is also gathering information on **TBB**. **Bromo Alkyl Ester** (CASRN 7415-86-3) has been cited in the World Health Organisation's (WHO) programme for chemical safety (WHO, 1997). **TBPA-Diol** has also been registered in the EU and is cited in the WHO programme for chemical safety (WHO, 1997). In Australia, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) prepared a report on the polybrominated flame retardants which references **TBPA-Diol** and **TBPA-Diol (mixed esters).** No hazard data were available for human health or ecotoxicity for these two chemicals (NICNAS, 2001). Hazard data have since been published for the commercial product, Firemaster®BZ-54 (Chemtura, 2012a; NICNAS, 2004), which is a mixture of **TBPH** and **TBB** (Chemtura, 2010).

In the US, the Consumer Product Safety Commission (CPSC) has published two risk assessments on the use of flame retardants: a preliminary risk assessment of FR chemicals in upholstered furniture foam (CPSC, 2006a) and a quantitative assessment of potential health effects from the use of fire retardant chemicals in mattresses (CPSC, 2006b). Firemaster®550 was included in this assessment; however, the associated BPC chemicals (**TBPH** and **TBB**) were not assessed due to the lack of toxicity data.

Screening-level data for two of the BPC chemicals [**TBPH** and **TBPA-Diol (mixed esters)**] were submitted to EPA/OPPT under the High Production Volume (HPV) Challenge Program (ACC, 2004; Albemarle - GLCC, 2004). In 2003, EPA/OPPT's Design for the Environment (DfE) program convened a multi-stakeholder group to undertake an assessment of viable alternatives to

[6] Generally followed guidance outlined for the High Production Volume Challenge Program at: http://www.epa.gov/chemrtk/pubs/general/datadfin.htm and http://www.epa.gov/champ/pubs/hpv/Methodology%20for%20HBP%20under%20ChAMP_March%202009.pdf and EPA Risk Assessment Guidance at: http://www.epa.gov/raf/

pentaBDE called the Furniture Flame Retardancy Partnership (FFRP), which included chemical manufacturers, furniture manufacturers, and governmental and non-governmental organizations. At the end of 2004, industry voluntarily ceased production of pentaBDE, and EPA/OPPT issued a Significant New Use Rule (SNUR) that effectively prohibited further manufacture of the chemical. In 2005, the partnership issued the report, "Environmental Profiles of Chemical Flame-Retardant Alternatives for Low-Density Polyurethane Foam (EPA, 2005). The report described the human health and environmental profiles of twelve pentaBDE alternatives which did not appear to pose the same level of concern as pentaBDE. DfE recently announced the development of an update to the Alternative Assessment for flame retardants in furniture foam (http://www.epa.gov/dfe/pubs/projects/flameret/about.htm). For the update, DfE identified nineteen flame retardants and blends relevant to the market in 2013 that may be used in upholstered consumer product containing flexible polyurethane foam. The report included an assessment of **TBPH** and TBB based on the available science at the time; the update will include revised profiles for these two substances and be complementary to this data needs assessment. In addition, data are available for the commercial product, Firemaster® BZ -54 (Chemtura, 2012a; NICNAS, 2001) which is a mixture of **TBPH** and **TBB** (Chemtura, 2010).

2 PROBLEM FORMULATION

The problem formulation stage is intended to determine the major factors to be considered in the assessment, including exposure pathways, receptors and health endpoints (EPA, 1998, 2014). Accordingly, this problem formulation summarized the exposure pathways, receptors and health endpoints EPA/OPPT has recommended for inclusion in the risk assessment. To make this determination, EPA/OPPT conducted a preliminary data review, to identify available fate, exposure and hazard data and determine its likely suitability for quantitative analysis and to identify exposure pathways, receptors and health endpoints for quantitative analysis. EPA/OPPT summarized the outcome of this evaluation in conceptual models that illustrate the exposure pathways, receptor populations and effects that will be considered in the risk assessment. EPA/OPPT also prepared data analysis plans to demonstrate the proposed approach to answering the defined assessment questions.

2.1 Physical and Chemical Properties

The physical and chemical properties are summarized in the technical supplement [EPA# 740-Q1-4001] titled “Physicochemical properties and environmental fate of the brominated phthalates cluster (BPC) chemicals” which can be found at Docket Number EPA-HQ-OPPT-2014-0491 on www.regulations.gov.

2.2 Uses

EPA/OPPT has prepared a data needs assessment (DNA) to facilitate the gathering of appropriate data needed to prepare a risk assessment of the BPC chemicals. To refine the scope of the DNA, use scenarios were evaluated and are summarized in the supporting document

(EPA# 740-Q1-4004 on www.regulations.gov). 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. As stated above, BPC use in PUF is a potential source of FR but EPA/OPPT's focus on dust will capture use in PUF products even if they cannot be directly correlated to the specific source. In addition, under the Commission for Environmental Cooperation (CEC), Canada, Mexico and the United States are evaluating the presence and migration of flame retardants, including members of the BPC, from consumer products. The information gathered from this effort will inform future risk assessment.

EPA/OPPT distinguishes the BPC flame retardants as either reactive or additive depending on whether or not the BPC chemical reacts with the isocyanate monomers to become incorporated into the polymer backbone via covalent bond formation. The BPC chemicals containing free hydroxy moieties chemically react with the isocyanate groups to make the polyurethane linkages. This process can be utilized to make both rigid and flexible PUF. However, the literature suggests that the reactive BPCs are more commonly used for rigid foam [(Dufton PF, 1998), US Patent 5637797 and US Patent application 20120238657]. They do not discount the use in flexible PUF products and suggest that the reactive BPC chemical may also be used in other products as an additive brominated flame retardant (BFR). These patents also suggest that additive BFR, like **TBPH/TBB**, or excess unreacted reactive BFR, are needed to make certain rigid foam applications meet certain safety requirements. In addition, both reactive and additive BPC BFR are patented for use with spray polyurethane foam applications (WO 2013003261 patent application).

According to the Polyurethane Foam Association (PFA) literature, Penta BDE was the BFR of choice for most all flexible PUF. The BPC chemicals were used as penta alternatives in the various flexible PUF products and alternatives to use of any brominated combustion modifying additive (CMA). Two statements by PFA reflect the uncertainly of making general statements, "... there is no "standard foam" which represents the performance of the flexible polyurethane foam (FPF) product category..." and "... there is no such thing as a "standard or real fire" by which performance of a material can be measured and projected to represent performance under all conditions." While PFA members do not make rigid foam, PFA did publish a comparison of the different foam products in 2011 (See Table_Apx A-1).

The report describes the cluster members in terms of their application in PUF and PUF-containing products as either additives or reactives.

2.2.1 Additives

These chemicals are added to the flexible polyurethane foams (PUF) formulation to function as flame retardants. It is anticipated, based on available monitoring data that they are migrating through the foam and being released from the foam into the surrounding environment.

2.2.1.1 TBPH and TBB

1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester (**TBPH**) and benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester (**TBB**) are described together because they are the major components of the Firemaster® brand of flame retardants (e.g. Firemaster®550 and Firemaster® BZ 54). They are used as additives, primarily in the production of polyurethane (PU) foam for use in furniture (flexible to rigid foam). Recycled foam products are not addressed specifically because they are comprised of the universe of foam which makes it difficult to identify the composition of the recycled foam or the source of the bromine present. However, carpet is considered a sink for indoor dust which may be a source of flame retardants (and other contaminants) indoors for release during future use (Batterman et al., 2009; Muenhor and Harrad, 2012). Therefore, because this assessment addresses exposure to flame retardants in dust, use of BPC chemicals in recycled PUF products would be captured in the assessment.

No textile uses have been identified for **TBPH/TBB**; however, **TBPH/TBB** were detected downstream from a textile manufacturing outfall to a municipal wastewater treatment plant (La Guardia et al., 2012). Because there are several foam manufacturing facilities (known sources of **TBPH/TBB**) in this area, it is uncertain that the **TBPH/TBB** detected in the stream can be attributed to the textile sector.

The use of flame retardants and brominated phthalates in plastic [e.g. polyvinyl chloride (PVC)] casings for electronics (e.g. cell phones, computers) or household items (e.g. shower curtains) is either being phased out (Greenpeace, 2013) or considered to be released through the use of the items. In addition, **TBPH** has been used in PVC for decades without detection in the environment. It is only since its use with **TBB** in the Firemaster formulations in PU foams that it has been detected in the environment. Based on its low vapor pressure, it is anticipated that **TBPH** exposure would be through the incidental ingestion of inhaled particulates rather than by the inhalation of the pure substance.

Information on the use of **TBPH/TBB** in sealants/adhesives is scarce and the use of flame retardant in these products is only a small amount of the overall market. There is no information on the release of the flame retardant from these products. If released over time due to wear and tear, it is likely that the chemical would be captured in the particulate matter and detected in dust, e.g. house dust.

TBPH is also used as a plasticizing flame retardant for flexible polyvinyl chloride (PVC) (CECBP SGP, 2008) and as a flame retardant additive for ethylene propylene diene monomer (EPDM) M-class rubber, styrene-butadiene rubber (SBR), and neoprene (Chemtura, 2007a, 2007b, 2007c; Unitex, 2009). Applications of **TBPH** as a flame retardant plasticizer are adhesives and coatings; carpet backing; coated fabrics; film and sheeting; wall coverings; and wire and cable (CECBP SGP, 2008). Generally, hard plastics contain 'reactive', rather than 'additive' brominated phthalates.

2.2.1.2 1, 2-Benzenedicarboxylic acid, 1, 2-bis(2, 3-dibromopropyl) ester (CASRN 7415-86-3)

Bromo Alkyl Ester (CASRN 7415-86-3) was identified as potentially used as a flame retardant in polyester fibers [textiles; (WHO, 1997)]; however, no uses have been identified for this cluster member to date.

2.2.2 Reactives

These chemicals are reacted into the polymer backbone of rigid polyurethane foams (PUF). Based on available data (nature of chemical reactivity and no detection in the environment), it is not anticipated that these chemicals are released from the PUF or PUF product. While they can be used as additives, information pertaining to this use is limited (Login et al., 1981) and available data suggest that the predominant use is as a reactive substance.

2.2.2.1 CASRNs 20566-35-2 and 77098-07-8

1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1-[2-(2-hydroxyethoxy)ethyl] 2-(2-hydroxypropyl) ester (**TBPA-Diol**; CASRN 20566-35-2) and 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, mixed esters with diethylene glycol and propylene glycol [**TBPA-Diol (mixed esters)**; CASRN 77098-07-8] are reacted into the polyurethane (PU) foam backbone for insulation use. They are typically used in rigid PU foams. Because the major use of this insulation is in appliances, such as refrigerators, it is anticipated that the release of the flame retardants is limited. However, there are no data to support this.

2.2.3 Confidential A and Confidential B

The uses for Confidential A and Confidential B are considered confidential business information.

2.3 Fate and Transport

The fate and transport of the BPC chemicals is summarized in the technical supplement [EPA# 740-Q1-4001] titled “Physicochemical properties and environmental fate of the brominated phthalates cluster (BPC) chemicals” which can be found at Docket Number EPA-HQ-OPPT-2014-0491 on www.regulations.gov.

2.4 Exposures

The exposure pathways and associated data for the BPC chemicals are summarized in the technical supplement [EPA# 740-Q1-4002] titled “Use and exposure of the brominated phthalates cluster (BPC) chemicals” which can be found at Docket Number EPA-HQ-OPPT-2014-0491 on www.regulations.gov.

2.4.1 Releases to the Environment

Production volumes of the BPC chemicals are summarized in Table 2-1. Available data suggest that **TBPH/TBB** are getting into the environment (Stapleton et al., 2008a) (Lam et al., 2009) (La Guardia et al., 2012) and being globally transported in the atmosphere (Ma et al., 2012). However, the attribution of the chemicals in the environment to any particular source is unclear. There is no evidence to suggest that release of BPC members from landfills occurs or that they are present in leachate under normal conditions. Some landfills now use incinerators where, at the normal functioning incineration temperatures (> 1000 C), it is anticipated that the **TBPH/TBB** will be completely destroyed and will not enter the environment (EPA-HQ-OPPT-2003-0071-0004).

There is no evidence to suggest that the debromination of the BPC chemicals occurs *in vivo*. However, under laboratory conditions, there is evidence to suggest that debromination can occur (Davis and Stapleton, 2009; Ronen and Abeliovich, 2000) suggesting that under photolytic or anaerobic conditions, the phthalate, namely *bis* (2-ethylhexyl) phthalate (DEHP), can be released. The EPA/OPPT action plan for phthalates outlines the environmental effects of DEHP including adverse effects to aquatic organisms with a broad range of endpoints and at concentrations that coincide with measured environmental concentrations (EPA, 2012d).

TBPH and **TBPA-diol (mixed esters)** are High Production Volume (HPV; produced or imported into the US at volumes ≥ one million pounds) chemicals. Information for the other cluster chemicals is considered confidential. The release of TBB to water from manufacturing and processing is regulated by EPA/OPPT (40 CFR Section 721.2925).

Table 2-1: Production Volumes of the Brominated Phthalates Cluster Chemicals

Cluster Member	Reporting
TBPH: CASRN 26040-51-7	2006 IUR PV ≥ 10 million pounds 2012 CDR PV = 1 to 10 million pounds Not on TRI
TBB: CASRN 183658-27-7	2006 IUR CDR National PV information for the chemical withheld. 2012 CDR National PV information for the chemical withheld. Not on TRI
TBPA-Diol: CASRN 20566-35-2	2006 IUR PV = no record 2012 CDR PV = 1 to 10 million pounds Not on TRI
TBPA-Diol (mixed esters): CASRN 77098-07-8	2006 IUR PV = 1 to 10 million pounds 2012 CDR National PV information for the chemical withheld. Not on TRI

Cluster Member	Reporting
Bromo Alkyl Ester: CASRN 7415-86-3	2006 IUR PV = no record 2012 CDR = no record Not on TRI
Confidential A	Consent Order – testing PV not triggered
Confidential B	2012 CDR National PV information for the chemical withheld.

IUR = Inventory Update Reporting; CDR = Chemical Update Reporting; PV = production volume; TRI = Toxic Releases Inventory

2.4.2 Presence in the Environment

Available data suggest that **TBPH/TBB** are getting into the environment (Stapleton et al., 2008a) (Lam et al., 2009) (La Guardia et al., 2012) and being globally transported in the atmosphere (Ma et al., 2012). However, the attribution of the chemicals in the environment to any particular source is unclear.

2.4.3 Occupational Exposures

EPA/OPPT considers inhalation and dermal exposure to be important exposure pathways for workers. Sometimes, the inhalation of air-suspended particulate matter that is subsequently trapped in mucous and moved from the respiratory system to the gastrointestinal tract (EPA, 2011) is a contributor to aggregate exposures. This will be referred to here as incidental ingestion of inhaled particulates.

The Occupational Safety and Health Administration (OSHA) is responsible for the oversight of various workplace exposures to workers in the chemical manufacture and production of foam (https://www.osha.gov/). At this time, there are no specific standards for workers involved in the production of the cluster members or their use in products.

Generally, during chemical manufacture, occupational exposure via the dermal and inhalation routes is likely for many chemicals. However, the cluster members are liquid and have low vapor pressures ($<1X10^{-6}$ mm Hg) suggesting that exposure to vapors via the inhalation route is not a cause for concern.

During polyurethane foams (PUF) (flexible to rigid) processing, there is some concern for foam handlers and the particulate matter generated during, for example, cutting and sizing foam for use in foam products. The OSHA Permissible Exposure Limit (PEL) for particulates not otherwise regulated (general industry) is 15 mg/m^3 TWA (time weighted average) [29 CFR 1910.1000 Table Z-1 (PNOR) and 29 CFR 1910.1000 Table Z-3 (Inert or Nuisance Dust)]. The American Conference of Governmental Industrial Hygienists (ACGIH) Guideline is 10 mg/m^3 TWA (inhalable particles).

There is limited data on the use of BPC chemicals in spray foam insulation. Spray polyurethane foam consists of two liquid chemical components, referred to as "Side A" and "Side B," that are mixed at the site of installation. Side A is mostly made up of isocyanates, while Side B usually contains polyol, flame retardants and amine catalysts (Badore, 2013). While most spray foam insulation formulations contain chlorinated flame retardants (Babrauskas et al., 2012) evidence from patent applications suggests that there is potential use of reactive BPC cluster members for this application (WIPO Patent Application WO/2013/003261).

In addition, there is evidence to suggest that occupational exposures to some sub-populations may lead to elevated levels of BPC member chemicals. Studies measuring polybrominated diphenyl ether (PBDE) congeners in carpet installers (serum concentrations) (Stapleton et al., 2008b) and flight attendants (air sampling) (Allen et al., 2013b) show that they are potentially exposed to higher levels of PBDEs when compared to the general population. The trend of **TBPH/TBB** substituting for PBDEs would likewise potentially lead to similar elevated exposures in these worker environments. In addition, there are data (Carignan et al., 2013) for gymnasts that demonstrate exposure to **TBPH/TBB**; however, the source of exposure is not clear. Gyms typically have foam pits which are a known source of **TBPH/TBB** (Carignan et al., 2013) and are a potential source of exposure not only to gymnasts but other subpopulations (e.g. toddlers and children) using the gym or other environments (e.g. motocross or skateboarding) containing foam pits (http://www.foamorder.com/foam-pit.html).

2.4.4 General Population Exposures

There is potential for the general population to be exposed to the brominated phthalates cluster (BPC) chemicals through the ingestion of potentially contaminated wildlife and vegetation. Available physical-chemical properties of the BPC chemicals suggest that they have limited solubility in water and low volatility. Therefore, for the general population and consumers, inhalation of volatile BPC chemicals is not anticipated to be a source of significant exposure. However, the BPC chemicals do partition into particulate matter (Weschler and Nazaroff, 2008, 2010) which is a potential source of exposure via incidental ingestion of inhaled particulates. Dermal exposure is not considered a significant route of exposure from BPC chemicals from polyurethane foams (PUF) products (Chemtura, 2012a).

2.4.5 Consumer Exposures

Consumer exposure to the BPC chemicals may include dermal exposure through direct skin contact with the chemicals on the surface of objects or articles, incidental ingestion of inhaled particulates (see 2.4.3) and incidental ingestion of indoor settled dust via hand-to-mouth behaviors. In addition, children may experience incidental ingestion via object-to-mouth behaviors. Inhalation exposure is not expected (see 2.4.4).

TBPH and **TBB** have been found in house dust in Boston, MA and California (Stapleton et al., 2008a) (Dodson et al., 2012). The source of these flame retardants is unclear but could be attributed to the number of flame-retardant-containing consumer goods found in homes.

Flexible polyurethane foam is used in both commercial and domestic furniture. Additional information on use in furniture can be found in the EPA/OPPT environmental profile of chemical flame-retardant alternatives for low-density PUF (EPA, 2005). **TBPH** and **TBB** are semi-volatile organic chemicals (SVOCs) with high log-KOA values. Hence, any breakdown of the consumer products *in situ* may lead to the release of the flame retardant which predominantly partitions into particulate matter e.g. house dust (Weschler and Nazaroff, 2008, 2010). Carpet in homes is considered a natural sink for house dust (Batterman et al., 2009; Muenhor and Harrad, 2012).

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. Since the introduction of **TBPH/TBB** as a replacement for PBDEs in foam, they have been detected in environmental monitoring e.g. sludge in San Francisco estuaries (Klosterhaus et al., 2009; La Guardia et al., 2010). Given that the vapor pressure of e.g. **TBPH** is very low, release from PVC will likely occur through mechanical action, again, suggesting that these particles will be detected in, for example, house dust.

Although insulation has been identified as a source for **TBPA-diol** and **TBPA-diol (mixed esters)**, if used as reactives (See 2.2.2.1), exposure is not expected; however, release from PUF needs to be confirmed. 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. EPA/OPPT has not identified current uses for **Bromo Alkyl Ester**.

2.5 Hazard Endpoints

The hazard data for the BPC chemicals are summarized and tabulated in the technical supplement [EPA# 740-Q1-4003] titled "Hazard Assessment of the brominated phthalates cluster (BPC) chemicals" which can be found at Docket Number EPA-HQ-OPPT-2014-0491 on www.regulations.gov.

2.5.1 Ecological Hazard

Insufficient experimental data are available to characterize hazard that would result from chronic exposure to wildlife population. Currently, information from experimental studies that address standard aquatic toxicity endpoints are limited to two chronic invertebrate studies conducted on two different species and two different flame retardant formulations [Firemaster® BZ-54, PM-PHT-4 Diol and **TBPH** (>95%)]. These studies present conflicting conclusions. Additional studies are available that attempt to address population-level effects.

These studies would not be sufficient to support a full risk assessment, but can be used to support qualitative hazard characterization for the brominated phthalates. These studies suggest aquatic and/or sediment dwelling invertebrate populations are likely to be impacted by chronic exposure to brominated phthalate flame retardants and suggest high hazard concern. Acute toxicity data were available for **TBPH/TBB** (Firemaster® BZ-54) that also suggest aquatic invertebrates as the most sensitive species; however, given the low water solubility and high Log K_{ow} of **TBPH/TBB** and the use of solvents and/or test concentrations above the limit of solubility, there is concern that these effects do not represent environmental conditions. Additional brominated phthalates presented in the cluster that have lower Log K_{ow} values may result in acute hazard, but insufficient acute toxicity information are available to characterize the hazard to these chemicals.

2.5.2 Human Health Hazard

Structural analogy suggests the potential for reproductive toxicity and “phthalate syndrome” associated with the structural analog, bis (2-ethylhexyl) phthalate (DEHP). Limited toxicity data are available for the human health endpoints for the brominated phthalates cluster members; however, EPA/OPPT has published a screening-level hazard characterization on the phthalate esters category (EPA, 2010a) which indicates a broad range of toxicity.

No hazard data are available for **TBB**. Available data for some members of the BPC [**TBPH** (purity > 95%)] and for Firemaster® BZ 54 (**TBPH/TBB** mixture) suggest that the acute oral and dermal toxicity in animals is low. The acute inhalation toxicity of **TBPA-Diol** is high.

A chronic dietary study with **TBPH** (purity >95%) did not identify a target organ although perturbations in clinical chemistry parameters suggested effects on the liver. In a chronic gavage study with Firemaster® BZ 54 (**TBPH/TBB** mixture), effects on the kidney were observed at all doses with females appearing to be more sensitive to exposure. Chronic toxicity data are not available for the remaining brominated phthalate cluster members [**TBPA-diol**, **TBPA-diol (mixed esters)**, **Bromo Alkyl Ester**, **Confidential A** and **Confidential B**).

Data from a two-generation reproductive toxicity study and a prenatal developmental toxicity study with the commercial product Firemaster® BZ 54 (**TBPH/TBB** mixture) showed the potential to affect fetal development at high doses. No data are available for reproductive/developmental toxicity for the remaining brominated phthalate cluster members [**TBPH**, **TBPA-diol**, **TBPA-diol (mixed esters)**, **Bromo Alkyl Ester**, **Confidential A** and **Confidential B**).

Genetic toxicity studies indicate that **TBPH** (purity >95%) is not mutagenic to bacteria but induces chromosomal aberrations *in vitro*. **TBPH** (purity >95%) did not induce mouse micronuclei *in vivo*. **TBPA-diol** and **TBPA-diol (mixed esters)** are not mutagenic to bacteria. No genetic toxicity data are available for the remaining brominated phthalate cluster members [**TBB, Bromo Alkyl Ester**, **Confidential A** and **Confidential B**].

2.6 Results of Problem Formulation

2.6.1 Conceptual Model

During problem formulation, a conceptual model (see Figure 2-1) was developed to identify important sources, pathways, and receptors of exposure. Potential exposures to the BPC chemicals (derived from the manufacture, processing and use of BPS--containing polyurethane products) in homes, offices, the environment, and occupational settings were linked to hazard endpoints in human and non-human receptors.

The conceptual model designed to identify important sources, pathways, and receptors of exposure, and to link potential exposures to BPC chemicals in dust (derived from PUF and PUF products) in homes, offices, the environment, and occupational settings to hazard endpoints (responses) of concern is shown in Figure 2-1[7]. The schematic depicts the pathways (arrows) of potential exposure to the BPC members found in dust generated during chemical manufacture, the manufacture of PUF and PUF products, and the use (and disposal) of PUF and PUF products. The dotted lines designate critical areas of data unavailability/uncertainty associated with exposure pathways.

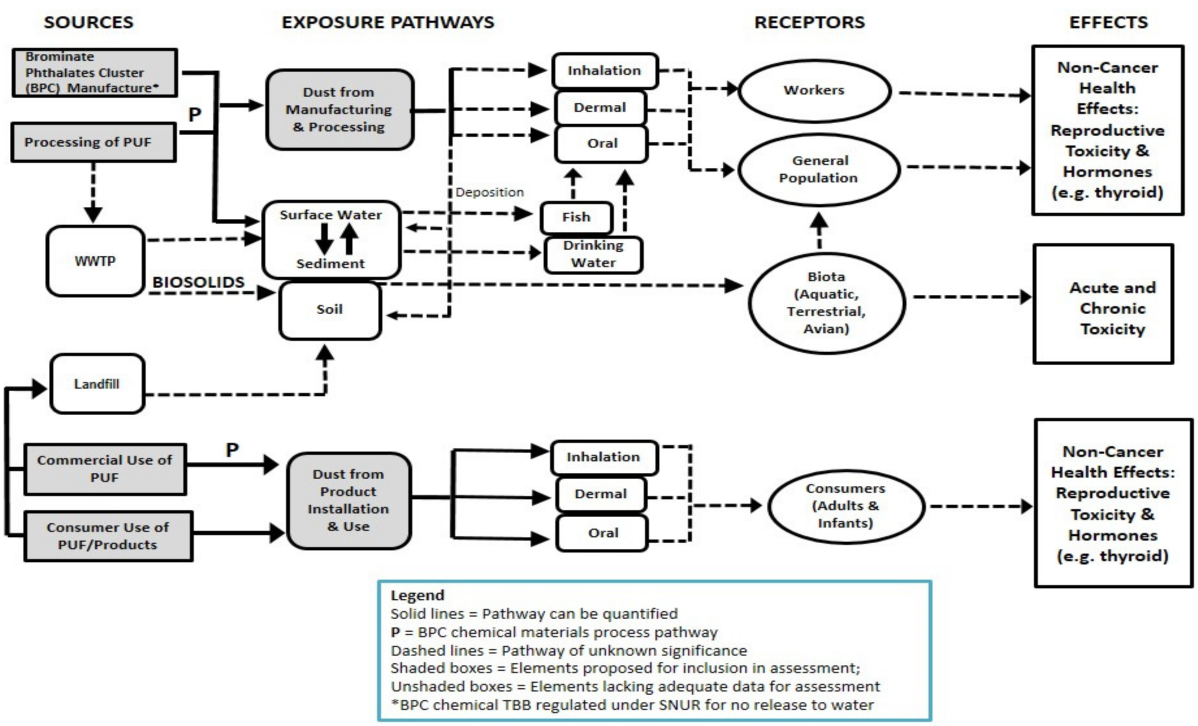


Figure 2-1: Conceptual Model for the Brominated Phthalates Cluster

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[7] The potential for environmental exposure to BPC chemicals during chemical manufacture is depicted as a potential source of environmental exposure but is not being addressed in this assessment.

EPA/OPPT developed a conceptual model to identify important sources, pathways, and receptors of exposure, and to link potential exposures to BPC chemicals in dust [derived from polyurethane foams (PUF) and PUF products] in homes, offices, the environment, and occupational settings to hazard endpoints (receptors/effects) of concern. The schematic depicts the pathways (arrows) of potential exposure to the BPC members found in dust generated during manufacture of PUF and PUF products. The dotted lines designate critical data gaps/uncertainties associated with the identified exposure pathways.

2.6.2 Analysis Plan

Based on concerns for the potential risk of the Brominated Phthalates Cluster (BPC) chemicals to human health and the environment, EPA/OPPT, as part of problem formulation, identified risk assessment questions to focus the assessment on TSCA uses. The following information is known.

- 1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) ester (**TBPH**) and benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl ester (**TBB**) have been detected in house dust and commercial environments.
    - Available hazard data on commercial products and emerging data from targeted studies with **TBPH** and **TBB** metabolites indicate disruption of thyroid hormone homeostasis and the potential for effects on testosterone levels.
- **TBPH** and **TBB** have been detected in waterways and remote species.
    - Available data on commercial products and **TBPH** indicate potential acute and chronic toxicity.

Based on the available information and keeping the focus on TSCA uses, the following assumptions were made in compiling the assessment questions.

- The major source of potential environmental and human exposure to the BPC chemicals is from the release of the BPC chemicals during polyurethane foams (PUF) manufacture or use of PUF products. There may be other sources of exposure for some of the BPC chemicals.
- Measuring **TBPH** and **TBB** in dust can be used to monitor potential human exposure

The general assessment questions are as follows with additional tiering below:

1. Which BPC chemicals are found in dust in environments where PUF and PUF products are manufactured and used?
2. What data are needed to characterize hazard to BPC chemicals found in dust?
3. What additional exposure data, if any, are needed to characterize exposure to BPC chemicals found in dust?
4. What is the hazard to human health from the BPC chemicals found in dust?
5. What is the hazard to sensitive species in the environment from the BPC chemicals found in dust?

6. Are the concentrations of BPC chemicals found in dust a risk to human health and the environment?

A. *Environmental Exposure*
   1. How persistent and bioaccumulative are the micronized particles of foam containing the BPC chemicals?
   2. Are the BPC chemicals persistent and bioaccumulative in the environment? If not “P”, are the degradates?
   3. Are non-dust releases to the environment during the manufacture of BPC chemicals more significant than BPC releases from PUF?
   4. What releases to the environment occur during the production of PUF and manufacture of articles containing PUF (particulates and dust)?
      a. How does the type of PUF relate to the amount released?
      b. Is this release relevant for the BPC chemicals covalently bound to the polymer backbone?
   5. Are there environmental releases of BPC chemicals from PUF during use and disposal of commercial or consumer products containing PUF?
      a. Can the analogous release of non-BPC FR be used as a surrogate for BPC releases?
   6. What hazard data need to be developed to address the potential risk to environmental species associated with any or all of these exposures?
      a. For BPC released chemicals?
      b. For persistent degradation products?

B. *Occupational Exposure*

   No information is available on the potential exposure to workers during manufacture of the BPC chemicals, PUF manufacture and processing, or the use of products containing PUF. Available data for **TBPH** and **TBB** suggest that there is the potential for occupational exposure.

   1. What is the potential worker exposure to BPC chemicals during their manufacture?
   2. What is the potential worker exposure to BPC chemicals during the manufacture of PUF and manufacture of articles containing PUF (particulates and dust)?
      a. Does the potential worker exposure differ between BPC chemicals used as additives versus BPC chemicals used as reactives?
   3. What is the potential worker exposure to BPC chemicals from the use of commercial or consumer products containing PUF?
      a. Does the potential worker exposure differ between BPC chemicals used as additives versus BPC chemicals used as reactives?
   4. What hazard data need to be developed to address the potential risk to human health associated with any or all of these exposures?

C. General Population and Consumer Exposure

TBPH and **TBB** have been detected in house dust. However, **TBPA-diol** and **TBPA-diol (mixed esters)**, including the primary degradation product tetrabromophthalic acid, have not been reported in literature as being present in the environment. The diols are the reactive BPC chemicals that are incorporated into the polymer structure via covalent bonds. This suggests that unlike **TBPH** and **TBB**, they are not being released from the PUF or from PUF manufacturing and processing facilities; or that if emission occurs, degradation is fast enough to prevent measurable accumulation. Information on the remaining BPC chemicals, **Confidential A** and **Confidential B**, cannot be released.

1. What is the potential consumer exposure to BPC chemicals in dust from the use of PUF and PUF products?
    a. Does the potential consumer exposure differ between BPC chemicals used as additives versus BPC chemicals used as reactives?
2. What hazard data need to be developed to address the potential risk to human health associated with any or all of these exposures?
3. Which PUF products contain BPC chemicals?
4. How do releases to the environment contribute to levels of **TBPH** or **TBB** found in dust from PUF potentially lead to general population exposure (e.g. particulates/dust from PUF manufacture and use)?
5. Are there **TBB / TBPH** dust releases that contribute to levels in the environment / biota?

2.6.3 Sources and Pathways Excluded From Further Assessment

In general, the data gaps preclude excluding sources and pathways from further assessment. However, the potential for environmental exposure to BPC chemicals during chemical manufacture may be a potential source of exposure. Assessment is contingent on obtaining information on releases of FR to the environment and the continued regulation of the releases of **TBB** to water.

2.6.4 Uncertainties and Data Gaps

Data gaps and data needs have been identified for the Brominated Phthalates Cluster (BPC) chemicals. However, data gaps are not necessarily data needs for a risk assessment. Figure 2-2 to Figure 2-7 outline the tiering of the data needs. Figure 2-2 depicts the overall source of dust from polyurethane foams (PUF). The BPC chemicals can be distinguished by the way they are predominantly used in PUF: additive or reactive use. Use as either additive or reactive in PUF is not precluded; however, the literature suggests that they are predominantly used as one or the other. **TBPH**, **TBB** and the **Bromo alkyl ester** are typically added to PUF. **TBPA-Diol** and **TBPA-Diol (mixed esters)** are typically reacted into the polymer backbone where they are covalently bound. Release from the PUF is not expected and there is no evidence from environmental monitoring that they are; however, this needs to be confirmed. The use profiles of **Confidential A** and **Confidential B** cannot be disclosed. Questions remain as to whether the additive migrates out of the foam and if the reactive releases from the foam.

If it is assumed, based on the covalent bonding, that the reactives once reacted are not released from the polymer backbone, as suggested by environmental monitoring, then exposure to these BPC chemicals is not expected from their use in PUF and PUF products. When exposure isn't expected, the characterization of hazard is not considered a priority, and while there may be hazard data gaps there is no need to generate these data to determine the risk for this exposure scenario. If it is determined that the reactives are released from the PUF and PUF products, then data are needed to characterize hazard. The data needs are outlined in Figure 2-3 and Figure 2-7. If the additive BPC migrates from the PUF and PUF products and exposure is likely, data needs have been identified to characterize the hazard to human health and the environment. The data needs are outlined in Figure 2-3, Figure 2-4, Figure 2-5 and Figure 2-6 and listed in Section 2.

2.6.4.1 Overview of Data Needs for Hazard and Exposure to Dust during Polyurethane Foams (PUF) manufacture and use of PUF Products

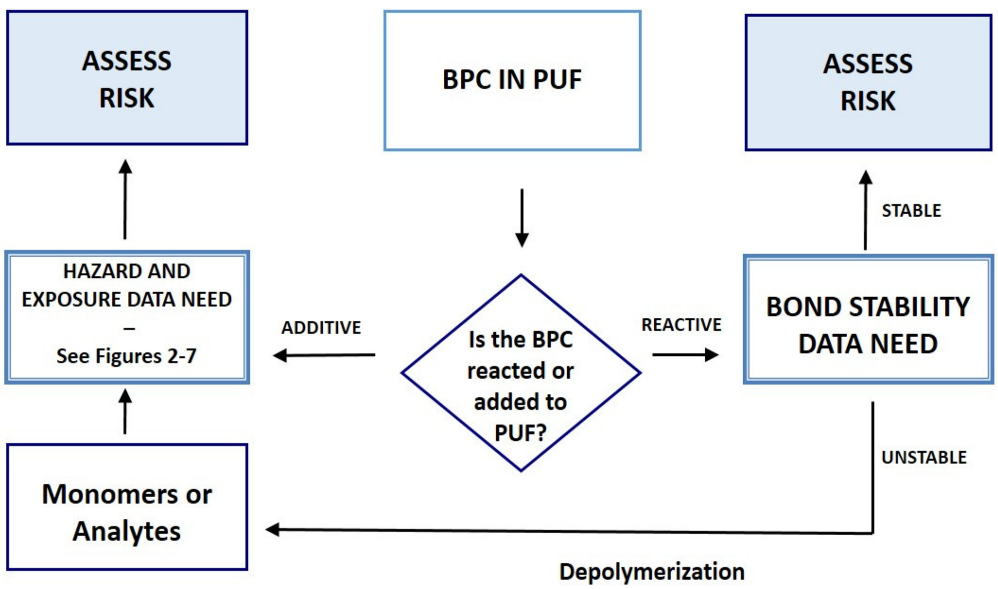

Figure 2-2: Overview of Data Needs for Hazard and Exposure to Dust during Polyurethane Foams (PUF) manufacture and use of PUF Products[8]

Brominated Phthalate Cluster (BPC) chemicals are in Polyurethane Foams (PUF) as a chemical additive or a reactant. Use of reactant BPCs that are covalently bonded to the polymer matrix will have a slightly different release pathway than additive BPCs as additional more extreme conditions, such as heat, UV process would have to be applied in order for the reactant BPC to be released from the PUF substrates. Based on dust monitoring data, it appears the conditions for covalent bond breakage are rare since dusts have not been found to contain the reactive BPCs.

[8] Confidential A and Confidential B not included: Some Confidential data may be applicable to the data gaps for the non-CBI cluster members

2.6.4.2 Overview of Data Needs for Ecotoxicity from Environmental Exposure to Brominated Phthalates Cluster (BPC) chemicals in Polyurethane Foams (PUF)

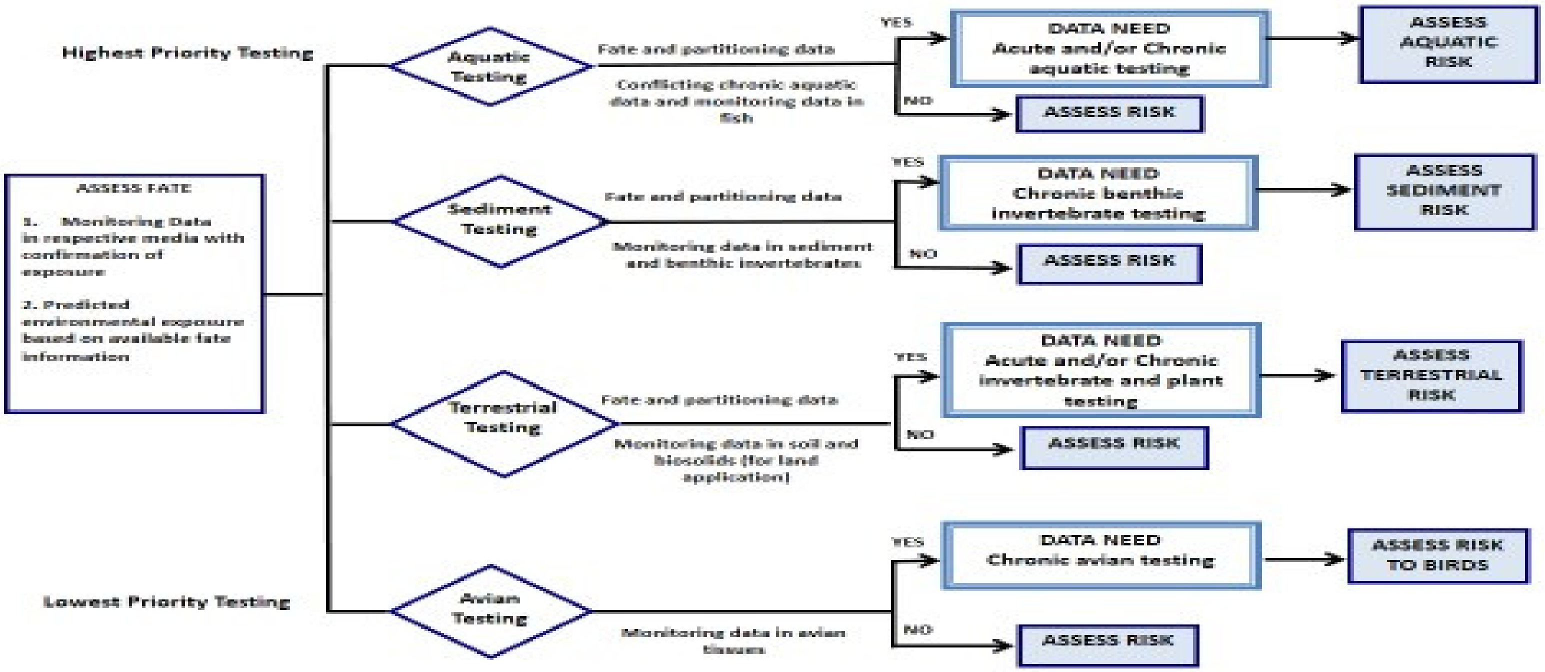

Figure 2-3: Overview of Data Needs for Ecotoxicity from Environmental Exposure to Brominated Phthalates Cluster (BPC) chemicals in Polyurethane Foams (PUF).

Figure 2-3 depicts the relationship between the information obtained from environmental fate monitoring and data and the need for testing in different environmental compartments. The data need in an environmental compartment is directly related to the environmental fate of the BPC chemicals. Brominated flame retardants (BFR) have been found in historic Publicly Owned Treatment Works (POTW) sludge samples. The source is uncertain but potential release from dust from drains in homes and offices cannot be discounted[9]. POTW sludge and land application of biosolids should be monitored for contamination and as source of exposure to earthworms, birds and humans through food.

[9] (Venkatesan and Halden, 2014)

2.6.4.3 Overview of Data Needs for Human Health Hazard from exposure to Brominated Phthalates Cluster (BPC) chemicals in Polyurethane Foams (PUF) Dust

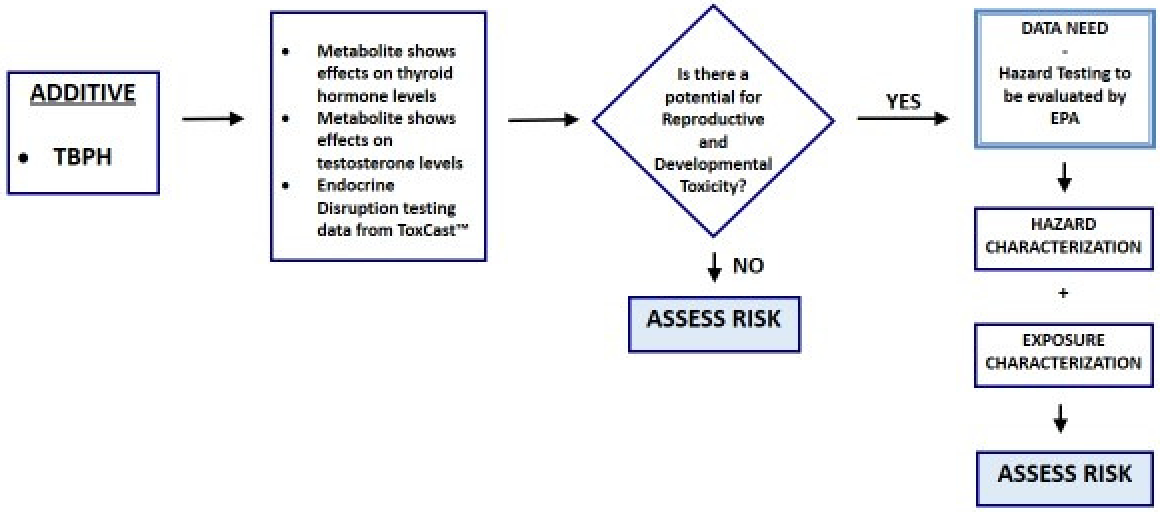

Figure 2-4: Overview of Data Needs for Human Health exposure to dust and TBPH from Polyurethane Foams (PUF)

There is evidence in the literature that **TBPH** is in the environment and in dust in commercial and residential settings. Figure 2-4 shows that data for hazard characterization are available for the reproductive and developmental toxicity endpoints for the commercial mixtures of Firemaster™550 and Firemaster™ BZ-54. Non-guideline data are available for the metabolite (TBMEHP; tetrabromomonoethylhexyl phthalate) and from ToxCast™. The nature and extent of reproductive and developmental effects observed as a result of exposure to commercial products that may be attributable to **TBB** or **TBPH** (or another component of the mixture) is confounded due to the lack of data with individual components. EPA/OPPT has determined that the available data neither conclusively indicate nor discount the potential for reproductive or developmental toxicity. Additional data for hazard characterization would allow human health risks from exposure to **TBPH** in dust derived from PUF and PUF products to be assessed.

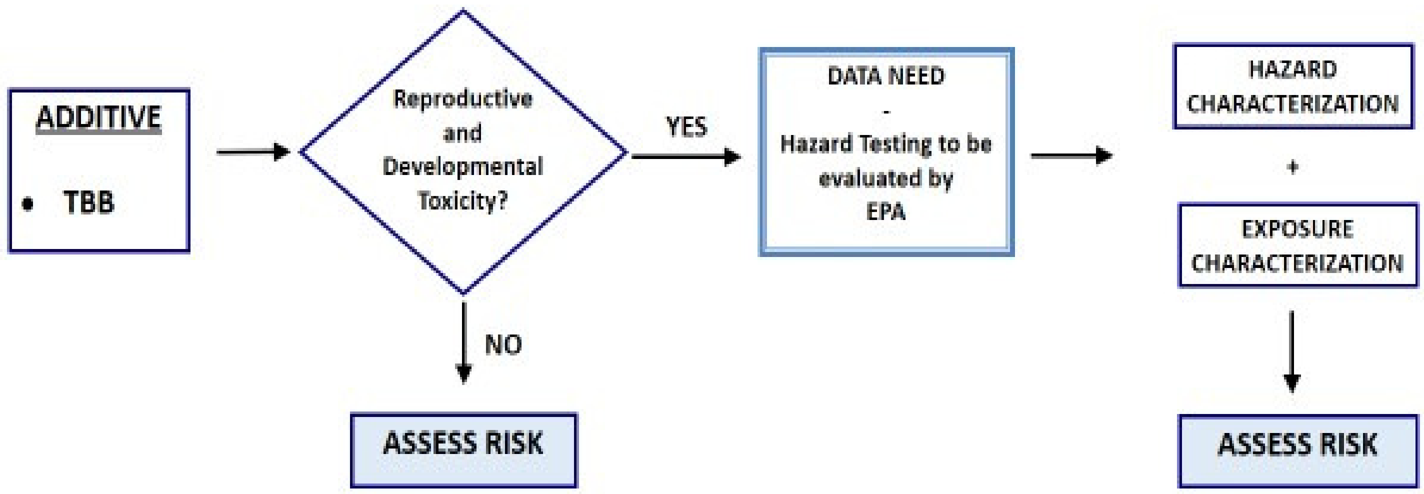

Figure 2-5: Overview of Data Needs for Human Health exposure to dust and TBB from Polyurethane Foams (PUF)

There is evidence in the literature that **TBB** is in the environment or in dust found in commercial and residential settings. Figure 2-5 shows that data for hazard characterization are available for reproductive and developmental toxicity endpoints for the commercial mixtures Firemaster™550 and Firemaster™BZ-54. The nature and extent of reproductive and developmental effects observed as a result of exposure to commercial products that may be attributable to **TBB** or **TBPH** (or another component of the mixture) is confounded due to the lack of data with individual components. Additional data for hazard characterization would allow human health risks from exposure to **TBB** in dust from PUF and PUF products to be assessed.

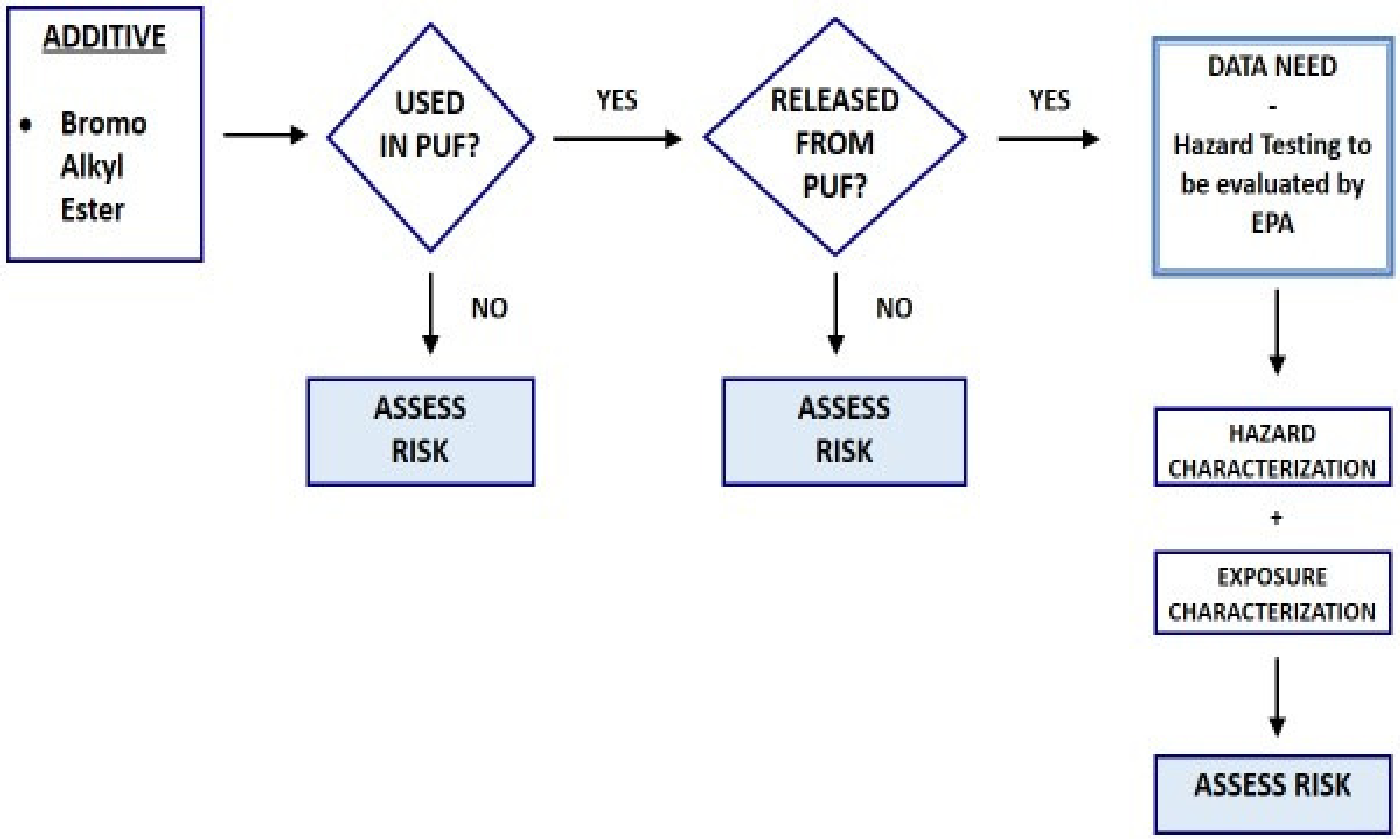

Figure 2-6: Overview of Data Needs for Human Health exposure to dust and Bromo Alkyl Ester from Polyurethane Foams (PUF)

There is no information in the literature that Bromo Alkyl Ester is being used in commerce in PUF and PUF products or that Bromo Alkyl Ester is found in dust in commercial or residential settings. Confirmation that Bromo Alkyl Ester is not used in PUF would be valuable information for a risk assessment because if there is no use in PUF and PUF-products, no human exposure to Bromo Alkyl Ester from its use in PUF and PUF products is anticipated and the risk can be assumed to be negligible. However, if there is evidence that Bromo Alkyl Ester is being used in PUF and PUF products, hazard and/or exposure characterization of Bromo Alkyl Ester would be needed for assessing risks.

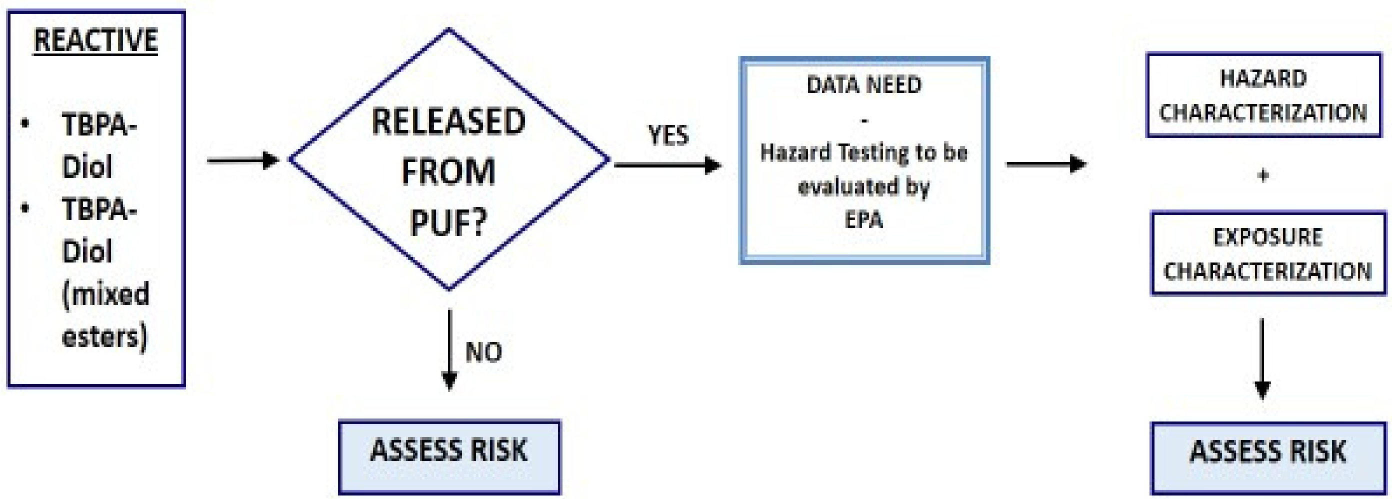

Figure 2-7: Overview of Data Needs for Human Health exposure to dust and TBPA-DIOL AND TBPA-DIOL (MIXED ESTERS) chemicals from Polyurethane Foams (PUF)

There is no information in the literature that TBPA-Diols are being used in commerce in PUF and PUF products or that TBPA-Diols are found in dust in commercial or residential settings. Confirmation that TBPA-Diols are not used in PUF would be valuable information for a risk assessment because if there is no use in PUF and PUF-products, no human exposure to TBPA-Diols from their use in PUF and PUF products is anticipated and the risk can be assumed to be negligible. However, if there is evidence that TBPA-Diols are being used in PUF and PUF products, hazard and/or exposure characterization of TBPA-Diols would be needed for assessing risks.

2.6.4.4 Releases to the Environment

2.6.4.4.1 Chemical Manufacture

Available data allow for a limited screening-level assessment of exposure to **TBPH** and **TBPA-Diol**. The release of **TBB** to water from manufacturing and processing is regulated by EPA/OPPT (40 CFR Section 721.2925). In general, there are uncertainties associated with the media type and frequency of releases of the cluster chemicals to the environment. To reduce these uncertainties, monitoring information (air, water, effluent) in and around the manufacturing facilities would aid the risk assessment. Alternatively, in the absence of monitoring/measured data, process specific information including site information, batch size, number of hours/batch, number of batches produced/year, days/year of operation, concentration of the chemical, release sources, estimated releases, frequency of releases, control technologies used to mitigate/reduce the releases, and waste disposal practice would assist in the assessment of environmental exposure from the manufacturing sector.

This information would enable EPA/OPPT to develop environmental release estimates, including frequency and media of release for an “average" or a “typical" manufacturing site.

2.6.4.4.2 Polyurethane Foams (PUF) Manufacture

There is no readily available information on the environmental releases of the chemicals in this cluster during the manufacture of polyurethane foams (PUF). The release of **TBB** to water from manufacturing and processing is regulated by EPA/OPPT (40 CFR Section 721.2925). An existing generic scenario for PU flexible foam manufacturing can be used to estimate releases and occupational exposures.

Available data allow for a limited screening-level assessment of releases of **TBPH** and **TBPA-Diol** to the environment, using the generic scenario and non-Confidential Business Information (CBI) Chemical Data Reporting (CDR) data.

Limited data are available for releases to the environment during PUF manufacture. To reduce uncertainties, monitoring information (air, water, effluent) in and around the PU manufacturing facilities would aid the risk assessment. Alternatively, in the absence of monitoring/measured data, process specific information including site information, batch size, number of hours/batch, number of batches/year, number of days/year of operation, concentration of the chemical, release sources, estimated releases, frequency of releases, and control technologies used to mitigate/reduce the releases, and waste disposal practice would aid the risk assessment.

This information would enable EPA/OPPT to develop non site-specific “typical facility” release estimates with frequency and media of release.

2.6.4.4.3 Manufacture of Products Containing Polyurethane Foams (PUF)

There is no readily available information on the environmental releases of the chemicals during the manufacture of products containing PUF. EPA/OPPT can use estimates following the approach taken in the New Chemicals Program to prepare a screening-level assessment based on a selected number of industries/exposure scenarios for the two chemicals for which data are available (**TBPH** and **TBPA-Diol**).

In addition to the inherent uncertainties of the estimates used to prepare a screening-level assessment, there would be uncertainties in the estimates of the media and frequency of releases. To reduce uncertainties, industry- wide monitoring information (air, water, effluent) in and around the relevant facilities would aid the risk assessment. Alternatively, in the absence of monitoring/measured data, process specific information including site information, number of articles manufactured per hour , number of hours/day, number of days/year, concentration of chemical in foam, release sources, estimated releases, frequency of releases, and control technologies used to mitigate/reduce the releases, and waste disposal practice would aid the risk assessment.

This information would enable EPA/OPPT to develop release estimates with frequency and media of release for one or more “generic facility” using foam containing chemicals in this cluster.

2.6.4.4.4 Occupational Use of Products Containing Polyurethane Foams (PUF)

No release information is available and EPA/OPPT is unable to assess release from the uses of products containing PU foam.

Data needs for an assessment include monitoring information (air, water, effluent) in and around the use sites. Alternatively, in the absence of monitoring/measured data, use specific information including the number of use sites, detailed description of use scenario, number of hours product is used/day, number of use days/year, concentration of chemical in the foam, amount of foam in the product, types and number of products per use site, estimated releases, frequency of releases, and control technologies used to mitigate/reduce the releases, and waste disposal practice would aid the risk assessment.

This information would enable EPA/OPPT to develop a "typical" use scenario for each use and assess releases, media of release and the frequency of release.

2.6.4.4.5 Consumer Use of Products Containing Polyurethane Foams (PUF)

Detection of **TBPH/TBB** in sludge, sediment, and indoor dust indicate a potential for exposures to the environment. Detection of both **TBPH** in remote biota and environmental media indicates exposures have occurred and that global transport is occurring as well. Additional environmental samples from soil, sludge, sediment, and biota will provide information about the prevalence and spread of BPCs in the environment.

Additional data are needed to understand how, at what rate, and in what form **TBPH** and **TBB** migrate out of many types of products. Source characterization, migration rates, and monitoring data are needed to demonstrate how the use of **TBPH**, **TBB** and Confidential A in certain products may result in subsequent exposure through migration of these chemicals into indoor and outdoor environments.

2.6.4.5 Occupational Exposure

2.6.4.5.1 Chemical Manufacture

The chemicals in this cluster are not on the Occupational Safety and Health Administration's (OSHA) list of regulated chemicals (OSHA, 2013). There is some non-confidential CDR information on the number of manufacturing workers and concentrations (EPA, 2012a). Based on the physical-chemical properties and available information, workers in cluster chemical manufacturing operations are not expected to be exposed to the chemicals via inhalation.

Limited data are available for occupational exposure to the cluster members leading to uncertainties in the exposure assessment. To reduce these uncertainties, workplace monitoring information (personal and/or area sampling for workers handling the chemical) would aid the risk assessment. Alternatively, in the absence of the monitoring data, information on manufacturing process, information on worker activities (activities performed during work shift, number of work hours/day, days/year of operation, concentration of the chemical and identification of worker activities which may result in inhalation exposure), and information on workplace industrial hygiene practices and control technologies would assist in the occupational exposure assessment.

This information would enable EPA/OPPT to develop an occupational exposure assessment for the workers at manufacturing sites.

2.6.4.5.2 Polyurethane Foams Manufacture (PUF)

Based on limited monitoring data and available information, limited screening-level exposure assessment may be possible. Without chemical-specific data, the exposure estimates would be based on particulate standards (i.e. total dust) and/or available data on other chemicals being monitored. The exposure estimates and the number of workers exposed may not be representative of this industry.

To reduce uncertainties, industry-wide workplace monitoring data (personal and/or area sampling for workers handling the chemical) would aid the risk assessment. Alternatively, in the absence of the monitoring data, manufacturing process information, information on worker activities (activities performed during work shift, number of work hours/day, number of days/year of operation, concentration of chemical and potential sources for inhalation exposure), information on workplace industrial hygiene practices and control technologies would aid the risk assessment.

This information would enable EPA/OPPT to develop non site-specific “typical foam manufacturing facility” occupational exposure estimates.

2.6.4.5.3 Manufacture of Products Containing Polyurethane Foams (PUF)

No data are available on occupational exposure to the cluster chemicals during the manufacture of products containing PU foam. Based on OSHA’s Particulates Not Otherwise Regulated (inhalable and respirable dust) a "high-end" exposure can be determined.

To reduce uncertainties, industry-wide workplace monitoring information (personal and/or area sampling for workers handling the chemical) would aid the risk assessment. Alternatively, in the absence of the measured data, process information, information on worker activities (activities performed during work shift, number of work hours/day, days/year of operation, concentration of chemical and potential sources for inhalation exposure), information on workplace industrial hygiene practices and control technologies would aid the risk assessment.

This information would enable EPA/OPPT to develop non site-specific “typical facility” occupational exposure estimates.

2.6.4.5.4 Occupational Use of Products Containing Polyurethanes Foams (PUF)

No data are available on occupational exposure to the cluster chemicals during the use of products containing PUF.

To reduce uncertainties, industry wide workplace air monitoring information would aid the risk assessment. Alternatively, in the absence of the measured data, use information, number of use sites, information on worker activities (activities performed during work shift, number of work hours/day, days/year of operation, concentration of chemical and potential sources for inhalation exposure), information on workplace industrial hygiene practices and control technologies would aid the risk assessment.

This information would enable EPA/OPPT to develop a "typical" use scenario for each use and assess occupational exposure assessment for each use.

2.6.4.6 Consumer Exposure from Use of Products Containing Polyurethane Foams (PUF)

The exposure potential of **TBPH** and **TBB** is influenced by several parameters of the source material to which these chemicals are added. One of the major sources of exposure is considered to be certain types of polyurethane (PU) foam products based on the following criteria as compared to other product end uses: major use-based production volume, higher percent of flame retardant chemicals within the product, long service life/product use within indoor environments, diverse set of large articles with large surface areas exposed, and multiple sources present within various indoor environments.

Additional information is needed to develop source characterization which includes the type of foam linked with the type of end-use product, the percent weight of chemical within the product, and properties of the foam, including density, rigidity, and structure. Differences in density, rigidity, and structure (closed vs. open cell) along with the thickness of the product and its exposed surface area influence the likelihood of migration and associated exposure potential of **TBB** and **TBPH** over time. Lower density, thinner, open-cell flexible foams, with large amounts of exposed surface area have may have greater potential for additive migration over time. However, it is not clear if there may be threshold values for one or a combination of these factors that could influence migration and exposure potential. Therefore, additional information is needed on the migration of additive chemicals out of Polyurethane Products, which include data on the thickness of product; surface area exposed; diffusion coefficient; partition coefficient; and migration rate of FR over time.

Additionally, monitoring data for indoor environments, homes, commercial buildings, cars, trains, where high concentrations of polyurethane products are present would decrease the level of uncertainty.

2.6.4.7 Human Health Data Assessment

The potential for exposure to the brominated phthalates cluster (BPC) members during chemical manufacture is not clearly understood. Similarly, there is evidence for potential exposure to some of the cluster members during occupational use of products containing some of the cluster members. There is also evidence to suggest potential consumer exposure to the BPC members during the use of some of the products containing some of the BPC members.

An overview of the data for the structural analog, bis (2-ethylhexyl) phthalate (DEHP; CASRN 117-81-7), was presented. It could be argued that conservatively, these data could be used to characterize the hazard for the brominated phthalates cluster (BPC) members. However, available data suggest that the mode of action of DEHP that elicits chronic (specifically reproductive and developmental) toxicity is not the same as that of the BPC members. In addition, the available data support this hypothesis. There is uncertainty characterizing the hazard for the BPC members because the chronic (including reproductive/developmental) toxicity observed in animal studies with the BPC members is via a mode of action not considered relevant to humans or at concentrations that either do not raise immediate concerns, or which are difficult to attribute to a particular chemical because the data were obtained using a commercial mixture.

Based on the available data for **TBPH**, there is a low hazard for acute toxicity. In the screening-level dietary study in rats with **TBPH** (described in the technical supplement), the potential for liver toxicity was observed by perturbations in clinical chemistry values. However, some liver effects have been attributed to a mode of action, peroxisome proliferation (PPARα), not considered relevant to humans (Springer et al., 2012). The 28-day repeated-dose study, two-generation reproductive toxicity study and a prenatal developmental toxicity study with the commercial product Firemaster® BZ 54 (**TBPH/TBB** mixture), showed the potential to affect fetal development at high doses. In addition, it appears that the kidney is a potential target organ. The uncertainty of using these data to characterize the hazard for **TBPH** or **TBB** lies in the attribution of the toxicity observed to either mixture component. No toxicity studies with **TBB** alone are available; however, given that the metabolites of **TBPH** and **TBB** are different, it is expected that any toxicity observed would not be by the same mode of action or attributable to the same chemical. (Springer et al., 2012) observed the potential for endocrine disruption with the metabolites of **TBPH** and **TBB** suggesting that the potential for reproductive/ developmental toxicity needs to be explored further. Screening level data do not suggest a concern for carcinogenicity with **TBPH** and the potential for a mode of action not relevant to humans (PPARα) further lowers the potential concern and the need for data for this chronic toxicity endpoint.

No data are available for **Bromo Alkyl Ester**. The acute toxicity of **TBPA-Diol** and **TBPA-Diol (mixed esters)** is considered low. No data for repeated-dose or reproductive/developmental toxicity are available for **TBPA-Diol** and **TBPA-Diol (mixed esters)**. The need for human health data for these chemicals is dependent on the potential exposure during manufacture and the potential for at least **TBPA-Diol** and **TBPA-Diol (mixed esters)** to be released from the polymer backbone. No uses have been identified for **Bromo Alkyl Ester**.

The available toxicity data for **TBPH** and **TBB** are considered adequate for use in a screening-level assessment based on the criteria described by (Klimisch et al., 1997). The data for **TBPH** were submitted to both EPA/OPPT and the European Chemicals Agency (ECHA) under the HPV Challenge Program[10] and REACH[11], respectively.

The available data for **TBB** were submitted to EPA/OPPT as data on the commercial product, Firemaster®BZ-54 (Chemtura, 2012a) and are considered adequate for use in screening-level assessments as described by (Klimisch et al., 1997).

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[10] United States High Production Volume (HPV) Challenge Program was a voluntary chemical data program administered by EPA and is described at: http://www.epa.gov/chemrtk/index.htm

[11] Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the European Union chemical regulatory program administered by ECHA and is described at: http://echa.europa.eu/web/guest/regulations/reach/

The available data for **TBPA-Diol** and **TBPA-Diol (mixed esters)** are similarly considered adequate as described above.

No data are available for **Bromo Alkyl Ester**.

2.6.4.8 Environmental Data Assessment

For environmental fate and bioaccumulation, comprehensive studies are needed for many endpoints for all cluster members. All cluster members should be tested individually and all major degradation products should be quantified. Comprehensive bioaccumulation studies are needed for all BPC cluster members, and these should include several aquatic and terrestrial species selected from organisms commonly used in bioaccumulation testing. This would assist in the determination of appropriate data needs for the ecotoxicity endpoints.

Insufficient data are available for brominated phthalates cluster members to support a category approach for assessing environmental hazard. Thus, each member will be considered independently to establish a preliminary testing approach. The testing approach may be subject to modifications based on the availability of fate and monitoring data that may inform on the likely routes of environmental exposure.

Even though a category approach cannot currently be supported, use information (i.e., additive or reactive flame retardants) infers certain fate characteristics that suggest exposure pathways likely to affect the preliminary testing strategy. The additive flame retardants all have high experimental Log K_{ow} values (≥8.8) and predicted Log K_{oc} values (≥4.5) suggesting predominant partitioning to sediment and soil and unlikely exposure in the water column. Cluster members identified as additive flame retardants include **TBPH** and **TBB**. The reactive flame retardants generally have Log K_{ow} values <5 suggesting their presence in the water column; however, use entails reacting the flame retardants into products suggesting these substances are less likely to distribute into the environment that may be better characterized with submission of fate data. Cluster members identified as reactive flame retardants include 2-(2-Hydroxyethoxy) ethyl 2-hydroxy propyl 3,4,5,6 tetrabromobenzene dicarboxylate (CASRN 20566-35-2) and 3,4,5,6 tetrabromo-1, 2-benzene dicarboxylic acid, mixed esters with diethylene glycol and propylene glycol (CASRN 77098-07-8). Use information is limited for 1, 2-(2, 3-dibromopropyl) benzene dicarboxylate (CASRN 7415-86-3), **Confidential A** and **Confidential B.**

For all cluster members, experimental environmental hazard data are limited to water column organisms. Available acute toxicity data suggest aquatic invertebrates as the most sensitive species; however, available data for this taxa are limited to the low water solubility and high Log K_{ow} additive flame retardants **TBPH** and the commercial mixture, Firemaster®BZ54 (i.e., **TBPH** and **TBB**) and. Available chronic aquatic toxicity data are limited to two chronic studies with two different species of invertebrates using the additive flame retardants **TBPH** and the commercial mixture Firemaster®BZ54 (i.e., **TBPH** and **TBB**). Given the low water solubility characteristics of these additive substances, future testing recommendations should resolve conflicting conclusions provided in chronic invertebrate toxicity testing. Testing should be completed using the individual cluster members and not the commercial mixtures. Remaining cluster members (i.e., reactive flame retardants and TBPA-Diols) are more likely to reside in the water column, but limited data (e.g., a single experimental fish acute toxicity test and no fate testing) hinder hazard determination. Thus, for these lower Log K_{ow} substances, testing recommendations should be based on the results of physiochemical and fate testing and should include preliminary acute water column toxicity tests.

Experimental monitoring data are available that suggest likely exposure of **TBPH** and **TBB** to organisms that do not currently have corresponding hazard data. Since detection of these cluster members in the environment suggests potential for long term exposure to wildlife, chronic testing is recommended to address those organisms likely exposed in order to characterize potential population level effects. **TBPH** and **TBB** have been detected in several species of birds, terrestrial mammals, aquatic mammals, fish, aquatic invertebrates, and sediment-dwelling invertebrates. Proposed test strategies for health effects will be considered prior to testing recommendations to address detected concentrations in mammals. Detection in fish, aquatic invertebrates, and sediment-dwelling invertebrates suggest potential for exposure and uptake by organisms present in water bodies including aquatic plants and thus, hazard and bioaccumulation characterization is needed for these organisms. Hazard data are needed to understand the detected concentrations in avian species, as well as exposure and fate testing given the variable exposure routes likely for birds and the absence of experimental data to characterize chronic hazard. Detected concentrations have also been reported in sediment and biosolids suggesting potential routes of exposure. Based on concentration detected in these media, hazard characterization of terrestrial invertebrates and terrestrial plants is needed in addition to previously described testing of sediment-dwelling invertebrates.

Given the limitations of monitoring studies (i.e., no representation of potential degradates, availability of only **TBB** and **TBPH** data, and insufficient coverage of potentially exposed organisms such as plants), if additional data on physicochemical and fate parameters become available, additional exposure scenarios will be assessed. Testing recommendations will focus on cluster members designated as reactive flame retardants, confidential substances (public information not available), and TBPA-Diols, as well as potential degradates for all cluster members.

3 DATA NEEDS ASSESSMENT

3.1 Data Needs Conclusions – Additive Brominated Phthalate Cluster (BPC) Chemicals

Table 3-1: Data Needs Assessment (DNA)

Additive* BPC Chemicals: These chemicals are added to the flexible polyurethane foams (PUF) formulation and it is anticipated, based on available data, that they are migrating through the foams and being released from the foams									
	AVAILABLE INFORMATION			**DATA GAPS**			**DATA NEEDS**		
BPC Chemical & CASRN	**Worker Exposure** **	**Releases to Environment**	**General population / Consumer exposure**	**Worker exposure** ***	**Releases to Environment**	**General population/ Consumer exposure**	**Worker exposure**	**Releases to Environment**	**General population / Consumer exposure**
EXPOSURE									
COMMENT	**TBPH** and **TBB** have been detected in the home and in the environment.			Rate of migration of **TBPH** and **TBB** from PUF and PUF products			Rate of migration of **TBPH** and **TBB** from PUF and/or PUF products		
TBPH 26040-51-7	Modeling and estimates available			See footnote	• Manufacturing Process Description for BPC chemical and PU foam & PU foam product • Type of PU foam associated with PU foam product • Amount of PU foam used in final PU foam product • Percent weight of chemical in PU foam & PU foam product • Migration of chemical out of PU foam product • Monitoring human exposure (blood)		• Source/ quantity/ media of releases • Waste Disposal • Products containin g BPC chemical • Environm ental sampling (soil, sludge,	• Manufacturing Process Description for BPC chemical and PUF & PUF product • Type of PUF associated with PUF product • Amount of PUF used in final PUF product • Percent weight of chemical in PUF & PUF product • Migration of chemical out of PUF product • Monitoring human exposure (blood)	

Additive* BPC Chemicals: These chemicals are added to the flexible polyurethane foams (PUF) formulation and it is anticipated, based on available data, that they are migrating through the foams and being released from the foams									
	AVAILABLE INFORMATION			**DATA GAPS**			**DATA NEEDS**		
BPC Chemical & CASRN	**Worker Exposure ****	**Releases to Environment**	**General population / Consumer exposure**	**Worker exposure *****	**Releases to Environment**	**General population/ Consumer exposure**	**Worker exposure**	**Releases to Environment**	**General population / Consumer exposure**
TBB 183658-27-7							sediment) • Biota samples		
Bromo alkyl ester 7415-86-3									
HAZARD – ENVIRONMENTAL FATE & ECOTOXICITY									
COMMENT	**TBPH** and **TBB** have been detected in the home and in the environment.								
COMMENT	Most data for physical-chemical properties and environmental fate are estimated.			Experimental data for physical –chemical properties and environmental fate			Experimental data for physical –chemical properties and environmental fate		
TBPH 26040-51-7	Available chronic toxicity data (TBPH purity >95%) are inconclusive			Reliable chronic toxicity data			Reliable chronic toxicity data for appropriate environments		
TBB 183658-27-7	Available chronic toxicity data (Firemaster®BZ-54) are inconclusive								
Bromo Alkyl Ester 7415-86-3	No Data			Acute and chronic toxicity data set for fish, invertebrates and algae			Exposure pathways need to be determined before data needs can be identified.		
HAZARD – HUMAN HEALTH									
COMMENT	**TBPH** and **TBB** have been detected in the home and in the environment.								
TBPH 26040-51-7	28-d (dietary) (TBPH purity >95%) NOAEL = 233 mg/kg-day [decreased body weights and effects on clinical chemistry]			• Reliable information to characterize the hazard for reproductive/developmental toxicity			• Reliable information to characterize the hazard for reproductive/developmental toxicity		

Additive* BPC Chemicals: These chemicals are added to the flexible polyurethane foams (PUF) formulation and it is anticipated, based on available data, that they are migrating through the foams and being released from the foams									
	AVAILABLE INFORMATION			**DATA GAPS**			**DATA NEEDS**		
BPC Chemical & CASRN	**Worker Exposure** **	**Releases to Environment**	**General population / Consumer exposure**	**Worker exposure** ***	**Releases to Environment**	**General population/ Consumer exposure**	**Worker exposure**	**Releases to Environment**	**General population / Consumer exposure**
	• low acute toxicity • potential long-term liver effects in animal studies which may or may not be by mode of action relevant to humans • potential reproductive/developmental effect unclear [no data on pure chemical] • potential for endocrine effects [thyroid and testes] • Additional Data for Firemaster BZ-54 (see CASRN • 183658-27-7)						• Evaluation of endocrine effects [thyroid and testes] and potential reproductive/developmental toxicity		
TBB 183658-27-7	Available data for (oral gavage) reproductive/developmental toxicity is on commercial product Firemaster®BZ-54 which is a mixture of **TBPH**/**TBB**. It is not clear if toxicity observed is attributable to **TBB** or **TBPH** NOAEL (Firemaster®BZ-54) = 50 mg/kg-day • Low acute toxicity (oral/dermal) • 28-d (oral) NOAEL = not established LOEL = 160 mg/kg-day (kidney identified as target organ)			Acute and chronic (repeated/reproductive/developmental) toxicity data set			• Reliable information to characterize the hazard for reproductive/developmental toxicity • Evaluation of potential endocrine effects [thyroid and testes]		

Additive* BPC Chemicals: These chemicals are added to the flexible polyurethane foams (PUF) formulation and it is anticipated, based on available data, that they are migrating through the foams and being released from the foams									
	AVAILABLE INFORMATION			**DATA GAPS**			**DATA NEEDS**		
BPC Chemical & CASRN	**Worker Exposure** **	**Releases to Environment**	**General population / Consumer exposure**	**Worker exposure** ***	**Releases to Environment**	**General population/ Consumer exposure**	**Worker exposure**	**Releases to Environment**	**General population / Consumer exposure**
	• Evidence of reproductive/developmental toxicity with Firemaster®BZ-54 • potential for endocrine effects								
Bromo Alkyl Ester 7415-86-3	• acute toxicity unknown • repeated/reproductive/ developmental toxicity unknown			Acute and chronic (repeated/reproductive/developmental) toxicity data set			No uses have been identified for CASRN 7415-86-3. Data need dependent on the potential for worker exposure during chemical manufacture**		

*The nature of Confidential A and Confidential B cannot be disclosed. Data Gaps and Data Needs should be considered for both reactive and additive uses.

**Based on the available data for physical-chemical properties, worker inhalation exposure during chemical manufacture is expected to be negligible and ingestion is not anticipated in an occupational setting.

***Workplace monitoring information (personal and/or area sampling for workers handling the chemical). In the absence of the monitoring data, information on manufacturing process, information on worker activities (activities performed during work shift, number of work hours/day, days/year of operation, concentration of the chemical and identification of worker activities which may result in inhalation exposure), and information on workplace industrial hygiene practices and control technologies would be useful.

3.2 Data Needs Conclusions – Reactive Brominated Phthalate Cluster (BPC) Chemicals

Table 3-2: Data Needs Assessment

Reactive* BPC Chemicals: These chemicals are reacted into the polymer backbone of rigid polyurethane foams (PUF). Based on available data (nature of chemical reactivity and no detection in the environment), it is not anticipated that these chemicals are released from the PU foam or product. While they can be used as additives, available data suggest that the predominant use is as a reactive substance.									
	AVAILABLE INFORMATION			**DATA GAPS**			**DATA NEEDS**		
BPC Chemical & CASRN	**Worker exposure ****	**Releases to environment**	**General population / Consumer exposure**	**Worker exposure *****	**Releases to environment**	**General population / Consumer exposure**	**Worker exposure**	**Releases to environment**	**General population/ Consumer exposure**
EXPOSURE									
FOR ALL	Not detected in the environment. Release from PUF unknown.						Release of 'reactives' from PUF and/or PUF products		
TBPA-Diol 20566-35-2 **TBPA-Diol (mixed esters)** 77098-07-8	Modeling and estimates available	• Not detected in environmental monitoring. • No other release data are available (e.g. from industrial sources)		**See *** Footnote**	• Manufacturing Process Description for BPC chemical and PUF and PUF products • Potential for release from PUF and PUF products		• Source/ • quantity/ media of releases • Waste Disposal • Products containing BPC chemical	• Manufacturing Process Description for BPC chemical and PUF and PUF products • Potential for release from PUF and PUF products	
HAZARD – ENVIRONMENTAL FATE & ECOTOXICITY									
FOR ALL	Most data for physical-chemical properties and environmental fate are estimated.			Experimental data for physical –chemical properties and environmental fate			Experimental data for physical-chemical properties and environmental fate		
TBPA-Diol 20566-35-2	Acute toxicity data for fish only			Acute toxicity data set for invertebrates and algae and chronic toxicity data set for fish, invertebrates and algae			Exposure pathways (i.e. release from PUF and PUF products and environmental fate) need to be		

Reactive* BPC Chemicals: These chemicals are reacted into the polymer backbone of rigid polyurethane foams (PUF). Based on available data (nature of chemical reactivity and no detection in the environment), it is not anticipated that these chemicals are released from the PU foam or product. While they can be used as additives, available data suggest that the predominant use is as a reactive substance.									
	AVAILABLE INFORMATION			**DATA GAPS**			**DATA NEEDS**		
BPC Chemical & CASRN	**Worker exposure ****	**Releases to environment**	**General population / Consumer exposure**	**Worker exposure *****	**Releases to environment**	**General population / Consumer exposure**	**Worker exposure**	**Releases to environment**	**General population/ Consumer exposure**
TBPA-Diol (mixed esters) 77098-07-8	No Data			Acute and chronic toxicity data set for fish, invertebrates and algae			determined before specific data needs can be identified.		
HAZARD – HUMAN HEALTH									
TBPA-Diol 20566-35-2 **TBPA-Diol (mixed esters)** 77098-07-8	• low acute toxicity • potential repeated/reproductive/ developmental toxicity unknown			Repeated-dose and reproductive/developmental toxicity			Potential for worker and consumer exposure needs to be evaluated to determine specific data needs.		

*The nature of Confidential A and Confidential B cannot be disclosed. Data Gaps and Data Needs should be considered for both reactive and additive uses.

**Based on the available data for physical-chemical properties, worker inhalation exposure during chemical manufacture is expected to be negligible and ingestion is not anticipated in an occupational setting.

*** Workplace monitoring information (personal and/or area sampling for workers handling the chemical). In the absence of the monitoring data, information on manufacturing process, information on worker activities (activities performed during work shift, number of work hours/day, days/year of operation, concentration of the chemical and identification of worker activities which may result in inhalation exposure), and information on workplace industrial hygiene practices and control technologies would be useful.

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APPENDICES

Appendix A

Table_Apx A-1: Comparison of Different Polyurethane Foam Products

COMPARISON OF DIFFERENT POLYURETHANE FOAM PRODUCTS
Flexible Polyurethane Foam (FPF) is not Rigid Polyurethane Foam (PUR) or Spray Polyurethane Foam (SPF).

Different types of foam products use different raw materials, have distinct compositions and unique properties and should not be confused with one another.

Type of Foam	Flexible Polyurethane Foam	Rigid Polyurethane Foam	Spray Polyurethane Foam(Rigid)
Referred to as	**FPF**	**PUR**	**SPF**
Applications	Cushioning in • upholstered furniture • mattresses • carpet cushion • automotive seating • arm rests and headliners Also, as • apparel padding • shoe insoles • filtration • packaging • sponges • applicators • medical and technical applications	Insulation in • refrigerator walls • building insulation panels Also found in: • decorative and architectural applications o molded picture frames o furniture trim and molding o exterior building shutters o detailing created by molding rather than intricate carving • flotation modules for docks	A wide variety of applications including but not limited to: • roofing • air barriers • insulation • spray-in-place packaging • flotation for boats
Method of application	Cut from blocks or molded	Mainly injected, molded or poured as blocks	Spray-applied -- installed as a liquid and then expands many times its original size
Cell structure	Open cell (>90% open cells); lightly cross-linked	Closed cell (> 90% closed cells); highly cross-linked	Closed cell (> 90% closed cells); highly cross-linked
Porosity	Porous	Ranges from semi-porous to non-porous	Ranges from semi-porous to non-porous
Compression	Recovers when compressed	Does not recover when compressed	Does not recover when compressed
Density	Low-Medium Density 0.62-4.99 lb/ft^3	Medium-High Density 2.0 -25 lb/ft^3 *25 is for wood-like pictures and carvings	Medium-High Density 2.0-3.5 lb/ft^3
Feel	Soft	Hard	Medium Hard
CAS Number	None	None	None
Resources	Polyurethane Foam Association, www.pfa.org (for flexible polyurethane foam only)	American Chemistry Council Center for the Polyurethanes Industry www.polyurethanes.org	Spray Foam Alliance, www.sprayfoam.org (for spray foam only)

Developed by the Polyurethane Foam Association April 2011