

## **Manufacturers and Importers of 20 High-Priority Chemicals and 30 Organohalogen Flame Retardants Must Submit Data to EPA**

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The U.S. Environmental Protection Agency (EPA) published a final rule on June 29, 2021, that requires manufacturers (including importers) of 50 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. [86 Fed. Reg. 34147](#). EPA is issuing the final rule pursuant to Section 8(d) of the Toxic Substances Control Act (TSCA) and the TSCA Health and Safety Data Reporting rule codified at 40 C.F.R. Part 716. The chemical substances subject to the rule consist of the 20 designated by EPA as high-priority substances and the 30 organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act (FHSA). EPA states that it is taking this action because the TSCA Interagency Testing Committee (ITC) added these chemical substances to the TSCA Section 4(e) Priority Testing List through its 69th and 74th Reports. EPA will use the submitted information to inform the risk evaluations currently underway for 20 high-priority substances and for future prioritization. The final rule will be effective **July 29, 2021**. Requests to withdraw a chemical substance from the final rule pursuant to 40 C.F.R. Section 716.105(c) must be received by **July 13, 2021**.

### **Substances Added to the TSCA Section 8(d) Health and Safety Data Reporting Rule**

EPA states that the 20 high-priority substances identified in the rule were designated high-priority under TSCA Section 6(b) because EPA found that each of the chemical substances may present an unreasonable risk of injury to health or the environment. According to the final rule, EPA is seeking unpublished health and safety studies to ensure that such studies are available to EPA to inform its risk evaluation findings of whether any of these high-priority substances present an unreasonable risk of injury to health or the environment. EPA will also consider this information, as appropriate, when reviewing potential analogue data for read across and/or category development in assessing new chemicals.

According to the final rule, EPA requests information regarding the identified organohalogen flame retardants to help support prioritization and evaluation activities under TSCA. EPA states that it will also consider this information, as appropriate, when reviewing potential analogue data for read

across and/or category development in assessing new chemicals. Additionally, CPSC, a representative member of the ITC, needs information on a group of organohalogen flame retardants because CPSC voted to grant a petition to begin rulemaking for this class of chemicals under the FHSA.

The table below lists the high-priority substances and organohalogen flame retardants included in the final rule.

Chemical Substance	Chemical Abstracts Service Registry Number
<b>High-Priority Substances</b>	
1,3-Butadiene	106-99-0
Butyl benzyl phthalate (BBP) (1,2-Benzene-dicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)	85-68-7
Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)	84-74-2
o-Dichlorobenzene	95-50-1
p-Dichlorobenzene	106-46-7
1,1-Dichloroethane	75-34-3
1,2-Dichloroethane	107-06-2
trans-1,2-Dichloroethylene	156-60-5
1,2-Dichloropropane	78-87-5
Dicyclohexyl phthalate	84-61-7
Di-ethylhexyl phthalate (DEHP) (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	117-81-7
Di-isobutyl phthalate (DIBP) (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-methylpropyl) ester)	84-69-5
Ethylene dibromide	106-93-4
Formaldehyde	50-00-0
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB)	1222-05-5
4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)	79-94-7
Phosphoric acid, triphenyl ester (TPP)	115-86-6

Phthalic anhydride	85-44-9
1,1,2-Trichloroethane	79-00-5
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8
<b>Organohalogen Flame Retardants</b>	
Bis(2-ethylhexyl) tetrabromophthalate	26040-51-7
Bis(hexachlorocyclopentadieno)cyclooctane	13560-89-9
1,2-Bis(2,4,6-tribromophenoxy)ethane	37853-59-1
1,1'-Ethane-1,2-diylbis(pentabromobenzene)	84852-53-9
2-Ethylhexyl-2,3,4,5-tetrabromobenzoate	183658-27-7
2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate	20566-35-2
2,2'-[(1-Methylethylidene)bis[(2,6-dibromo-4, 1-phenylene)oxymethylene]]bis[oxirane]	3072-84-2
Mixture of chlorinated linear alkanes C14-17 with 45-52 % chlorine	85535-85-9
N,N-Ethylene-bis(tetrabromophthalimide)	32588-76-4
Pentabromochlorocyclohexane	87-84-3
(Pentabromophenyl)methyl acrylate	59447-55-1
Pentabromotoluene	87-83-2
Perbromo-1,4-diphenoxybenzene	58965-66-5
Phosphonic acid, (2-chloroethyl)-, bis(2-chloroethyl) ester	6294-34-4
Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) ester	38051-10-4
Propanoic acid, 2-bromo-, methyl ester	5445-17-0
Tetrabromobisphenol A- bis(2,3-dibromopropyl ether)	21850-44-2
Tetrabromobisphenol A bis(2-hydroxyethyl) ether	4162-45-2
Tetrabromobisphenol A diallyl ether	25327-89-3
Tetrabromobisphenol A dimethyl ether	37853-61-5
2,4,6-Tribromoaniline	147-82-0

1,3,5-Tribromo-2-(prop-2-en-1-yloxy)benzene	3278-89-5
Tris(2-chloroethyl)phosphite	140-08-9
Tris(1-chloro-2-propyl)phosphate	13674-84-5
Tris(2-chloro-1-propyl)phosphate	6145-73-9
Tris(2,3-dibromopropyl)phosphate	126-72-7
1,3,5-Tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	52434-90-9
Tris(1,3-dichloro-2-propyl)phosphate	13674-87-8
Tris(tribromoneopentyl)phosphate	19186-97-1
2,4,6-Tris-(2,4,6-tribromophenoxy)-1,3,5-triazine	25713-60-4

Listed below are the reporting requirements for chemical substances added by the final rule to the TSCA Health and Safety Data Reporting rule: **The Reporting Requirements**

- Persons who, in the ten years preceding the date a chemical substance is listed, either have proposed to manufacture (including import) or have manufactured (including imported) the listed chemical substance must submit to EPA a copy of each specified type of health and safety study that is in their possession at the time the chemical substance is listed.
- Persons who, at the time the chemical substance is listed, propose to manufacture (including import) or are manufacturing (including importing) the listed chemical substance must submit to EPA:
  - A list of the specified types of health and safety studies known to them but not in their possession at the time the chemical substance is listed;
  - A list of the specified types of health and safety studies that are ongoing at the time the chemical substance is listed and are being conducted by or for them;
  - A list of the specified types of health and safety studies that are initiated after the date the chemical substance is listed and will be conducted by or for them;
  - A copy of each specified type of health and safety study that is in their possession at the time the chemical substance is listed; and
  - A copy of each specified type of health and safety study that was previously listed as ongoing or subsequently initiated and is now complete, regardless of completion date.
- Persons who, after the time the chemical substance is listed, propose to manufacture (including import) the listed chemical substance must submit to EPA:
  - A list of the specified types of health and safety studies known to them but not in their

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possession at the time they propose to manufacture (including import) the listed chemical substance;

- A list of the specified types of health and safety studies that are ongoing at the time they propose to manufacture (including import) the listed chemical substance and are being conducted by or for them;
- A list of the specified types of health and safety studies that are initiated after the time they propose to manufacture (including import) the listed chemical substance and will be conducted by or for them;
- A copy of each specified type of health and safety study that is in their possession at the time they propose to manufacture (including import) the listed chemical substance; and
- A copy of each specified type of health and safety study that was previously listed as ongoing or subsequently initiated and is now complete, regardless of the completion date.

The information listed above is due to EPA by **September 27, 2021**. Any person who manufactures (including imports) or who proposes to manufacture (including import) listed chemical substances from **July 29, 2021**, to **September 27, 2021**, must inform EPA by submitting a list of any studies initiated during the period from **July 29, 2021**, to **September 27, 2021**, within 30 days of their initiation, but in no case later than **October 27, 2021**. In addition, if any such person has submitted lists of studies that were ongoing or initiated during the period from **July 29, 2021**, to **September 27, 2021**, to EPA, such person must submit a copy of each study within 30 days after its completion, regardless of the study's completion date.

EPA states that persons reporting under the rule may also assert confidential business information (CBI) claims for certain information included in their submission. Submissions claiming CBI must meet the following requirements:

- CBI claims must be asserted at the time the information claimed as CBI is submitted to EPA. Information submitted with a confidentiality claim may be made public without further notice;
- Information claimed as CBI must be substantiated at the time of submission, with the exception of those types of information exempt from substantiation under TSCA Section 14(c)(2);
- All persons making a CBI claim must provide a standard statement concerning the need for the CBI claim and a certification that the statement of need is true and correct; and
- Where a specific chemical identity is claimed as CBI, a structurally descriptive generic name must be provided for disclosure to the public.

## **Types of Studies That Must Be Submitted**

Under the final rule, manufacturers (including importers) of TSCA high-priority substances are

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required to submit the following:

- Lists and copies of unpublished health and safety studies for all high-priority substances specified in the rule on health effects, such as toxicity studies (*in vivo* and *in vitro*) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetics (absorption, distribution, metabolism, or elimination), including modeling studies, in humans or animals;
- All unpublished studies on environmental effects, environmental fate, and physical-chemical properties if performed as described in 40 C.F.R. Section 716.50 are also required under the rule;
- All unpublished studies on occupational (both users and non-users), general population, consumer, and environmental exposure, such as: unpublished studies on inhalation and dermal exposure, human biomonitoring, environmental monitoring of indoor and outdoor air, soil, water, and household dust, chamber emission rates from products or polymeric matrices, and unpublished modeling studies that estimate environmental concentrations or human exposures; and
- Studies showing any measurable content of the high-priority substance in the tested substance (single substances or mixture) must be reported. The composition and purity of test substances must be reported if included as part of the study.

Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA Section 4 action are exempt from the submission of lists of health and safety studies required under 40 C.F.R. Section 716.35 and the submission of studies required under the rule.

Under the final rule, manufacturers (including importers) of organohalogen flame retardants are required to submit the following:

- Lists and copies of unpublished health and safety studies for all organohalogen flame retardants specified in the rule on health effects, such as toxicity studies (*in vivo* and *in vitro*) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetics (absorption, distribution, metabolism, or elimination), including modeling studies, in humans or animals;
- All unpublished studies on environmental effects, environmental fate, and physical-chemical properties if performed as described in 40 C.F.R. Section 716.50 are also required under the rule;
- All unpublished studies on occupational (both users and non-users), general population, consumer, and environmental exposure, such as unpublished studies on inhalation and dermal exposure, human biomonitoring, environmental monitoring of indoor and outdoor air, soil, water, and household dust, chamber emission rates from products or polymeric matrices, and unpublished modeling studies that estimate environmental concentrations or human exposures, must be submitted; and
- Studies showing any measurable content of the organohalogen flame retardant in the tested

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substance (single substances or mixture) must be reported. The composition and purity of test substances must be reported if included as part of the study.

Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA Section 4 action are exempt from the submission of lists of health and safety studies requirements under 40 C.F.R. Section 716.35 and the submission of studies requirements under the final rule.

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