Email Template for Distribution of TSCA Test Orders
[Each Order is Assigned a UIN by CDX when the Order is finalized for issuance]

Subject: Order Under TSCA Section 4(a)(2) for [Insert Chemical name] (CASRN [insert#])

Dear [insert POC for Company],

Attached is a Test Order issued to your company under section 4(a)(2) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq.

The effective date of this Test Order is Click or tap to enter a date. Your response options and the timeframes for responding are specified in Unit IV.C. of the Order. Please note that your initial response is due: Click or tap to enter a date (30 days after effective date of the order).

Your responses to the Order should be submitted through EPA's Central Data Exchange (CDX) application (https://cdx.epa.gov/), and you will receive a subsequent email that provides the Order number that you need to use in responding to this Order via CDX. The Order contains further instructions on how to respond to EPA. The EPA also encourages you to review the presentation available on the TSCA Section 4 Test Order webpage (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4-test-orders), which gives an overview on Orders issued pursuant to TSCA section 4.

If you have questions regarding this Order or the CDX system, please do not hesitate to email me, the assigned manager for this Order.

Regards,

[Insert First Name Last Name of EPA Order Manager]
Data Gathering and Analysis Division (7410M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave., NW., Washington, DC 20460-0001
telephone number: (202) 564-XXXX
email address: lastname.firstname@epa.gov

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

Order Under Section 4(a)(2) of the Toxic Substances Control Act

Chemical Substance Subject to this Order:

Chemical Name: 4,4'-(1-Methylethylidene)bis[2, 6-Dibromophenol] (TBBPA)

Chemical Abstracts Service Registry Number (CASRN): 79-94-7

Docket Identification (ID) Number: EPA-HQ-OPPT-2018-0462[1]

Testing Required by this Order:

1. Consumer Exposure

    - Transfer of Chemical From Source to Settled Dust From Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing 4,4'-(1-Methylethylidene)bis[2, 6-Dibromophenol] (TBBPA)

    - Chemical Loading on the Skin Surface From Contact With Settled Dust on Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing 4,4'-(1-Methylethylidene)bis[2, 6-Dibromophenol] (TBBPA)

Recipients of this Order:

[Insert Company Name(s)]

Dear Recipient:

This Order requires you and the other named manufacturer(s) and/or processor(s) of 4,4'-(1-methylethylidene)bis[2, 6-dibromophenol] (TBBPA) (CASRN 79-94-7) to develop and submit certain information for TBBPA, or otherwise respond to the U.S. Environmental Protection Agency (referred to herein as "the EPA" or "the Agency"). Failure to respond to this Order, or failure to otherwise comply with its requirements, is a violation of section 15 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2614. Any person who violates TSCA shall be liable to the United States for penalties in accordance with TSCA section 16, 15 U.S.C. § 2615.

This Order is **effective 5 calendar days after its date of signature by the EPA**. The timeframes and options for responding are described in **Unit IV** (Response Options). Please note that the email transmitting this Order to you will provide the calendar date for the response deadlines as defined in **Unit III** (Deadlines for Responding to this Order). A subsequent email will provide a company specific Order number for you to use in responses and communications about this Order.

[1] To access the docket, go to https://www.regulations.gov.

This Order is organized as follows:

I. PURPOSE AND AUTHORITY

A. OVERVIEW

This Order is being issued under the authority of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. TSCA section 4 authorizes the EPA to require the development of necessary information related to chemical substances and mixtures.

This Order requires the identified recipients to develop and submit new information on TBBPA (CASRN 79-94-7) that is necessary for the EPA to perform a risk evaluation under TSCA section 6(b).

Information on testing requirements is provided in **Appendix E**. The EPA encourages the formation of industry consortia to jointly conduct testing between the recipients of this Order. See **Unit VIII** for more information on this topic.

The Order provides four response options, listed below. More information on each of these options is provided in **Unit IV**. Timeframes for these options is provided in **Unit III**. Note that the deadline to identify as a manufacturer, processor, or both is 30 calendar days of the effective date of this Order. This

step is necessary for purposes of this Order to ensure that your company can appropriately access the CDX application used for responding to section 4 orders.

Option 1: Develop the Information

Use this option to develop information in response to all of the requirements of this Order that apply to you, or use this option in conjunction with other response options identified in this section as appropriate.

Manufacturers who are required to test a chemical substance or mixture pursuant to a TSCA section 4 order are also required to pay a fee (see **Unit VII**).

Option 2: Submit Existing Information

Use this option to submit an existing study and/or other scientifically relevant information that you believe the EPA has not considered, along with supporting rationale that explains how the submittal(s) meets part or all of the information described as necessary in **Unit II**. If the Agency determines that the submitted information satisfies one or more data needs identified by this Order, the Agency will extinguish any associated test requirement(s).

Option 3: Request an Exemption

Use this option to request an exemption from a testing requirement of this Order. The EPA will grant an exemption if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement; and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

Option 4: Claim that You Are Not Subject to this Order

Use this option to claim that you are not subject to this Order. You may claim that you are not subject to this Order if all of the following are true:

1. You do not currently manufacture or process the chemical(s) identified by this Order;

2. You do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order; and

3. You have not manufactured or processed the chemical(s) at any time during the five years preceding the date of this Order.

You must provide an explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim.

B. Terminology Used in this Order

The term "manufacture" means to import into the customs territory of the United States, to produce, or to manufacture. 15 U.S.C. § 2602(9). Import also includes importing the chemical as an impurity in an article.

The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture. 15 U.S.C. § 2602(13).

The term "chemical" or "substance" means a chemical substance or mixture.

C. Persons Subject to this Order

1. Persons Identified

An order issued under section 4(a) of TSCA may require the development of information by any person who manufactures or processes, or intends to manufacture or process, a chemical substance or mixture subject to the order. The recipients of this Order are listed at the top of the Order.

For purposes of this Order, a recipient identified by this Order is subject to the Order if it has manufactured or processed the chemical at any time during the five years preceding the date of this Order. If a recipient identified by this Order has not manufactured or processed the chemical during the prior five years, the recipient is nevertheless subject to the Order if they intend to manufacture or process the chemical within the period of testing provided by this Order.

A person who contracts with a producing manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the producing manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

A recipient who is an importer of record of a chemical substance identified by this Order is responsible for the testing requirements of this Order, even if the recipient does not store, handle, use, or otherwise directly deal with the chemical.

The means by which the EPA identified each recipient subject to this Order does not govern whether a recipient is subject to this Order. Ultimately, any recipient that meets the criteria discussed in this section is subject to this Order, regardless of the basis on which the Agency identified the recipient.

2. Corporate Structure of Recipients: Changes of Ownership

The EPA has attempted to identify the highest-level U.S. corporate entity for purposes of issuing this Order. The highest-level U.S. corporate entity is ultimately responsible for satisfying the obligations of this Order, although the highest-level U.S. corporate entity may delegate its responsibilities under this Order to a U.S. subsidiary. Where the corporate entity named in this Order is not the highest-level U.S. corporate entity, the Agency nonetheless considers notification of the company named in this Order to constitute notification of the highest-level U.S. corporate entity and holds the highest-level U.S. corporate entity ultimately responsible for satisfying the obligations of this Order.

Should you wish to modify the name of the recipient or identify another U.S. corporate entity in the corporate structure as the point of contact in place of the recipient named in this Order, you must submit a request to the EPA. Submit your request, justification for the change, and contact information for the representatives of the newly named entity to TSCAtestorders@epa.gov. A representative from the Agency will contact you and any other representatives regarding this request.

In the event of mergers, acquisitions, or other transactions that create a corporate successor in interest (subsequent to the manufacturing or processing that triggered the reporting obligation, and either before or after receipt of this Order), that successor in interest is responsible for satisfying the obligations of this Order. The successor in interest must notify the EPA of its identity within 14 days following the transaction.

D. Previously Issued Orders

The EPA previously issued a test order for TBBPA, effective January 19, 2021, to meet other data needs. See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-44-1-methylethylidenebis26[2].

Since issuing that test order, the EPA's continuing review of the reasonably available information has identified additional information needed to inform the associated risk evaluation. Accordingly, the Agency is issuing this additional Order for TBBPA. See the Statement of Need for further details. This Order does not alter the requirements of any previous test orders.

II. STATEMENT OF NEED

The basis for requiring the development of new information by this Order is described in this unit and in **Appendix E**. This statement of need, as required by TSCA section 4(a)(3), includes: (A) the need for the new information; (B) how information reasonably available to the Administrator was used to inform the decision to require the new information; and (C) why issuance of this Order is warranted instead of promulgating a rule or entering into a consent agreement. **Appendix E** (Testing Requirements of This Order) indicates which tests apply specifically to manufacturers and/or processors subject to this Order.

A. The Need for the New Information

This section and **Appendix E** explain what new information is being required in this Order and why such information is needed for the risk evaluation of TBBPA under TSCA section 6(b).

The EPA has identified the following information in this section as necessary to conduct a risk evaluation to determine whether TBBPA presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use (COU).

The next unit will outline how the EPA came to determine these new information needs. Note that additional details for these testing requirements are provided in **Unit V** and **Appendix E**.

[2] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-44-1-methylethylidenebis26*

1. Consumer Exposure

Information on exposures from the use of certain consumer products is needed to conduct a risk evaluation. The relevant consumer products exposure data needs that this Order seeks to address for TBBPA, are as follows:

- Transfer of Chemical From Source to Settled Dust From Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA

- Chemical Loading on the Skin Surface From Contact With Settled Dust on Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA

B. How Information Reasonably Available to the Administrator Was Used to Inform The Decision to Require New Information

This section details the "Scoping and Conceptual Models" and "Systematic Review of Reasonably Available Existing Information" processes used by the EPA to identify, respectively, what information is reasonably available to integrate into the risk evaluation for the conditions of use of TBBPA and ascertain, via a "Discipline-Specific Approach for Identifying Data Needs" what needed information is not reasonably available in existing literature (i.e., what testing to require).

1. Scoping and Conceptual Models

The *Final Scope of the Risk Evaluation for TBBPA* (https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-94-7_44-1-methylethylidenebis2_6-dibromophenol_TBBPA_finalscope.pdf[3]) (hereinafter "*Final Scope*") includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects to consider in the TSCA section 6(b) risk evaluation for TBBPA. The Agency has used the scope document and the conceptual models therein for workers and occupational non-users (ONUs), consumers and bystanders, general population, and environmental releases as a starting point for identifying information needs under this Order. The conceptual models visually represent the human and environmental exposures (pathways and routes), receptors, and hazards associated with the conditions of use of TBBPA. For each exposure (pathway and route), receptor, and hazard that is visually represented, the EPA has identified the information needed to conduct a risk evaluation for this chemical.

2. Systematic Review of Reasonably Available Existing Information

The systematic review process began with searching peer-reviewed literature databases (*e.g.*, Agricola, PubMed, Science Direct, ECOTOX Knowledgebase) for studies using TBBPA, synonyms, and trade names. The EPA also conducted a search of gray literature (*e.g.*, technical reports, reference books, dissertations, and other information not found in standard, peer-reviewed literature databases), as well as review of public comments posted to the docket for this chemical substance during the prioritization process and following publication of the draft scope document, relevant data and information submitted to the Agency under TSCA sections 4, 5, 8(e), 8(d), and For Your Information (FYI) submissions. The collected compilation of information was then screened for relevance. This process applied title/abstract screening and/or full-text screening based on screening criteria developed *a priori* for environmental

[3] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-94-7_44-1-methylethylidenebis2_6-dibromophenol_TBBPA_finalscope.pdf*

hazard and consumer exposure (Population, Exposure, Comparator and Outcomes (PECO)); physical and chemical properties (Pathways and Processes, Exposure, Setting or Scenario, and Outcomes (PESO)) or occupational exposure literature (Receptors, Exposure, Setting or Scenario, and Outcomes (RESO)).

3. Discipline-Specific Approach for Identifying Data Needs

a. Consumer Exposure

As determined in the *Final Scope*, the use of consumer products or articles containing TBBPA can result in exposures to users and bystanders. The EPA expects to assess risks to consumers and bystanders and therefore requires data to inform the estimation of inhalation, dermal, and/or oral exposures to chemicals contained in consumer products and/or articles.

Evaluation of reasonably available information for TBBPA included consideration of existing data that has gone through initial stages of the systematic review process (full-text screening) and was tagged for this chemical for relevant consumer exposure pathways and conditions of use. A data gap analysis of the systematic review data source pool was undertaken to support this data request. Data on concentrations of this chemical in house dust and dermal absorption characteristics were available; however, data on chemical migration to dust on article surfaces and chemical loading on the skin surface from contact with the referenced consumer condition of use (i.e., additive flame retardant in plastic battery enclosures) were not found for TBBPA.

Determining the transfer of TBBPA from a known source to settled dust and migration to sweat (i.e., chemical loading on the skin surface) is needed to estimate consumer and bystander exposure to products containing TBBPA. Therefore, transfer of the chemical from products and articles to settled dust and chemical migration from product to sweat would enable the EPA to discern potential exposures. Furthermore, EPA needs to characterize the rate of chemical migration from product or article to settled dust that is in direct contact with product or article, and to semi-quantitatively or qualitatively determine if gas-phase transfer plays a role in chemical transfer from consumer articles to settled dust for battery plastic enclosures. In addition, EPA needs to determine chemical loading on the surface of the skin/sweat due to direct contact with an article or product, and to quantify potential chemical availability for dermal exposure for plastic battery enclosures

C. Why Issuance of this Order is Warranted Instead of Promulgating a Rule or Entering Into a Consent Agreement

The EPA is using its order authority under TSCA section 4(a)(2) to inform the risk evaluation for TBBPA under TSCA section 6(b) in accordance with the requirements and timeframes for conducting the risk evaluation. Use of this TSCA section 4(a)(2) authority will allow the Agency to target known manufacturer and processor recipients to obtain the needed information more quickly than if the EPA were to issue a TSCA section 4 rulemaking or consent agreement.

III. DEADLINES FOR RESPONDING TO THIS ORDER

This section describes the deadlines for this Order and possible modifications to such deadlines.

A. Deadlines for Responses to this Order

The table below provides the deadlines for this Order. Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday. Descriptions of these response options and the required process associated with each option is provided in **Unit IV**.

Table 1. Deadlines for Responses, Study Plans, and Test Reports

Order Requirement	Recipient's Deadline (Days after the effective date of the Order)	EPA Response Deadline*
• Identify as a Manufacturer, Processor or Both	30	n/a
• Submit Request to Modify Corporate Identity Identified	30	n/a
• Choose to Submit Existing Data (Option 2)	30	45
• Claim that You Are Not Subject to this Order (Option 4)	45	60
• Choose to Develop the Information - On Own or as Part of a Consortium (Option 1)	65	n/a
• Request an Exemption (Option 3)	65	80
• Submit Draft Study Plan	80	95
• Submit Final Study Plan	110	125
• Submit Final Test Report	Deadline varies per Test Requirement (See **Unit V** and **Appendix E**)	

*See **Unit III.B** for potential automatic extensions associated with the EPA responses. Deadlines for submitting final test reports for each required test are provided in **Appendix E**.

B. Automatic Extensions to Deadlines

The EPA will automatically extend deadlines should the Agency fail to meet any EPA response deadline set forth in **Unit III.A**. Specifically, deadlines will be automatically extended should the Agency fail to respond within 15 calendar days of the deadline for a response option if the response was submitted in the CDX application prior to the deadline provided. For each day exceeding the 15-day period following the associated deadline, the EPA will extend subsequent deadlines by one day.

Should a recipient amend their response, at any time, the EPA will not extend any associated or subsequent deadlines. Therefore, the Agency recommends that recipients submit their amendments or extension requests as early as practicable to ensure adequate time to perform any required testing given that the Agency will not automatically extend deadlines for any such amendments to responses.

The EPA will not automatically extend a deadline for a response should the recipient submit its response after the deadline for the given response option. Additionally, the EPA will not automatically extend a deadline for a response should the Agency respond within 15 days of the deadline for a given response option that was submitted on or before the deadline for that response option.

Other than potential automatic extensions to deadlines described here, **Unit III.C** provides the process for requesting an extension to a deadline.

C. Requesting An Extension To A Deadline For Responding To This Order

If you believe you cannot submit the required identification as a manufacturer, processor, or both; Order response; draft study plan; final study plan; or final test report to the EPA by the deadline(s) specified in this Order and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency through the EPA's CDX portal as soon as you know you may need an extension. Your request must include: (1) a detailed description of the expected difficulty, including technical and laboratory difficulties, and (2) a proposed schedule including alternative dates for meeting such requirement(s) on a step-by-step basis.

The EPA will grant or deny deadline extension requests at its discretion.

IV. RESPONDING TO THIS ORDER

You are required to respond to this Order even if you believe your company is not subject to this Order. Failure to provide a response is a violation of section 15 of TSCA.

A. Identify As A Manufacturer, Processor, Or Both

Within 30 calendar days of the effective date of this Order, you, as a recipient of this Order, are required to respond to this Order through the EPA's Central Data Exchange (CDX) portal, informing the Agency whether you will be responding to this Order as manufacturer or processor (if you manufacture and process the chemical, select manufacturer). To provide your preliminary response to this Order, you will receive an e-mail from the EPA within five days of the Order being signed (i.e., by the effective date of the Order) that provides a CDX Order number for purposes of complying with this Order.

You may claim that you are not subject to this Order if you (1) do not currently manufacture or process the chemical(s) identified by this Order; (2) do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and (3) have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order. See **Unit VI.B.4** for more information on how to claim that you are not subject to this Order.

B. Four Response Options

A recipient has four available options for purposes of responding to this Order. See **Unit III** to review the deadlines for this Order.

Option 1: Develop the Information

If you choose to develop information in response to this Order, you must select this option in the CDX portal form.

For details on the steps of this response option, see **Unit VI**.

For more information on this Order's required tests, required protocols/methodologies, and deadlines for submission of test reports see **Unit V** and **Appendix E**.

Option 2: Submit Existing Information

If you choose to respond to this Order by submitting an existing study and/or other scientifically relevant information that you believe the EPA has not considered, your response in the EPA's CDX portal must be submitted to the EPA 30 days after the effective date of the Order and include the study(ies) and/or other scientifically relevant information, along with supporting rationale that explains how the study and/or other scientifically relevant information meets part or all of the information or obviates the need for the information described as necessary in **Unit II**.

The EPA's determination regarding whether the study and/or other relevant information satisfies part or all of the information or obviates the need for the information described as necessary in **Unit II** will be based on the weight of the scientific evidence from all relevant information reasonably available to the Agency. The Agency will notify you of its determination through CDX. If the Agency determines that the study and/or other scientifically relevant information satisfies the need in lieu of the testing required in this Order and/or the original testing requirement is no longer needed, the EPA will extinguish those testing obligations from this Order that are no longer necessary, with respect to the appropriate recipients of this Order. If the study was your only testing obligation under the Order, all your obligations under this Order will be extinguished upon notification by the Agency.

If the EPA determines that the study and/or other scientifically relevant information does not satisfy that need, you must modify your response in the EPA's CDX portal to choose one of the other response options in **Unit IV** within 10 calendar days of being notified by the Agency.

Note that the submission of existing information will not extend the deadline for the draft study plan submission for that testing requirement unless the existing information is submitted within 30 days of the effective date of the Order and the EPA does not respond within 45 days of the effective date of the Order. Thus, failure to submit existing information prior to the 30-day deadline will result in a need to submit a draft study plan by the 80-day deadline. See Unit **III.B** for information on the potential automatic extension of deadlines.

Option 3: Request an Exemption

Any person required by this Order to conduct tests and submit information on a chemical may apply for an exemption from such requirement (TSCA section 4(c)(1)).

The EPA will grant a request for exemption from the requirement to conduct tests and submit information on a chemical substance if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement, and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

An exemption request must be submitted through the CDX portal and contain the following:

1. This Order number, the chemical identity, and the CAS Registry No. of the test substance subject to this Order on which the application is based.

2. The specific testing requirement(s) from which an exemption is sought.

3. The basis for the exemption request when another company(ies) has/have submitted the information or is/are developing information for the subject chemical or an equivalent chemical pursuant to a TSCA section 4(a) rule, order, or consent agreement. Your request must identify the company(ies) that submitted or is/are developing the information.

4. The chemical identity of the equivalent chemical (the test substance in the information submitted or being developed) on which the application is based.

5. The equivalence data ("chemical data or biological test data intended to show that two substances or mixtures are equivalent" (see **Appendix A**)), if data on an equivalent chemical is being submitted.

6. The name, mailing address, telephone number, and e-mail address of applicant.

7. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.

8. A Statement of Financial Responsibility: The following sworn statement (i.e., signed and notarized) must accompany each request for an exemption:

> "I understand that if this application is granted, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit information and upon whose information the granting of my application was based."

The EPA's grant of an exemption is conditional upon the completion of the required tests according to the specifications of this Order (or other applicable rule, order, or consent agreement), including any modifications approved by the Agency. If the EPA subsequently determines that equivalent data has not been submitted in accordance with the applicable rule, order, or consent agreement, the Agency will provide notice through CDX of its preliminary decision to terminate the exemption. Within 30 days after receipt of such notice, the exemption holder may submit information in the CDX portal either to rebut the EPA's preliminary decision to terminate the exemption or notify the Agency of its intent to develop the required information pursuant to the specifications established in this Order and any modifications approved by the EPA. If the exemption holder submits information to rebut the EPA's preliminary decision to terminate the exemption, then the Agency will provide the exemption holder an opportunity to request a hearing prior to issuing a final decision to terminate the exemption. Following the receipt of information to rebut the EPA's preliminary decision and any subsequent hearing, the Agency will render a final decision on whether to terminate the exemption, taking into account information submitted to rebut the EPA's preliminary decision and information presented at any hearing, as applicable.

If you receive the EPA's preliminary decision to terminate the exemption and do not submit information to rebut that preliminary decision or request a hearing, or if you receive the Agency's final decision to terminate the exemption following the submission of information to rebut that preliminary decision or a hearing, you must resubmit a response in accordance with one of the options described in **Unit IV.B** of this Order within 30 calendar days of receipt of the EPA's decision to terminate the exemption, including as applicable the information required under **Unit V** of this Order. Failure to timely resubmit the response will constitute a violation of this Order and of TSCA section 15(1). Should the Agency

terminate the exemption, a draft study plan will be due 30 days from the termination, with the final study plan being due 60 days from the termination.

If the EPA extinguishes a testing obligation pursuant to **Unit IV.B.2** of this Order, the corresponding exemption will be extinguished, as the exemption will no longer be necessary. In such a situation, companies who requested an exemption from that specific testing obligation are not required to reimburse the company that submitted existing data.

As explained in **Appendix B** on Cost Sharing, persons who receive exemptions from testing have an obligation to reimburse the person(s) who perform the required testing and submit the required information for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Normally, this is worked out by the parties involved, without the involvement of the EPA. However, if agreement cannot be reached on the amount or method of reimbursement, and the company who is entitled to reimbursement requests in accordance with the procedures in **Appendix B** that the Agency order reimbursement, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement. See TSCA section 4(c).

Option 4: Claim that You Are Not Subject to this Order

You may claim that you are not subject to this Order if you do not manufacture or process the chemical(s) identified by this Order; do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order.

An explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim, must accompany your response in the CDX portal so that the EPA can evaluate the claim.

Note that if your company ceased manufacturing (including import) or processing of the chemical substance(s) subject to this Order more than five years prior to the effective date of this Order, you can claim that you are not subject to this Order.

In the instance that you claim you are Not Subject to this Order, your claim must include (1) a statement explaining why your company is not subject to this Order, such as no longer importing, manufacturing or processing the subject chemical substance (intentionally or unintentionally) within the five years prior to the effective date of this Order, and not intending to manufacture (including import) or process the chemical within the period of testing provided by this Order (see **Unit V**), and (2) the certifying statement "I certify that the statements made in this letter are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law."

If based on the evidence you provide and other evidence available to the EPA, the Agency deems your claim to be inadequately substantiated, the EPA will deny your claim, and the original requirements and deadlines in this Order will remain. If your claim is approved, the Agency will notify you that you are not subject to this Order through CDX correspondence. The EPA expects to provide such notification within 45 days of the effective date of this Order.

To select this option, you must do so within 45 days of the effective date of this Order.

V. OVERVIEW OF TESTING REQUIRED BY THIS ORDER

This unit applies to Option 1: Develop the Information and Option 2: Submit Existing Information (**Units IV.B.1** and **IV.B.2**).

Where the required protocol is an EPA guideline, the guideline is available on the EPA website at http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances[4] and from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-605-6000). This EPA website also provides information on OECD guidelines, which are also available via OECD's website at https://www.oecd.org/chemicalsafety/testing[5]. **Appendix E** provides additional sources for guidelines associated with specific testing.

The EPA reserves the right to revise this Order to extinguish specific testing obligations where existing information subsequently comes to the Agency's attention that in the EPA's scientific judgment obviates the need for specific test data required under this Order. Specific information for ordered test(s) are provided in **Appendix E**.

See **Appendix E** for details on the required test protocols.

Table 2. Entities Responsible and Deadlines for Required Testing Protocol(s)/Methodology(ies)
Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday.

Test Names	Protocols Methodologies	Entities Responsible for Testing	Deadlines to Submit Final Reports to EPA
Consumer Exposure			
Transfer of Chemical From Source to Settled Dust From Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA	Exposure Testing Protocol 6: Direct Transfer of Chemicals from Source to Settled Dust	Manufacturers and Processors	215 days after the effective date of the Order
Chemical Loading on the Skin Surface From Contact With Settled Dust on Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA	Exposure Testing Protocol 9: Migration to Sweat (Dermal Exposure)	Manufacturers and Processors	170 days after effective date of the Order

VI. REQUIREMENTS OF RESPONSE OPTION 1: DEVELOP THE INFORMATION REQUIRED BY THIS ORDER

A. OVERVIEW

The draft study plan is due to the EPA **80 days** after the effective date of this Order. The EPA will then review the draft study plan and provide input to ensure adequacy of the final study plan. For the final study plans and the final test reports, see the Deadlines for Responses, Study Plans, and Test Reports table in **Unit III.A**.

All testing described in **Unit V** must be conducted in accordance with the Good Laboratory Practice (GLP) standards in 40 CFR part 792, as specified in the CFR on the Effective Date of this Order. You

[4] *http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances*
[5] *https://www.oecd.org/chemicalsafety/testing*

must provide a statement of compliance with these GLP standards when submitting information to the EPA pursuant to this Order.

Deviations from the test guideline or specific GLP standards are allowed provided justifications for such deviations are approved by the EPA. A justification is required for each deviation. Justifications should demonstrate that, despite the deviation from the given test guideline or GLP standard, that data integrity, control of bias, and study quality will be maintained with similar effectiveness. Any requested deviations and corresponding justifications must be included in the draft study plan for the Agency's consideration and, if approved, described in the test report.

Once the EPA has completed its review of the submitted test reports and accepts the information as fully complying with your testing obligations under this Order, the Agency will notify you.

B. Draft Study Plan Requirements

1. Study Plan Requirements for All Categories of Tests

If you choose to develop the required information to comply with this Order, you must obtain and review the required protocols/methodologies. **Unit V** and **Appendix E** provide the protocols/methodologies that must be followed to perform each required test.

If questions and/or issues arise during Study Plan development, the EPA encourages questions/comments be submitted along with the Study Plan submission in accordance with the draft study plan deadline. If the Agency's review of the draft study plan that includes the questions/comments is delayed, the procedure outlined in **Unit III.B** will be followed for automatic extensions of the study plan.

In addition to requirements provided in **Appendix E** for a given test required by this Order, the Study Plans must contain the following information:

1. This Order number, excluding the unique 6-digit company number using X's in place of the unique company number so as to protect each company's private access to the reporting module via Central Data Exchange (CDX). For example, if your Order number is TO-2020-0000-438435-00-0 then provide this number in the Study Plan: TO-2020-0000-XXXXXX-00-0.

2. Name of test to be covered by the test protocol/methodology.

3. The name/number of the protocol/methodology identified in this Order which you intend to follow, a copy of the identified protocol/methodology with your proposed modifications, or a copy of the alternate protocol/methodology you propose to use. Justification(s) must be provided for any deviation from the protocol/methodology provided in this Order.

4. The identity of and supporting data on the chemical substance to be tested including physical constants, spectral and chromatographic data, chemical analysis, and stability under test and storage, and test conditions required by the protocol. A Certificate of Analysis of the test substance must be provided.

5. The sampling and analytical method that will be used.

6. A description of the preparation and processing of samples that will be done before sampling and during sampling, including equilibration, weighing, calibration, test conditions (temperature, humidity), number and type of samples, and identification of equipment and accessories used (make, model, size/capacity, and operating conditions), including the specific sampling media and sampling instruments that will be used.

7. A description of all quality assurance and quality control protocols used.

8. The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.

9. The name(s), mailing address(es), phone number(s), and e-mail address(es) of the appropriate individual(s) for the EPA to contact concerning the planned test.

10. The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol follows appropriate quality assurance and quality control procedures.

2. Modifying a Required Protocol/Methodology in a Draft Study Plan

The draft study plan must include the required protocols/methodologies outlined in **Unit VI.A.1** and **Appendix E**. If you believe modifications of these required protocols/methodologies are necessary, you should propose the modification in the draft study plan and submit to the EPA with request for the Agency to consider the modifications. Any consultation regarding modifications to the required protocols/methodologies will not extend the deadline for submission of the draft study plan.

Any submitted requests for modifications of the required protocols/methodologies must include a detailed description of the proposed modification as well as a detailed description of the justification and reasoning for such modifications. Requests for modifications of protocol/methodology or the use of an alternate protocol/methodology must discuss why such changes are appropriate and whether they could alter the validity of the study. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant section of the study plan describing the protocols/methodologies.

If the EPA has concerns about the requested protocol/methodology or your requested modifications of the required protocol/methodology, the Agency will inform you of concerns that must be addressed before the EPA will approve your study plan. The Agency has 15 days from the deadline for the study plan to respond. For each day following this period that the EPA does not respond, the Agency will extend the deadline for the final study plan by one day (see **Unit III**).

3. EPA Review of Study Plans and Final Test Report

The EPA will not conduct a substantive review of any draft study plan that does not meet the requirements as provided in **Unit IV.B.1** and **Appendix E**. Such a submission does not constitute meeting the deadline for the draft study plan submission. **Unit III** provides information on deadlines and the EPA response timelines.

Failure to submit a draft study plan, final study plan, and final test report which do not fully comply with the terms of this Order and by the deadlines provided in **Unit III** may result in a violation of TSCA section 15.

a. Study Plans

Following review of a draft study plan submission, the EPA will indicate what modifications, if any, are required and must be incorporated into the final study plan. Accompanying a proposed final study plan submission, the submitter must provide a clean and red-lined version. The red-lined version will indicate the changes incorporated into the final study plan as compared with the draft study plan submission.

If the EPA requires modifications to a submitted draft study plan, the Agency may elect to provide a line-by-line list of comments that must be addressed and corrected before a final study plan will be approved. If the submitter receives a line-by-line list of comments, the submitter must address each individual comment and include this in their response to the Agency along with the proposed final study plan.

Prior to initiating any test, the Company/Consortium must first address the EPA's input on the study plan and receive the Agency's acceptance of the final study plan.

The EPA's acceptance of a final study plan does not constitute pre-acceptance of any future test results. If testing conducted according to a requested protocol/methodology or requested modifications of the required protocol/methodology is initiated prior to EPA approval, that testing will not satisfy the requirements of the Company under this Order.

If, after the final study plan has been approved or after testing is underway, you wish to make a modification to an identified protocol/methodology or use a different protocol/methodology, you must submit a request to the EPA to make these changes in your study and you must still meet the deadlines set out in **Unit V** and **Appendix E** for the relevant test or request an extension (see also **Unit III.C**), if needed.

Note that submitting questions to the EPA regarding study plan requirements will not extend the deadline for a study plan submission.

b. Final Test Reports

Once the EPA has completed its initial review and accepted data for all test reports subject to this Order for a given testing requirement, the Agency will notify the designated contact for the company or consortium subject to this Order that this testing requirement has been satisfied, which in turn will close out the testing requirement of this Order for the companies and participants in any consortium subject to this Order. Failure to file a final test report meeting all the requirements in this Order by the deadline in **Unit III** is a violation of TSCA. Your final test report must be submitted along with the data in the associated Organisation for Economic Co-operation and Development (OECD) harmonized template format, if available. OECD harmonized templates can be located at https://www.oecd.org/ehs/templates/harmonised-templates.htm[6]:

[6] *https://www.oecd.org/ehs/templates/harmonised-templates.htm*

VII. FEES FOR SUBMITTING INFORMATION

Per 40 CFR § 700.45, and taking into account the inflation adjustment that went into effect on January 1, 2022, the Test Order fee is $11,650 to be split evenly among the manufacturers who are required to test a chemical substance or mixture subject to the Test Order (accounting for small business considerations). Processors are not subject to this fee, nor are manufacturers who submit existing information or receive an exemption in compliance with this Order.

Small businesses may be subject to no more than 20% of the amount of the applicable fee. A company may qualify for a "small business concern" discount if their total number of employees is at or below the maximum allowed in the final rule for that company's North American Industry Classification System (NAICS) code (see 40 CFR 700.43). In order for an entity to qualify as a "small business concern," its number of employees shall not exceed the size standard for the applicable industry. When calculating the number of employees, the company must include the employees of all parent and subsidiary companies within the corporate chain. Please note that small business fees are only applicable to qualifying small businesses who are either not associated with a consortium or associated with an all-small business consortium. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses[7].

A company can identify itself as a small business when responding to this Order via the CDX application. The "small business concern" discount will be included in the determination of company-specific invoices for the distribution of the $11,650 fee across all manufacturers conducting testing for the given Test Order. Where a consortium is responsible for the fee for its members for purposes of this Order, and at least one of the members is not a small business, the EPA does not apply a "small business concern" discount to the portion of the $11,650 distributed to the consortium.

Fees for Test Orders under TSCA section 4 will be invoiced electronically by the EPA. Invoice notices will be populated into the specific user's "Copy of Record" screen in CDX and will contain a button that will initiate the payment process. When an invoice is generated, notification e-mails will be sent to the user's CDX inbox and the e-mail address associated with the relevant CDX account. Payment information will be collected in CDX and then submitted to Pay.gov for processing.

Note that there are many fees associated with TSCA-related activities. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-table[8]. The TSCA section 4 Test Order fee is separate from these fees. A company's inclusion in or exclusion from other TSCA fees is unrelated to that company's status with regards to TSCA section 4 Test Order fees.

Pursuant to 40 CFR § 700.45, the applicable fee shall be paid in full no later than 120 days after the effective date of the Order. Should the EPA invoice the fee more than 90 days after the effective date of the Order, payment will be due within 30 days of such invoicing.

VIII. INSTRUCTIONS IF YOU CHOOSE TO PARTICIPATE IN A CONSORTIUM

If you choose to form or join a consortium to share in the cost of developing the required information, you (as well as the other Order recipients who are participants in the consortium) must, individually in the CDX portal, state your intention to participate in a testing consortium for each specific chemical and

[7] *https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses*
[8] *https://www.epa.gov/tsca-fees/tsca-fees-table*

specific test. Consortium participants must individually respond in the CDX portal with their intent to participate before designated leads are able to add them to the consortium.

In addition, the designated lead for the consortium must submit a consortium response to the EPA in the CDX portal. The response must confirm the formation of the consortium, identify its member companies, and list the testing obligations that the consortium plans to fulfill on behalf of each company by indicating each specific test. The response must also include contact information for the designated lead of the consortium, who must be domiciled in the United States. The designated lead for the consortium must submit the response and required information on behalf of the consortium and its member companies by the deadlines listed in **Unit III.A**. Submissions made on behalf of the consortium must be in accordance with instructions in **Appendix C**. Note that a consortium lead need not be a recipient of an Order; other entities (such as trade organizations) may act as a lead and submit the information required under this Order. After the results of the last required test of this Order are submitted and the EPA accepts the information as complying with this Order, or the Agency accepts existing information submitted by the Consortium, the EPA will provide notification of compliance with this Order to this Order's recipients and the designated lead of the consortium.

Even if you agree to jointly submit the information as part of a consortium, each Order Recipient is still required to comply with this Order (with the study plan and results being submitted by the consortium) and is individually liable in the event of any failure to comply with this Order. If the consortium fails to submit the information or meet any of the requirements of this Order on your behalf, you will be in violation of this Order unless you submit the required information or meet the requirement individually.

The Agency has provided a list of the manufacturers and processors that have received this Order at the top of this Order in the Summary Information section. This list of manufacturers and processors can be used to help Order Recipients form a consortium to jointly develop information, consolidate testing and share the cost of testing. Information on cost sharing is provided in **Appendix B**.

IX. CONFIDENTIALITY

Under TSCA section 14(b)(2), health and safety studies submitted under TSCA and data reported to or otherwise obtained by the Administrator from health and safety studies are not protected from disclosure if the studies and data concern a chemical that is offered for commercial distribution, or for which testing is required under TSCA section 4 or notification is required under TSCA section 5. However, TSCA section 14(b)(2) does not apply to information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised of the chemical subject to this Order. Therefore, some or all of the information in the studies required to be submitted under this Order might not be eligible for TSCA confidential business information (CBI) protections.

Information submitted under TSCA that you wish to have the EPA protect as CBI must be clearly identified as such when submitted. For sections of the report that are claimed as CBI, the report must be accompanied by a sanitized version of the report only removing the specific information claimed as CBI. A sanitized test report that redacts all or most of the study may be rejected by the Agency as not satisfying the requirements of this Order.

When claiming information as CBI, you must certify to the following:

"I hereby certify to the best of my knowledge and belief that all information entered on this form

is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001."

In addition, information claimed as CBI must be substantiated upon submission, with the exception of information described in TSCA section 14(c)(2). Guidance for substantiating CBI claims may be found at https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations.

Failure to follow the statutory requirements for asserting and substantiating a CBI claim may result in the information being made available to the public without further notice to the submitter.

When a claim of CBI under TSCA section 14 is approved by the EPA, the Administrator will generally protect that information from disclosure for 10 years (unless the protection from disclosure is withdrawn by the person that asserted the claim), whereupon the claim must be reasserted and re-substantiated if the submitter wishes to maintain the CBI claim. In certain cases, the Agency may review claims prior to the expiration of the 10-year period.

Under circumstances stated in TSCA section 14(d), the EPA may disclose information claimed as CBI to other persons including, for example, Federal and State authorities, health and environmental professionals, poison control centers, and emergency responders.

X. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS ORDER

Failure to comply with any of the requirements in this Order is a violation of TSCA section 15 and could subject you to civil and/or criminal penalties under TSCA section 16, 15 U.S.C. § 2615 as modified by the Federal Civil Penalties Inflation Adjustment Act. Each day that failure to meet the requirements continues constitutes a separate violation.

XI. REFERENCES

The following is a listing of the documents that are generally applicable to this Order. **Appendix E** provides references specific to certain testing requirements in this Order. Please note that references,

guidance, and information from additional sources could be considered, with EPA approval, during the development of study plans.

The docket includes these documents and other information considered by the EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

General References for this Test Order

1. U.S. EPA (2021). 4,4'-(1-Methylethylidene)bis[2, 6-Dibromophenol] (TBBPA) Test Order [EPA-HQ-OPPT-2018-0462]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-44-1-methylethylidenebis26[9]

2. U.S. EPA (2020a). Final Scope of the Risk Evaluation for 4,4'-(1-Methylethylidene)bis[2, 6-Dibromophenol] (TBBPA) [740-R-20-008]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-94-7_44-1-methylethylidenebis2_6-dibromophenol_tbbpa_finalscope.pdf[10]

3. U.S. EPA (2020b). Use Report for 4,4'-(1-Methylethylidene)bis[2, 6-Dibromophenol] (TBBPA) (CASRN 79-94-7) [EPA-HQ-OPPT-2018-0462]. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (OPPT). https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0462-0024[11]

Transfer of Chemical From Source to Settled Dust From Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA Test References

4. U.S. EPA (2005). Method 527: Determination of Selected Pesticides and Flame Retardants in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS) [815-R-05-005]. Cincinnati, OH: U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water. https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF[12]

5. U.S. EPA (2017). Indoor Exposure Product Testing Protocols Version 2.0 [740-S1-7002]. [Washington, DC]: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf[13]

[9] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-44-1-methylethylidenebis26*
[10] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-94-7_44-1-methylethylidenebis2_6-dibromophenol_tbbpa_finalscope.pdf*
[11] *https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0462-0024*
[12] *https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF*
[13] *https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf*

Chemical Loading on the Skin Surface From Contact With Settled Dust on Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA Test References

6. U.S. EPA (2005). Method 527: Determination of Selected Pesticides and Flame Retardants in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS) [815-R-05-005]. Cincinnati, OH: U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water. https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF[14]

7. U.S. EPA (2017). Indoor Exposure Product Testing Protocols Version 2.0 [740-S1-7002]. [Washington, DC]: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf[15]

XII. PAPERWORK REDUCTION ACT NOTICE

This collection of information is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. (OMB Control No. 2070-0033). Responses to this collection of information are mandatory under the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 137 hours for the average response on a per-chemical basis. Under the PRA, burden is defined at 5 CFR 1320.3(b). Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

XIII. FOR FURTHER INFORMATION CONTACT

For technical information contact: TSCATestOrders@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

XIV. SIGNATURE

Under the authority in TSCA section 4(a)(2), the United States Environmental Protection Agency hereby issues this Order to take effect on the date of my signature.

Date: [RSB will insert the coded field in the PDF final version.]

Authenticated Digital Signature: [RSB will insert the coded field in the PDF final version.]

[14] *https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF*
[15] *https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf*

Dated: Click or tap to enter eSignature date.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Enclosures

APPENDIX A - EQUIVALENCE DATA

For purposes of this Order, "equivalence data" means "chemical data or biological test data intended to show that two substances or mixtures are equivalent." Also, when a chemical substance is "equivalent," it means "that a chemical substance is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance," as defined in 40 CFR § 790.3.

If testing under TSCA section 4(a) is required of an equivalent chemical substance, the EPA may grant an exemption from testing to the manufacturer or processor of one substance if the information required under TSCA section 4(a) is submitted or is being developed on the other, and the manufacturer or processor submits the following information to support equivalence with its exemption application:

1. The chemical identity of each chemical substance or mixture manufactured or processed by the applicant for which the exemption is sought. The exact type of identifying data required may be specified in this Order and may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining whether the applicant's substance or mixture is equivalent to the specific test substance.

2. The basis for the applicant's belief that the substance or mixture for which the exemption is sought is equivalent to the test substance or mixture.

3. Any other data which exemption applicants are directed to submit in this Order which may have bearing on a determination of equivalence. This may include a description of the process by which each chemical substance or mixture for which an exemption is sought is manufactured or processed prior to use or distribution in commerce by the applicant.

APPENDIX B - COST SHARING

The EPA encourages Order recipients that are responsible for developing the same information on the same chemical(s) to avoid duplicative testing and share the cost of information development. If a test is conducted according to a final, approved protocol, it is sufficient that the test is conducted once. Two ways to avoid duplicative testing are discussed in this Order. They are forming or joining a consortium, discussed in **Unit VIII**, or requesting an exemption, discussed in **Unit IV.B.3**.

Consortia

Persons that form or join a consortium typically execute an agreement with the other members of the consortium concerning how costs will be shared and how the consortium will operate.

Exemptions

Persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the testing and submit the required information that is the basis for the exemption for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Apportionment of costs between persons receiving exemptions and the person who actually conducts the test(s) is ideally negotiated between the companies involved, without the EPA's participation. The Agency has promulgated regulations that explain how the EPA views fair and equitable reimbursement in the context of TSCA section 4(a) test rules. In general, those regulations (40 CFR § 791.40 through § 791.52) make a presumption that a person's fair share of the test costs is in proportion to their share of the total production volume of the test chemical over a specified period of time that begins one calendar year before the effective date of the rule and continues up to the latest data available upon resolution of a dispute. While those regulations do not apply to TSCA section 4 orders, you may wish to consider them as you decide how to share the costs.

If persons subject to an order include a person that has been granted an exemption and agreement cannot be reached on the amount and method of sharing the cost of developing the information, the person whose information is the basis for the exemption may request that the Administrator order the person(s) granted the exemption to provide fair and equitable reimbursement after considering all relevant factors, including the share of the market and the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed. See TSCA section 4(c)(3)(A). Upon receipt of such a request, the EPA will determine fair and equitable reimbursement and issue an order accordingly. The Agency may, at its discretion, make use of procedures and standards applicable to data reimbursement regarding TSCA section 4 rules, contained in 40 CFR part 791.

APPENDIX C - HOW TO ACCESS THE CDX APPLICATION AND RECORDKEEPING REQUIREMENTS

How to Access the CDX Application

The initial response, draft and final study plans, final test reports with underlying data, existing studies, any testing related requests, and all related correspondence must be submitted electronically to the EPA as follows:

1. Submit to the EPA's CDX system. CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for submissions to the Agency.

2. The URL for the CDX website is *https://cdx.epa.gov/*[16] which takes you to the CDX homepage.

3. On the homepage you may select "Log in" or, if you haven't already registered, select "Register with CDX."

4. Once you have logged on to CDX, follow the instructions for submitting TSCA section 4 order information. To access the instructions, select "Report electronically" on the EPA Internet homepage at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*[17].

5. The CDX Help Desk is available for data submission technical support between the hours of 8:00 am and 6:00 pm (EST) at 1-888-890-1995 or helpdesk@epacdx.net. The CDX Help Desk can also be reached at 970-494-5500 for international callers.

The EPA may revise these submission instructions with advance notice.

Recordkeeping

You must retain copies of all information documenting your compliance with this Order for ten years. This includes your response and other documents and correspondence submitted to comply with this Order, such as test protocols, testing related requests, final test reports with their underlying data, and any penalties remitted.

[16] *https://cdx.epa.gov/*
[17] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*

APPENDIX D - ORDER RECIPIENT SELECTION

This Appendix describes the process by which the EPA identified recipients of this Order. This information is for your use, and does not govern the obligations under this Order or the identities of the companies subject to this Order. A recipient of this Order that manufactures or processes the chemical as per the definitions provided in **Unit I.B** is subject to this Order, regardless of the basis on which the Agency identified the recipient.

The manufacturers and processors of the chemical subject to this Order were determined in the following manner:

The EPA included in this Order as recipients all companies comprising the final list of manufacturers subject to fee payments[18] for *p*-dichlorobenzene developed under the "Fees for Administration of Toxic Substances Control Act" rule in 2020, as well as, manufacturers identified by other sources, including Toxics Release Inventory[19] (TRI) reporting from 2016 to 2020 and Chemical Data Reporting (CDR) reporting from 2020. The Agency also included in this Order Companies who reported as "Processors" of this chemical to the 2016 to 2020 TRI. Although the EPA recognizes that there are processors who do not report to TRI, this database was used to identify processors for the purposes of this order because it is the Agency's most comprehensive source to establish a well-verified list of processing companies.

[18] *https://www.epa.gov/tsca-fees/final-list-fee-payers-next-20-risk-evaluations*
[19] *https://www.epa.gov/toxics-release-inventory-tri-program*

APPENDIX E - SPECIFIC REQUIREMENTS AND GUIDANCE FOR THIS ORDER

This appendix provides requirements of study plans and test reports for specific testing requirements of this Order. Additionally, this appendix provides additional reference material(s) associated with the testing required in this Order.

For information on how the EPA determined the need for the testing requirements of this Order, refer to **Unit II.B.**

I. CONSUMER EXPOSURE

a. Transfer of Chemical From Source to Settled Dust From Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA (Exposure Testing Protocol 6: Direct Transfer of Chemicals from Source to Settled Dust)

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to Exposure Testing Protocol 6 (U.S. EPA, 2017) include:

1. Identify all products in all available forms matching description in test order.

2. For each product example and form, identify all products that contain TBBPA. If more than 10 product examples are identified, select 50% of the product examples with limited variability across the components for those products.

3. Follow the test protocol recommendations for the number of samples. If a sample number is not provided, default to five (5) samples per product example that are representative of the whole product, or a statistically representative number of samples and provide rationale for selection.

4. This test is for a solid product that can be cut into representative samples and set alongside blanks inside the chamber.

5. The EPA recommends using EPA Method 527 (2005) for sample extraction and analysis. This method uses Solid Phase Extraction (SPE) for sample extraction and sample chemical analysis by gas chromatography–mass spectrometry (GC–MS) in drinking water. Although the EPA Method 527 list of analytes does not specifically list TBBPA, it is possible to modify the method to include TBBPA in the standards and report on accuracy and precision while other Quality Control (QC) steps of the method are already described. Requested samples for this test will be in a liquid mixture, consider using water in the QC and test samples preparation. The recommended method is likely to be useful, but alternative methods may be proposed by the manufacturer with sufficient rationale and background information.

6. Indicate whether the sampling method was validated by an approved organization (e.g., NIOSH, OSHA, the American Society for Testing and Materials (ASTM), the International Standards Organization (ISO)) or an industrial hygiene/analytical laboratory.

7. Indicate the sampling strategy that will be used for sample collection, including sample

location, flow rates, sampling time, field blanks and sample replication; the sample handling, storage and transport procedures and whether they will be followed; the sample pumps and other instruments and whether they will be properly calibrated with primary standard equipment.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 215 days after the effective date of the Order and must include the following, as applicable:

1. List of products to be tested that fit the product example and form, description of product, total product quantity, and amount used for testing.

2. List of standards, how and when they were prepared, or/and purchased, and stored.

3. Calibration curve range and each point used, at least 5 points should be used for the calibration curve.

4. All Quality Control (QC) samples described in suggested methods.

5. Chemical analysis queue containing standards, blanks, QC, samples in order they were analyzed, date and time.

6. Specify methods used if different from recommendations. Similarly, provide details of instruments, detectors, column description and specifications if they differ from the recommendations. Any deviations from the Test Protocols' experimental set up, sampling, extraction and analytical methods must be substantiated.

7. Which house dust standard reference material was used if other than NIST SRM 2585.

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. U.S. EPA (2005). Method 527: Determination of Selected Pesticides and Flame Retardants in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS) [815-R-05-005]. Cincinnati, OH: U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water. https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF[20]

2. U.S. EPA (2017). Indoor Exposure Product Testing Protocols Version 2.0 [740-S1-7002]. [Washington, DC]: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf[21]

[20] *https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF*
[21] *https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf*

b. Chemical Loading on the Skin Surface From Contact With Settled Dust on Electrical and Electronic Products (e.g., Additive Flame Retardant in Plastic Battery Enclosures) Containing TBBPA (Exposure Testing Protocol 9: Migration to Sweat (Dermal Exposure))

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to Exposure Testing Protocol 9 (U.S. EPA, 2017) include:

1. Follow the test protocol recommendations for the number of samples. If a sample number is not provided, default to five (5) samples per product example that are representative of the whole product or a statistically representative number of samples and provide rationale for selection.

2. For each product example, identify all products that claim to contain TBBPA. If more than 10 product examples are identified, select 50% of the product examples with limited variability across the components for those products.

3. Follow Section 9.3.2 which describes how the products are submerged in a simulated sweat solution matrix.

4. The EPA recommends using EPA Method 527 for the request of Migration to Sweat Test Protocol 9 in solid products. This method uses Solid Phase Extraction (SPE) for sample extraction and sample chemical analysis by gas chromatography–mass spectrometry (GC–MS) in drinking water. Although the EPA Method 527 list of analytes does not specifically list TBBPA, it is possible to modify the method to include TBBPA in the standards and report on accuracy and precision while other QC steps of the method are already described. Requested samples for Test Protocol 9 will be in a water-based mixture of simulated sweat; therefore, the recommended method is likely to be useful. However, an alternative may be proposed by the manufacturer with sufficient rationale and background information.

5. Indicate whether the sampling method was validated by an approved organization (e.g., NIOSH, OSHA, the American Society for Testing and Materials (ASTM), the International Standards Organization (ISO)) or an industrial hygiene/analytical laboratory.

6. Indicate the sampling strategy that will be used for sample collection, including sample location, flow rates, sampling time, field blanks and sample replication; the sample handling, storage and transport procedures and whether they will be followed; the sample pumps and other instruments and whether they will be properly calibrated with primary standard equipment.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 170 days after effective date of the Order and must include the following, as applicable:

1. List products to be tested that fit the product example and form, description of product, total product quantity, and amount used for testing.

2. List standards, how and when they were prepared, or/and purchased, and stored.

3. Provide calibration curve range and each point used, at least 5 points should be used for the calibration curve.

4. Provide all QC samples described in suggested methods.

5. Chemical analysis queue containing standards, blanks, QC, samples in order they were analyzed, date and time.

6. Specify methods used if different from recommendations. Similarly, provide details of instruments, detectors, column description and specifications if they differ from the recommendations. Any deviations from the Test Protocols' experimental set up, sampling, extraction and analytical methods must be substantiated.

7. Specify which simulated sweat solution was used and any deviations from protocol.

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. U.S. EPA (2005). Method 527: Determination of Selected Pesticides and Flame Retardants in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS) [815-R-05-005]. Cincinnati, OH: U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water. https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF[22]

2. U.S. EPA (2017). Indoor Exposure Product Testing Protocols Version 2.0 [740-S1-7002]. [Washington, DC]: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf[23]

[22] *https://nepis.epa.gov/Exe/ZyPDF.cgi/P1005E96.PDF?Dockey=P1005E96.PDF*
[23] *https://www.epa.gov/sites/default/files/2018-01/documents/indoor_exposure_testing_protocols_version_2.pdf*