

(f) *Adverse determinations and notice period.* Final determinations will be issued by the General Counsel or their designee, including personnel outside of the Office of General Counsel. Except for instances where claims were waived, if EPA determines that information claimed confidential does not qualify for protection from disclosure, EPA will provide written notice to the person who asserted the claim. The notice will be provided electronically, as described in §703.5(h)(2). The 30-day notice period described in TSCA section 14(g)(2)(B) begins on the next business day following the date the notice is made available to the submitter in their CDX account.

(g) *Disclosure of Information.* After a final determination has been made by EPA to release some or all of the information claimed as confidential, the Agency shall make the information available to the public (in the absence of a court order prohibiting disclosure) whenever:

(1) The period provided for commencement by a business of an action to obtain judicial review of the determination has expired without notice to EPA of commencement of such an action; or

(2) The court, in a timely-commenced action, has denied the person's motion for a preliminary injunction, or has otherwise upheld the EPA determination.

(h) *Notice relating to public requests for records.* Any person whose request for release of the information under 5 U.S.C. 552 is pending at the time notice is given under paragraph (f) of this section shall be furnished notice under 5 U.S.C. 552 either stating the circumstances under which the some or all of the information will be released or denying the request if all requested information was found to be entitled to confidential treatment.

PART 704—REPORTING AND RECORDKEEPING REQUIREMENTS

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AUTHORITY: 15 U.S.C. 2607(a).

Subpart A—General Reporting and Recordkeeping Provisions for Section 8(a) Information-Gathering Rules

§ 704.1 Scope.

(a) This part specifies reporting and recordkeeping procedures under section 8(a) of the Toxic Substances Control Act (TSCA) for manufacturers, importers, and processors of chemical substances and mixtures (hereafter collectively referred to as substances) that are identified in subpart B of this part. The reporting and recordkeeping provisions in subpart A of this part apply throughout this part unless revised in any other subpart.

(b) Subpart B of this part sets out chemical-specific reporting and recordkeeping requirements under section 8(a) of TSCA.

[53 FR 51715, Dec. 22, 1988, as amended at 60 FR 31920, June 19, 1995]

§ 704.3 Definitions.

All definitions as set forth in section 3 of TSCA apply in this part. In addition, the following definitions are provided for the purposes of this part.

Annual means the corporate fiscal year.

Article means a manufactured item (1) which is formed to a specific shape

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or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

Byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

CAS Number means Chemical Abstracts Service Registry Number.

Coproduct means a chemical substance produced for a commercial purpose during the manufacture, processing, use, or disposal of another chemical substance or mixture.

Customer means any person to whom a manufacturer, importer, or processor directly distributes any quantity of a chemical substance, mixture, mixture containing the substance or mixture, or article containing the substance or mixture, whether or not a sale is involved.

Domestic means within the geographical boundaries of the 50 United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

Enclosed process means a manufacturing or processing operation that is designed and operated so that there is no intentional release into the environment of any substance present in the operation. An operation with fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases.

EPA means the United States Environmental Protection Agency.

Import means to import for commercial purposes.

Import for commercial purposes means to import with the purpose of obtaining an immediate or eventual commercial advantage for the importer, and includes the importation of any amount of a chemical substance or mixture. If a chemical substance or mixture containing impurities is imported for commercial purposes, then those impurities also are imported for commercial purposes.

Import in bulk form means to import a chemical substance (other than as part of a mixture or article) in any quantity, in cans, bottles, drums, barrels, packages, tanks, bags, or other containers, if the chemical substance is intended to be removed from the container and the substance has an end use or commercial purpose separate from the container.

Importer means (1) any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the United States, and includes:

(i) The person primarily liable for the payment of any duties on the merchandise, or

(ii) An authorized agent acting on his behalf.

(2) Importer also includes, as appropriate:

(i) The consignee.

(ii) The importer of record.

(iii) The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with 19 CFR 141.20.

(iv) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144.

(3) For the purposes of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the

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purpose of altering the rates of such chemical reactions.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Manufacture means to manufacture for commercial purposes.

Manufacture for commercial purposes means: (1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among other things, such "manufacture" of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

Manufacturer means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance.

Non-isolated intermediate means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity

transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers "isolates" the substance by removing it from process equipment in which it is manufactured.

Own or control means ownership of 50 percent or more of a company's voting stock or other equity rights, or the power to control the management and policies of that company. A company may own or control one or more sites. A company may be owned or controlled by a foreign or domestic parent company.

Parent company is a company that owns or controls another company.

Person includes any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Possession or control means in the possession or control of any person, or of any subsidiary, partnership in which the person is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the person in the research, development, test marketing, or commercial marketing of the substance in question. Information is in the possession or control of a person if it is:

(1) In the person's own files including files maintained by employees of the person in the course of their employment.

(2) In commercially available data bases to which the person has purchased access.

(3) Maintained in the files in the course of employment by other agents of the person who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

Process means to process for commercial purposes.

Process for commercial purposes means the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with

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the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes.

Processor means any person who processes a chemical substance or mixture.

Production volume means the quantity of a substance which is produced by a manufacturer, as measured in kilograms or pounds.

Propose to manufacture, import, or process means that a person has made a firm management decision to commit financial resources for the manufacture, import, or processing of a specified chemical substance or mixture.

Site means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one plant on a single site. The site for a person who imports a substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction and may in some cases be the organization's headquarters office in the United States.

Small government means the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

Small manufacturer means a manufacturer (including importer) that meets either of the following standards:

(1) *First standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$120 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 lbs), the manufacturer (including importer) will not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer (including importer) qualifies

as small under paragraph (2) of this definition.

(2) *Second standard.* A manufacturer (including importer) of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$12 million, regardless of the quantity of substances produced or imported by that manufacturer (including importer).

(3) *Inflation index.* EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the five-year average of the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or May 28, 2020, whichever is later. EPA shall provide FEDERAL REGISTER notification when changing the total annual sales values.

Small quantities solely for research and development (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

Substance means either a chemical substance or mixture unless otherwise indicated.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, article containing that chemical substance or mixture, or a mixture containing that substance, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to

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the broader distribution of that chemical substance, mixture, or article in commerce.

Total annual sales means the total annual revenue (in dollars) generated by the sale of all products of a company. Total annual sales must include the total annual sales revenue of all sites owned or controlled by that company and the total annual sales revenue of that company's subsidiaries and foreign or domestic parent company, if any.

TSCA means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

[53 FR 51715, Dec. 22, 1988, as amended at 76 FR 50858, Aug. 16, 2011; 76 FR 54933, Sept. 6, 2011; 85 FR 31995, May 28, 2020]

§ 704.5 Exemptions.

A person who is subject to reporting requirements for a substance identified in this part is exempt from those requirements to the extent that the person and that person's use of the substance is described in this section. This section is superseded by any TSCA section 8(a) rule that adds to, removes, or revises the exemptions described in this section.

(a) *Articles.* A person who imports, processes, or proposes to import or process a substance identified in this part solely as part of an article is exempt from the reporting requirements of this part with regard to that substance.

(b) *Byproducts.* A person who manufactures, imports, or proposes to manufacture or import a substance identified in this part solely as a byproduct is exempt from the reporting requirements of this part.

(c) *Impurities.* A person who manufactures, imports, processes, or proposes to manufacture, import, or process a substance identified in this part solely as an impurity is exempt from the reporting requirements of this part.

(d) *Non-isolated intermediate.* A person who manufactures or proposes to manufacture a substance identified in this part solely as a non-isolated intermediate is exempt from the reporting requirements of this part.

(e) *Research and development.* A person who manufactures, imports, processes, or proposes to manufacture, import, or process a substance identified

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in this part only in small quantities solely for research and development is exempt from the reporting requirements of this part.

(f) *Small manufacturers and importers.* Small manufacturers and importers are exempt from the reporting requirements of this part.

[53 FR 51717, Dec. 22, 1988]

§ 704.7 Confidential business information claims.

(a) Any person submitting a notice under this rule may assert a business confidentiality claim covering all or any part of the notice. Any information covered by a claim will be disclosed by EPA only to the extent and by means of the procedures set forth in part 2 of this title.

(b) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file available to the public without further notice to the respondent.

(c) To assert a claim of confidentiality for data contained in a notice, the respondent must submit two copies of the notice.

(1) One copy of the notice must be complete. In that copy the respondent must indicate what data, if any, are claimed as confidential by marking the specific information on each page with a label such as "confidential", "proprietary", or "trade secret".

(2) If some data in the notice are claimed as confidential, the respondent must submit a second copy. The second copy must be complete except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy of the notice will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(4) Failure to furnish a second copy of the notice when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent has 15 days from the date of receipt of notification to submit the required second copy. Failure to submit the second

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copy will cause EPA to place the first copy in the public file.

(d) In submitting a claim of confidentiality, a person attests to the truth of the following four statements concerning all information which is claimed confidential:

(1) My company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.

(2) The information is not, and has not been, reasonably obtainable without our consent by other persons (other than government bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).

(3) The information is not publicly available elsewhere.

(4) Disclosure of the information would cause substantial harm to our competitive position.

[48 FR 23420, May 25, 1983, as amended at 53 FR 51717, Dec. 22, 1988]

EFFECTIVE DATE NOTE: At 88 FR 37171, June 7, 2023, § 704.7 was revised, effective Aug. 7, 2023. For the convenience of the user, the revised text is set forth as follows:

§ 704.7 Confidential business information claims.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

§ 704.9 Where to send reports.

Reports must be submitted by certified mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: 8(a) Reporting.

[60 FR 34463, July 3, 1995, as amended at 71 FR 33641, June 12, 2006]

§ 704.11 Recordkeeping.

Each person who is subject to the reporting requirements of this part must retain the following records for 3 years following the creation or compilation of the record.

(a) A copy of each report submitted by the person in response to the requirements of this part.

(b) Materials and documentation sufficient to verify or reconstruct the values submitted in the report.

(c) A copy of each notice sent by the person, return receipt requested, to that person's customers for the purpose of notifying their customers of the customer's reporting obligations under this part.

(d) All return receipts signed by the person's customers who received the notice described in paragraph (c) of this section.

[53 FR 51717, Dec. 22, 1988, as amended at 58 FR 34204, June 23, 1993]

§ 704.13 Compliance and enforcement.

Violators of the requirements of this part may be subject to civil administrative penalties up to \$25,000 per day of violation or criminal prosecution, as provided in sections 15 and 16 of TSCA. In addition, under section 17, EPA may seek judicial relief to compel submission of required information.

[53 FR 51717, Dec. 22, 1989]

Subpart B—Chemical-Specific Reporting and Recordkeeping Rules

§ 704.20 Chemical substances manufactured or processed at the nanoscale.

(a) *Definitions.* For purposes of this section the terms below are defined as follows:

An *agglomerate* is a collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components.

An *aggregate* is a particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components.

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

CISS tool means the Chemical Information Submission System, EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

Discrete form of a reportable chemical substance differs from another form of

the same reportable chemical substance in one or more of the following 3 characteristics:

(i) The change in the reportable chemical substance is due to all of the following:

(A) There is a change in process to effect a change in size, a change in one or more of the properties of the reportable chemical substances identified in paragraph (i)(C) of this definition, or both;

(B) There is a size variation in the mean particle size that is greater than 7 times the standard deviation of the mean particle size (± 7 times the standard deviation); and

(C) There is a change in at least one of the following properties: Zeta potential, specific surface area, dispersion stability, or surface reactivity, that is greater than 7 times the standard deviation of the measured value (± 7 times the standard deviation).

(ii) The reportable chemical substance has a different morphology. Examples of morphologies include but are not limited to sphere, rod, ellipsoid, cylinder, needle, wire, fiber, cage, hollow shell, tree, flower, ring, torus, cone, and sheet.

(iii) A reportable chemical substance that is coated with another chemical substance or mixture at the end of manufacturing or processing has a coating that consists of a different chemical substance or mixture.

Nanoscale Materials Stewardship Program was a program conducted by EPA from January 2008 to December 2009 under which some nanoscale material manufacturers and processors voluntarily provided EPA available information on engineered nanoscale materials that were manufactured, processed or used.

Particle is a minute piece of matter with defined physical boundaries.

Primary particles are particles or droplets that form during manufacture of a chemical substance before aggregation or agglomeration occurs.

Reportable chemical substance is a chemical substance as defined in section 3 of TSCA that is solid at 25 °C and standard atmospheric pressure, that is manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one di-

mension, and that is manufactured or processed to exhibit unique and novel properties because of its size. A reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1% of any particles, including aggregates, and agglomerates, measured by weight are in the size range of 1–100 nm.

Small manufacturer or processor means any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than \$11 million. The definition of *small manufacturer* in section 704.3 of this title does not apply to reporting under this section (40 CFR 704.20).

Specific surface area means the ratio of the area of the surface of the reportable chemical substance to its mass or volume. Specific surface area by mass is the ratio of the area of the surface of a nanoscale material divided by the mass (m^2/kg) and the specific surface area by volume is the area of the surface of the reportable chemical substance divided by its volume m^2/m^3 .

Surface reactivity means the reactivity at the surface of a reportable chemical substance. It is dependent upon factors such as redox potential, which is a measure of the tendency of a substance to lose or acquire electrons, photocatalytic activity, including the potential to generate free radicals.

Unique and novel properties means any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance, and such properties are a reason that the chemical substance is manufactured or processed in that form or size.

Zeta potential is the electrostatic potential near the particle surface.

(b) *Persons who must report.* (1) Persons who can reasonably ascertain that they are manufacturers and processors of a discrete form of a reportable chemical substance during the three years prior to the final effective date of the rule must report except as provided in paragraph (c) of this section.

(2) Persons who can reasonably ascertain that they propose to manufacture or process a discrete form of a reportable chemical substance after the final

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effective date of the rule which was not reported under paragraph (b)(1) of this section must report except as provided in paragraph (c) of this section.

(c) *When reporting is not required.* (1) The following chemical substances are not subject to reporting under this section:

(i) Chemical substances formed at the nanoscale as part of a film on a surface.

(ii) DNA.

(iii) RNA.

(iv) Proteins.

(v) Enzymes.

(vi) Lipids.

(vii) Carbohydrates.

(viii) Peptides.

(ix) Liposomes.

(x) Antibodies.

(xi) Viruses.

(xii) Microorganisms.

(xiii) Chemical substances which dissociate completely in water to form ions that are smaller than 1 nanometer.

(xiv) Chemical substances that are not on the TSCA Chemical Substance Inventory at the time reporting would otherwise be required under this section.

(2) Persons who submitted a notice under 40 CFR parts 720, 721, or 723 for a reportable chemical substance on or after January 1, 2005 are not required to submit a report for the reportable chemical substance submitted except where the person manufactures or processes a discrete form of the reportable chemical substance.

(3) Section 704.5(a) through (e) apply to reporting under this section. Small manufacturers and processors as defined in paragraph (a) of this section are exempt from reporting under this section.

(4) Persons who submitted some or all of the required information for a reportable chemical substance as part of the Nanoscale Materials Stewardship Program are not required to report the information previously submitted except where the person manufactures or processes a discrete form of the reportable chemical substance.

(d) *What information to report.* The following information must be reported for each discrete form of a reportable chemical substance to the extent that

it is known to or reasonably ascertainable by the person reporting:

(1) The common or trade name, the specific chemical identity including the correct Chemical Abstracts (CA) Index Name and available Chemical Abstracts Service (CAS) Registry Number, and the molecular structure of each chemical substance or mixture. Information must be reported as specified in § 720.45.

(2) Material characteristics including particle size, morphology, and surface modifications.

(3) Physical/chemical properties.

(4) The maximum weight percentage of impurities and byproducts resulting from the manufacture, processing, use, or disposal of each chemical substance.

(5)(i) Persons described in paragraph (b)(1) of this section must report the annual production volume for the previous three years before the effective date of the final rule and an estimate of the maximum production volume for any consecutive 12-month period during the next two years of production after the final effective date of this rule.

(ii) Persons described in paragraph (b)(2) of this section must report the estimated maximum 12 month production volume and the estimated maximum production volume for any consecutive 12 month period during the first three years of production.

(iii) Estimates for paragraphs (d)(5)(i) and (ii) of this section must be on 100% chemical basis of the discrete form of the solid nanoscale material.

(6) Use information describing the category of each use by function and application, estimates of the amount manufactured or processed for each category of use, and estimates of the percentage in the formulation for each use.

(7) Detailed information on methods of manufacturing or processing.

(8) Exposure information with estimates of the number of individuals exposed in their places of employment, descriptions and duration of the occupational tasks that cause such exposure, descriptions and estimates of any general population or consumer exposures.

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(9) Release information with estimates of the amounts released, descriptions and duration of the activities that cause such releases, and whether releases are directly to the environment or to control technology.

(10) Risk management practices describing protective equipment for individuals, engineering controls, control technologies used, any hazard warning statement, label, safety data sheet, customer training, or other information which is provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the substance.

(11) Existing information concerning the environmental and health effects.

(e) *How to report.* You must use CDX and the CISS tool to complete and submit the information required under this part to EPA electronically.

(1) *Reporting form.* You must complete EPA Form No. 7710-xx, TSCA §8(a) Reporting for Nanoscale Materials: Information Submission Form.

(2) *Electronic submission.* You must submit the required information to EPA electronically via CDX and using the CISS tool.

(i) To access the CDX portal, go to <https://cdx.epa.gov>.

(ii) The CISS tool is accessible in CDX.

(f) *When to report.* (1) Persons specified in paragraph (b)(1) of this section must report the information specified in paragraph (d) of this section within one year after the final effective date of the rule.

(2) Persons specified in paragraph (b)(2) of this section must report the information specified in paragraph (d) of this section at least 135 days before commencing manufacture or processing of a discrete form of the reportable chemical substance, except where the person has not formed an intent to manufacture or process that discrete form at least 135 days before commencing such manufacture or processing, in which case the information must be filed within 30 days of the formation of such an intent.

(g) *Recordkeeping.* Any person subject to the reporting requirements of this

section is subject to the recordkeeping requirements in §704.11(a) and (b).

(h) *Confidential business information.*

(1) Persons submitting a notice under this rule are subject to the requirements for confidential business information claims in §704.7(a) through (c).

(2) In submitting a claim of confidentiality, a person attests to the truth of the following four statements concerning all information which is claimed confidential:

(i) My company has taken 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 the person.

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

[82 FR 3653, Jan. 12, 2017]

§ 704.25 11-Aminoundecanoic acid.

(a) *Definitions*—(1) *11-AA* means the chemical substance 11-aminoundecanoic acid, CAS Number 2432-99-7.

(2) *Enclosed process* means a process that is designed and operated so that there is no intentional release of any substance present in the process. A process with fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to an environmental contamination from the releases.

(3) *Internal subunit* means a subunit that is covalently linked to at least two other subunits. *Internal subunits* of polymer molecules are chemically derived from monomer molecules that have formed covalent links between two or more other molecules.

(4) *Monomer* means a chemical substance that has the capacity to form links between two or more other molecules.

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(5) *Polymer* means a chemical substance that consists of at least a simple weight majority of polymer molecules but consists of less than a simple weight majority of molecules with the same molecular weight. Collectively, such polymer molecules must be distributed over a range of molecular weights wherein differences in molecular weight are primarily attributable to differences in the number of internal subunits.

(6) *Polymer molecule* means a molecule which includes at least four covalently linked subunits, at least two of which are internal subunits.

(7) *Small processor* means a processor that meets either the standard in paragraph (a)(7)(i) of this section or the standard in paragraph (a)(7)(ii) of this section.

(i) *First standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company, if any, are less than \$40 million. However, if the annual processing volume of a particular chemical substance at any individual site owned or controlled by the processor is greater than 45,400 kilograms (100,000 pounds), the processor shall not qualify as small for purposes of reporting on the processing of that chemical substance at that site, unless the processor qualifies as small under paragraph (a)(7)(ii) of this section.

(ii) *Second standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of the particular chemical substance processed by that company.

(iii) *Inflation index.* EPA will use the Inflation Index described in the definition of *small manufacturer* set forth in §704.3, for purposes of adjusting the total annual sales values of this small processor definition. EPA will provide notice in the FEDERAL REGISTER when changing the total annual sales values of this definition.

(8) *Subunit* means an atom or group of associated atoms chemically derived from corresponding reactants.

(b) *Persons who must report.* Except as provided in paragraph (c) of this section, the following persons are subject to this section:

(1) Persons who manufacture or propose to manufacture 11-AA:

(i) For use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11-AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(2) Persons who import or propose to import 11-AA:

(i) For use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11-AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(3) Persons who process or propose to process 11-AA:

(i) For use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11-AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(c) *Persons not subject to this section.* The following persons are not subject to this section:

(1) Small manufacturers (includes importers) as described in §704.3.

(2) Small processors.

(3) Persons described in §704.5.

(4) Persons who, at any time during the 3-year period ending July 22, 1986, manufactured, imported, or processed 11-AA:

(i) For use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11-AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(d) *What information to report.* Persons identified in paragraph (b) of this section must submit a Premanufacture Notice Form (EPA Form 7710-25).

(e) *When to report.* (1) Persons who intend to manufacture, import, or process 11-AA for use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11-AA will be fully polymerized during the manufacturing process or for use as a component in photoprocessing solutions must notify EPA within 30 days after making a

firm management decision to commit financial resources for the manufacturing, importing, or processing of 11-AA.

(2) Persons who initiated manufacturing, importing, or processing of 11-AA for use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11-AA will be fully polymerized during the manufacturing process, or for use as a component in photoprocessing solutions during the time period between July 22, 1986 and July 13, 1987 must notify EPA by August 10, 1987.

(f) *Recordkeeping.* Persons subject to the reporting requirements of this section must retain documentation of information contained in their reports for a period of 5 years from the date of submission of the report.

(g) *Where to send reports.* Reports must be submitted by certified mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: 11-AA Notification.

[52 FR 19864, May 28, 1987, as amended at 60 FR 16308, Mar. 29, 1995; 60 FR 34463, July 3, 1995; 71 FR 33641, June 12, 2006]

§ 704.33 P-tert-butylbenzoic acid (P-TBBA), p-tert-butyltoluene (P-TBT) and p-tert-butylbenzaldehyde (P-TBB).

(a) *Definitions*—(1) *P-TBBA* means the substance p-tert-butylbenzoic acid, also identified as 4-(1,1-dimethylethyl)benzoic acid, CAS No. 98-73-7.

(2) *P-TBT* means the substance p-tert-butyltoluene, also identified as 1-(1,1-dimethylethyl)-4-methylbenzene, CAS No. 98-51-1.

(3) *P-TBB* means the substance p-tert-butylbenzaldehyde, also identified as 4-(1,1-dimethylethyl)benzaldehyde, CAS No. 939-97-9.

(4) *Small processor* means a processor that meets either the standard in paragraph (a)(4)(i) of this section or the standard in paragraph (a)(4)(ii) of this section.

(i) *First standard.* A processor of a chemical substance is small if its total annual sales, when combined with

those of its parent company, if any, are less than \$40 million. However, if the annual processing volume of a particular chemical substance at any individual site owned or controlled by the processor is greater than 45,400 kilograms (100,000 pounds), the processor shall not qualify as small for purposes of reporting on the processing of that chemical substance at that site, unless the processor qualifies as small under paragraph (a)(1)(ii) of this section.

(ii) *Second standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of the particular chemical substance processed by that company.

(iii) *Inflation index.* EPA shall use the Inflation Index described in the definition of *small manufacturer* that is set forth in § 704.3, for purposes of adjusting the total annual sales values of this small processor definition. EPA shall provide FEDERAL REGISTER notification when changing the total annual sales values of this definition.

(b) *Persons who must report.* Except as provided in paragraph (c) of this section, the following persons are subject to the reporting requirements of this rule; a person may become subject to this rule more than once, for more than one substance or under more than one of the criteria listed in this paragraph (b).

(1) Persons who manufactured, imported, or processed P-TBBA, P-TBT, and/or P-TBB for commercial purposes during the person's latest complete corporate fiscal year prior to June 25, 1986. For purposes of this provision, processors of P-TBBA, P-TBT, and/or P-TBB shall include only those persons who processed the substances other than as non-isolated intermediates.

(2) Persons who commence manufacture or importation of P-TBBA, P-TBT, and/or P-TBB for commercial purposes after June 25, 1986. This provision is applicable to persons who cease manufacture or importation of P-TBBA, P-TBT, and/or P-TBB after June 25, 1986 and then subsequently resume manufacture or importation of the substance(s).

(3) Persons who process P-TBBA, P-TBT, and/or P-TBB for commercial purposes in any way other than as a

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non-isolated intermediate after June 25, 1986.

(c) *Persons not subject to this rule.* In addition to the persons described in § 704.5, small processors, as defined in paragraph (a)(4) of this section, are not subject to this rule.

(d) *Information to report.* Persons subject to this rule as described in paragraph (b) of this section shall report information to EPA as specified in this paragraph (d). Respondents to this rule shall report all information that is known to or reasonably ascertainable by the person reporting. For purposes of importer reporting under this paragraph, a site is the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction. The import site may in some cases be the organization's headquarters office in the United States.

(1) All manufacturers, importers, and processors specified in paragraph (b) of this section shall report their name and headquarters address.

(2) All manufacturers, importers, and processors specified in paragraph (b) of this section shall report the name, address, and office telephone number (including area code) of their principal technical contact.

(3) All manufacturers, importers, and processors specified in paragraph (b) of this section shall report the name and address of each site where P-TBBA, P-TBT, and/or P-TBB is manufactured, imported, or processed.

(4) All manufacturers, importers, and processors specified in paragraph (b)(1) of this section only shall report the information described in this paragraph (d)(4). Respondents to this paragraph (d)(4) shall report separately for each substance that they manufacture, import, or process, and for each site at which they do so. However, if the information to be reported in response to this paragraph (d)(4) is the same for different sites, the respondent need not report separately for each site but need only notify EPA that the information is the same for each site. The information to be reported under this paragraph (d)(4) shall cover the respondent's latest complete corporate fiscal year prior to June 25, 1986. Respondents

to this paragraph (d)(4) shall report the following information:

(i) The total quantity (by weight) of P-TBBA, P-TBT, or P-TBB manufactured, imported, or processed for commercial purposes per site.

(ii) A narrative description of the manufacturing, importing, or processing operation(s) involving P-TBBA, P-TBT, or P-TBB at each site.

(iii) A narrative description of worker activities involving P-TBBA, P-TBT, or P-TBB at each site, including the number of workers potentially exposed to each substance and, if applicable, the number of workers potentially exposed to more than one substance.

(iv) The potential routes of worker exposure to P-TBBA, P-TBT, or P-TBB at each site (e.g., inhalation, ingestion, dermal absorption).

(v) Available monitoring data from employee breathing zones with potential exposure to P-TBBA, P-TBT, or P-TBB at each site, including a description of the method of monitoring, the number of samples taken, and the potential number of workers similarly exposed for each worker job category. Respondents to this paragraph (d)(4)(v) shall submit data showing a range of 8-hour time weighted averages (TWAs), provided that the data are available in that form. Respondents also shall submit a calculated geometric mean of these data, with an explanation of the method by which the mean was derived. However, if the monitoring data are not available in the form of 8-hour TWAs, respondents shall submit raw sample data results and the duration time of sampling for each job category.

(vi) A narrative description of any personal protective equipment and/or engineering controls used to prevent exposure to P-TBBA, P-TBT, or P-TBB at each site.

(vii) A listing of the estimated quantities of P-TBBA, P-TBT, or P-TBB released directly into air, water, or land from each site.

(viii) A narrative description of the times during the manufacturing, importing, or processing operations involving P-TBBA, P-TBT, or P-TBB when environmental release occurs at each site.

(ix) A narrative description of any engineering controls used to prevent

environmental release of P-TBBA, P-TBT, or P-TBB at each site.

(x) A narrative description of all known end uses of any P-TBBA, P-TBT, or P-TBB that is manufactured, imported, or processed by the respondent. The narrative need not include customer identity.

(xi) A narrative description of the methods used at each site for disposing of wastes generated during the manufacture, importation, or processing of P-TBBA, P-TBT, or P-TBB, including the quantity and content of such wastes (per site), the method of disposal, and an identification of the disposal site(s).

(5) All manufactureres, importers, and processors specified in paragraph (b) of this section shall report the information described in this paragraph (d)(5). Respondents to this paragraph (d)(5) shall report separately for each substance that they intend to manufacture, import, or process during the first 2 years following the date on which they become subject to this rule. The data reported under this paragraph (d)(5) shall cover that 2-year period. Respondents to this paragraph (d)(5) shall report separately for each site at which they intend to manufacture, import, or process each substance. Respondents need not comply with this paragraph (d)(5) if the information to be reported is identical to that reported by the respondent under paragraph (d)(4) of this section, provided that the respondent makes note of that fact to EPA. Respondents to this paragraph (d)(5) shall report the following information:

(i) An estimate of the total quantity (by weight) of P-TBBA, P-TBT, or P-TBB that the respondent intends to manufacture, import, or process for commercial purposes per site during each of the first 2 years following the date on which the respondent becomes subject to this rule.

(ii) A narrative description of the intended manufacturing, importing, or processing activities involving P-TBBA, P-TBT, or P-TBB at each site during the first 2 years following the date on which the respondent becomes subject to this rule. The description shall include a summary of the intended manufacturing, importing, or

processing operation(s); a summary of intended worker activities involving the substances, including an estimate of the number of persons anticipated to be exposed annually to P-TBBA, P-TBT, or P-TBB (per site) during the 2-year period, the anticipated routes of worker exposure to the substances (e.g., inhalation, ingestion, dermal absorption); and a summary of any personal protective equipment and/or engineering controls that the respondent intends to use to prevent exposure to the substances.

(iii) A narrative description of anticipated environmental releases of P-TBBA, P-TBT, or P-TBB at each site from the manufacture, importation, or processing of these substances during the first 2 years following the date on which the respondent becomes subject to this rule. The narrative shall include the anticipated quantities of each substance released directly into air, water, or land, the anticipated routes of environmental release, and any intended engineering controls to be used to prevent environmental release of the substances.

(iv) A narrative description of all anticipated end uses or P-TBBA, P-TBT, or P-TBB resulting from the respondent's manufacture, importation, or processing of the substances during the first 2 years following the date on which the respondent becomes subject to this rule. The summary need not include customer identity.

(v) A narrative summary of the anticipated disposal of wastes generated from the manufacture, importation, or processing of P-TBBA, P-TBT, or P-TBB during the first 2 years following the date on which the respondent becomes subject to this rule. The summary shall include the anticipated quantity and content of such wastes (per site), the intended method of disposal, and an identification of intended disposal site(s).

(e) *When to report.* Persons subject to this rule must submit the requisite information to EPA within 60 days of becoming subject to the rule under the standards set forth in paragraph (b) of this section.

(f) *Certification.* Persons subject to this rule must attach the following

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statement to any information submitted to EPA in response to this rule: "I hereby certify that, to the best of my knowledge and belief, all of the attached information is complete and accurate." This statement shall be signed and dated by the company's principal technical contact.

(g) *Recordkeeping.* Persons subject to the reporting requirements of this section must retain documentation of information contained in their reports for a period of 5 years from the date of the submission of the report.

[51 FR 17339, May 12, 1986; 51 FR 18323, May 19, 1986, as amended at 52 FR 20083, May 29, 1987; 58 FR 34204, June 23, 1993]

§ 704.43 Chlorinated naphthalenes.

(a) *Definitions*—(1) *Extent of chlorination* means the percent by weight of chlorine.

(2) *Import* means to import in bulk form or as part of a mixture.

(3) *Isomeric ratio* means the relative amounts of each isomeric chlorinated naphthalene that composes the chemical substance; and for each isomer the relative amounts of each chlorinated naphthalene designated by the position of the chlorine atom(s) on the naphthalene.

(4) *Polychlorinated biphenyl* means any chemical substance that is limited to the biphenyl molecule and that has been chlorinated to varying degrees.

(5) *Small manufacturer* means a manufacturer (including importers) who meets either paragraph (a)(5) (i) or (ii) of this section:

(i) A manufacturer of a chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production volume of a particular chemical substance at any individual site owned or controlled by the manufacturer is greater than 45,400 kilograms (100,000 pounds), the manufacturer shall not qualify as small for purposes of reporting on the production of that chemical substance at that site, unless the manufacturer qualifies as small under paragraph (a)(5)(ii) of this section.

(ii) A manufacturer of a chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than

\$4 million, regardless of the quantity of the particular chemical substance produced by that manufacturer.

(iii) For imported mixtures containing a chemical substance identified in paragraph (b) of this section, the 45,400 kilograms (100,000 pounds) standard in paragraph (a)(5)(i) of this section applies only to the amount of the chemical substance in a mixture and not the other components of the mixture.

(6) *Waste* means any solid liquid, semisolid, or contained gaseous material that results from the production of a chemical substance identified in paragraph (b) of this section and which is to be disposed.

(b) *Substances for which reports must be submitted.*

CAS registry number	Chemical substance
90-13-1	Naphthalene, 1-chloro-
91-58-7	Naphthalene, 2-chloro-
1321-64-8	Naphthalene, pentachloro-
1321-65-9	Naphthalene, trichloro-
1335-87-1	Naphthalene, hexachloro-
1335-88-2	Naphthalene, tetrachloro-
1825-30-5	Naphthalene, 1,5-dichloro-
1825-31-6	Naphthalene, 1,4-dichloro-
2050-69-3	Naphthalene, 1,2-dichloro-
2050-72-8	Naphthalene, 1,6-dichloro-
2050-73-9	Naphthalene, 1,7-dichloro-
2050-74-0	Naphthalene, 1,8-dichloro-
2050-75-1	Naphthalene, 2,3-dichloro-
2065-70-5	Naphthalene, 2,6-dichloro-
2198-75-6	Naphthalene, 1,3-dichloro-
2198-77-8	Naphthalene, 2,7-dichloro-
2234-13-1	Naphthalene, octachloro-
25586-43-0	Naphthalene, chloro-
32241-08-0	Naphthalene, heptachloro-
70776-03-3	Naphthalene, chloro derivatives.

(c) *Persons who must report.* (1) Persons who are manufacturing or importing a chemical substance identified in paragraph (b) of this section on October 8, 1984.

(2) Persons who propose to import a chemical substance identified in paragraph (b) of this section on or after October 8, 1984.

(3) Persons who manufacture a chemical substance identified in paragraph (b) of this section after October 8, 1984.

(4) A person is required to report only once for each chemical substance identified in paragraph (b) of this section.

(d) *Persons exempt from reporting.* (1) Small manufacturers.

(2) Persons described in § 704.5.

(e) *What information to report.* Persons described in paragraph (c) of this section must notify EPA of current or

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prospective manufacture or import. The notice must include, to the extent that it is known to or reasonably ascertainable by the person making the report, the following information:

(1) Company name and address.
(2) Name, address, and telephone number of the principal technical contact.

(3) For chemical substances proposed to be imported, the proposed date of import.

(4) A description of the use(s) or intended use(s) for the chemical substance.

(5) A description of the isomeric ratio and extent of chlorination of the chemical substance and the impurity level of polychlorinated biphenyls.

(6) The quantity (by weight) manufactured or imported within 12 months prior to October 8, 1984, if any, and the estimated quantity (by weight) to be manufactured or imported for the first 3 years following the date of the report or the date of the intended start of import whichever occurs later.

(7) The number of persons exposed to the chemical substance during manufacture, import, processing, distribution in commerce, use, and disposal.

(8) If a manufacturer's waste contains one or more of the chemical substances identified in paragraph (b) of this section, the manufacturer must:

(i) Provide the quantity (by weight) of the chemical substances identified in paragraph (b) of this section present in the waste.

(ii) Identify the constituents of the waste and their concentrations.

(iii) State the rate of waste generation as a percentage of production volume.

(iv) Describe where in the manufacturing process the waste is generated, and

(v) Describe the method for disposal of the waste.

(f) *When to report.* (1) Persons who are manufacturing or importing a chemical substance identified in paragraph (b) of this section on October 8, 1984 must notify EPA by November 6, 1984.

(2) Persons who propose to import a chemical substance identified in paragraph (b) of this section on or after October 8, 1984 must notify EPA by November 6, 1984, or 15 days after making

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the management decision described in § 704.3, whichever is later in time.

(3) Persons who manufacture a chemical substance identified in paragraph (b) of this section after October 8, 1984 must notify EPA within 30 days after the initial date of manufacture.

[49 FR 33653, Aug. 24, 1984; 49 FR 45133, Nov. 15, 1984; 50 FR 1215, Jan. 10, 1985; 51 FR 19839, June 3, 1986; 52 FR 20083, May 29, 1987. Redesignated at 53 FR 51717, Dec. 22, 1988]

§ 704.45 Chlorinated terphenyl.

(a) *Definitions*—(1) *Chlorinated terphenyl* means a chemical substance, CAS No. 61788-33-6, comprised of chlorinated ortho-, meta-, and paraterphenyl.

(2) *Extent of chlorination* means the percent by weight of chlorine for each isomer (ortho, meta, and para).

(3) *Isomeric ratio* means the ratios of ortho-, meta-, and parachlorinated terphenyls.

(4) *Polychlorinated biphenyl* means any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees.

(5) *Small manufacturer* means a manufacturer (importers are defined as manufacturers under TSCA) who meets either of the following standards under this rule:

(i) *First standard.* A manufacturer of an existing chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production volume of a particular chemical substance at any individual site owned or controlled by the manufacturer is greater than 45,400 kilograms (100,000 pounds), the manufacturer shall not qualify as small for purposes of reporting on the production of that chemical substance at the site, unless the manufacturer qualified as small under paragraph (a)(5)(ii) of this section.

(ii) *Second standard.* A manufacturer of an existing chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of chemicals produced by that manufacturer.

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(b) *Persons who must report.* Except for small manufacturers and as provided in §704.5, the following persons are subject to the rule:

(1) Persons who manufacture or propose to manufacture chlorinated terphenyl.

(2) Persons who import (importers) or propose to import chlorinated terphenyl as a chemical substance in bulk or as part of a mixture.

(c) *What information to report.* Persons subject to this rule as described in paragraph (b) of this section must notify EPA of current or proposed manufacture or import of chlorinated terphenyl. The notice must include, to the extent that it is known to the person making the report or is reasonably ascertainable, the following information:

- (1) Company name and address.
- (2) Name, address, and telephone number of principal technical contact.
- (3) A description of the use(s) or intended use(s) for chlorinated terphenyl.
- (4) A description of the isomeric ratio and extent of chlorination of the chlorinated terphenyl and the impurity level of polychlorinated biphenyls.
- (5) The quantity (by weight) manufactured or imported within 12 months prior to the effective date of the rule, if any, and the estimated quantity (by weight) to be manufactured or imported for the first three years following the date of the report or the date of the intended start of production, whichever occurs later.
- (6) The proposed date for the initiation of manufacturing or importation of chlorinated terphenyl, if appropriate.

(d) *When to report.* Persons who are manufacturing or importing chlorinated terphenyl on the effective date of the rule must notify EPA within 30 days of the effective date of the rule. Persons who propose to manufacture or import chlorinated terphenyl must notify EPA within 15 days after making the management decision described in §704.3 "Proposed to manufacture or import".

[49 FR 11184, Mar. 26, 1984, as amended at 49 FR 32068, Aug. 10, 1984; 50 FR 2048, Jan. 15, 1985; 52 FR 20083, May 29, 1987. Redesignated at 53 FR 51717, Dec. 22, 1988; 58 FR 34204, June 23, 1993]

§ 704.95 Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis-(methylene)]]tetrakis- (EDTMPA) and its salts.

(a) *Substances for which reporting is required.* The chemical substances for which reporting is required under this section are:

CAS No.	Chemical name
1429-50-1	Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis (methylene)]] tetrakis- (EDTMPA)
15142-96-8	Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis(methylene)]] tetrakis-, hexasodium salt
34274-30-1	Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis(methylene)]] tetrakis-, potassium salt
57011-27-5	Phosphonic acid, [1,2-ethanediyl-bis[nitrilobis (methylene)]] tetrakis-, ammonium salt
67924-23-6	Cobaltate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis-[phosphonato]] (8-)-, pentapotassium hydrogen, (OC-6-21)-
67969-67-9	Cobaltate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis- [phosphonato]] (8-)-N,N',O,O',O''',O''''-], pentasodium hydrogen, (OC-6-21)-
67989-89-3	Cuprate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis- [phosphonato]] (8-)-, pentapotassium hydrogen, (OC-6-21)-
68025-39-8	Cobaltate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis- [phosphonato]] (6-)-N,N',O,O',O''',O''''-], pentaammonium hydrogen, (OC-6-21)-
68188-96-5	Phosphonic acid, [1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis-, tetrapotassium salt
68309-98-8	Cadmate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis- [phosphonato]] (8-)-, pentapotassium hydrogen, (OC-6-21)-
68901-17-7	Phosphonic acid, [1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis-, octaammonium salt
68958-86-1	Nickelate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis- [phosphonato]] (8-)-, pentaammonium hydrogen, (OC-6-21)-
68958-87-2	Nickelate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis- [phosphonato]] (8-)-, pentapotassium hydrogen, (OC-6-21)-
68958-88-3	Nickelate (6-), [[[1,2-ethanediylbis [nitrilobis (methylene)]] tetrakis [phosphonato]] (8-)-, pentasodium hydrogen, (OC-6-21)-

(b) *Persons who must report.* Unless exempt as provided in §704.5, reports must be submitted by:

(1) Persons who manufacture or import any of the substances identified in paragraph (a) of this section.

(2) Persons who propose to manufacture or propose to import any of the substances identified in paragraph (a) of this section. For the purposes of importer reporting under this section, an import site is the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction; the import site may in some cases be the organization's

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headquarters office in the United States.

(c) *What information to report.* Persons identified in paragraph (b) of this section must report to EPA, for each of the substances identified in paragraph (a) of this section, the following information to the extent known to or reasonably ascertainable by them.

(1) Initial Report:

(i) Name and Chemical Abstracts Service Registry Number of the substance for which the report is submitted.

(ii) Company name and headquarters address.

(iii) Name, address, and telephone number of the principal technical contact.

(iv) The total quantity (by weight in pounds) of the substance manufactured or imported for the person's most recently completed corporate fiscal year.

(v) A description of the commercial uses of the substance during the person's most recently completed corporate fiscal year, including the production volume for each use.

(vi) The estimated quantity (by weight in pounds) of the substance proposed to be manufactured or imported in the person's current corporate fiscal year.

(vii) A description of the intended commercial uses of the substance during the person's current corporate fiscal year, including the estimated production volume for each use.

(2) Follow-up Report:

(i) Name and Chemical Abstracts Service Registry Number of the substance for which the report is submitted.

(ii) Company name and headquarters address.

(iii) Name, address, and telephone number of the principal technical contact.

(iv) The estimated quantity (by weight in pounds) of the substance proposed to be manufactured or imported in the person's current corporate fiscal year.

(v) A description of the intended commercial uses of the substance during the person's current corporate fiscal year, including the estimated production volume for each use.

(d) *When to report.* (1) Persons specified in paragraph (b)(1) of this section who are manufacturing or importing the substance as of December 5, 1988 must submit an initial report described in paragraph (c)(1) of this section by January 3, 1989.

(2) Persons specified in paragraph (b)(2) of this section must submit an initial report within 30 days after making the management decision described in §704.3 or by January 3, 1989, whichever is later.

(3) Persons specified in paragraph (b) of this section, who submitted a report described in paragraph (c)(1) of this section, must submit a follow-up report described in paragraph (c)(2) of this section within 30 days of making the management decision, described at §704.3, to do either of the following events:

(i) Manufacture or import the substance in a quantity 50 percent greater than the quantity reported in the most recently submitted report.

(ii) Manufacture or import the substance for a use not reported for that substance in any previous report.

(e) *Certification.* Persons subject to this section must attach the following statement to any information submitted to EPA in response to this section: "I hereby certify that, to the best of my knowledge and belief, all of the attached information is complete and accurate." This statement must be signed and dated by the company's principal technical contact.

(f) *Recordkeeping.* Persons subject to the reporting requirements of this section must retain documentation of information contained in their reports for a period of 5 years from the date of the submission of the report.

[53 FR 41337, Oct. 21, 1988, as amended at 58 FR 34204, June 23, 1993]

§ 704.102 Hexachloronorbornadiene.

(a) *Definitions*—(1) *Endrin* means the pesticide 2,7:3,6-Dimethanonaphth[2,3-b]oxirene,3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1a α , 2 β , 2a β , 3 α , 6 α , 7, 7a α)-, CAS Number 72-20-8.

(2) *HEX-BCH* means the chemical substance 1,2,3,4,7,7-hexachloronorbornadiene, CAS Number 3389-71-7.

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(3) *Isodrin* means the pesticide 1,4:5,8-Dimethanonaphthalene,1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-, (*1alpha*, *4alpha*, *4beta*, *5beta*, *8beta*, *8abeta*)-, CAS Number 465-73-6.

(4) *Small business* means any manufacturer, importer, or processor who meets either paragraph (a)(4)(i) or (ii) of this section:

(i) A business is small if its total annual sales, when combined with those of its parent (if any), are less than \$40 million. However, if the annual manufacture, importation, or processing volume of a particular chemical substance at any individual site owned or controlled by the business is greater than 45,400 kilograms (100,000 pounds), the business shall not qualify as small for purposes of reporting on the manufacture, importation, or processing of that chemical substance at that site, unless the business qualifies as small under paragraph (a)(4)(ii) of this section.

(ii) A business is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of the particular chemical substance manufactured, imported, or processed by that business.

(iii) For imported and processed mixtures containing HEX-BCH, the 45,400 kilograms (100,000 pounds) standard in paragraph (a)(4)(i) of this section applies only to the amount of HEX-BCH in a mixture and not the other components of the mixture.

(5) *8-hour time weighted average* means the cumulative exposure for an 8-hour work shift computed as follows:

E = (C_a T_a + C_b T_b + . . . C_n T_n) / 8

Where:

E is the equivalent exposure for the working shift.

C_i is the concentration (i.e., parts per million) during any period of time (T_i) where the concentration remains constant.

T_i is the duration in hours of the exposure at the concentration C_i.

(6) *Year* means corporate fiscal year.

(b) *Persons who must report.* (1) Reports must be submitted by:

(i) Persons who are manufacturing, importing, or processing HEX-BCH for use as an intermediate in the produc-

tion or isodrin or endrin on or after January 2, 1986; and

(ii) Persons who propose to manufacture, import, or process HEX-BCH for use as an intermediate in the production of isodrin or endrin, on or after January 2, 1986.

(2) Persons described in paragraph (b)(1) of this section who engage or propose to engage in more than one activity (i.e., manufacture and processing) must report the information required in paragraph (d) separately for each activity.

(c) *Persons exempt from reporting.* (1) Small businesses.

(2) Persons described in §704.5(a) and (c).

(d) *Information to report.* (1) Initial reports must include, to the extent that it is known to or reasonably ascertainable by the person reporting, the following information:

(i) Company name and address.

(ii) Name, address, and telephone number of the principal contact.

(iii) Name and address of plant sites where HEX-BCH is or is proposed to be manufactured, imported, or processed, noting for each plant site which activity takes or would take place at each site.

(iv) If applicable, the intended date for initiating the manufacture, import, or processing of HEX-BCH.

(v) If applicable, the actual quantity (by weight) of HEX-BCH manufactured, imported, or processed during the most recently concluded year.

(vi) The estimated quantity (by weight) of HEX-BCH to be manufactured, imported, or processed each year during the first 3 years following the date of the report or the date of the intended start of manufacture, import, or processing, whichever occurs later.

(vii) For each year described in paragraphs (d)(1) (v) and (vi) of this section: the number or expected number of employees exposed to HEX-BCH during the manufacture, import, processing, distribution in commerce, use, and disposal; the routes of exposure; and the 8-hour time weighted average of exposure.

(viii) If employees are exposed or expected to be exposed to HEX-BCH, state for each reported route of exposure, whether personal protective

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equipment is used or expected to be used, and a description of the personal protective equipment.

(ix) The actual or anticipated quantity, content, method of disposal, and disposal site of any wastes generated or expected to be generated during the manufacture, importation, or processing of HEX-BCH.

(2) Subsequent reports must provide, to the extent known to or reasonably ascertainable by the person reporting, the information in paragraph (d)(1) of this section and a statement explaining why the subsequent report is required.

(e) *When to report.* (1) Persons who are manufacturing, importing, or processing HEX-BCH on January 2, 1986, must submit an initial report to EPA by February 3, 1986.

(2) Persons who propose to manufacture, import, or process HEX-BCH on or after January 2, 1986, must submit an initial report to EPA by February 3, 1986, or 30 days after making the management decision described in §704.3 "Propose to manufacture, import, or process," whichever is later in time.

(3) Persons described in paragraph (b) of this section, who have submitted a report described in paragraph (d) of this section, must submit a subsequent report within 30 days of any of the following events. Based on the most recently submitted report:

(i) The manufacture, importation, or processing of HEX-BCH begins at a plant site different than that reported pursuant to paragraph (d)(1)(iii) of this section.

(ii) The actual quantity (by weight) of HEX-BCH manufactured, imported, or processed in a given year is greater than or equal to 200 percent of the estimated value for that year reported pursuant to paragraph (d)(1)(vi) of this section.

(iii) The total number of employees exposed to HEX-BCH is greater than 130 percent of the projected value reported pursuant to paragraph (d)(1)(vii) of this section.

(iv) The route of exposures to HEX-BCH differs from that reported pursuant to paragraph (d)(1)(vii) of this section.

(v) The actual 8-hour time weighted average exposure for any activity exceeds the projection reported pursuant

to paragraph (d)(1)(vii) of this section by more than 100 percent.

(vi) The method of disposal or disposal site reported pursuant to paragraph (d)(1)(ix) of this section has changed.

(vii) Three years have passed since the most recent submission of a report and the person is still engaged in the manufacture, importation, or processing of HEX-BCH.

(f) *Certification of review.* Each person who submits a report under this section must for 3 years following the submission date of the most recent submission, review their activities at the end of each year to determine whether any reportable event specified in paragraph (e)(3) of this section has occurred. If a review shows that none of these events has occurred, the person is required to certify this fact in writing.

(g) *Recordkeeping.* Any person subject to the reporting requirements of this section must:

(1) Retain documentation of information contained in their reports. This documentation must be maintained for a period of 3 years from the date of the submission of the report; and

(2) Retain the certification required by paragraph (f) of this section for 3 years from the date of its creation.

[50 FR 47536, Nov. 19, 1985, as amended at 52 FR 20083, May 29, 1987. Redesignated at 53 FR 51717, Dec. 22, 1988; 58 FR 34204, June 23, 1993]

§ 704.104 Hexafluoropropylene oxide.

(a) *Definitions.* (1) "HFPO" means the chemical substance hexafluoropropylene oxide, CAS Number 428-59-1. [Listed in TSCA Inventory as oxirane, trifluoro(trifluoromethyl)-]

(2) "Enclosed process" means a process that is designed and operated so that there is no intentional release of any substance present in the process. A process with fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases.

(3) "Small processor" means a processor that meets either the standard in paragraph (a)(3)(i) of this section or the standard in paragraph (a)(3)(ii) of this section.

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(i) *First standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company, if any, are less than \$40 million. However, if the annual processing volume of a particular chemical substance at any individual site owned or controlled by the processor is greater than 45,400 kilograms (100,000 pounds), the processor shall not qualify as small for purposes of reporting on the processing of that chemical substance at that site, unless the processor qualifies as small under paragraph (a)(3)(ii) of this section.

(ii) *Second standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of the particular chemical substance processed by that company.

(iii) *Inflation index.* EPA will use the Inflation Index described in the definition of "small manufacturer" that is set forth in §704.3 for purposes of adjusting the total annual sales values of this small processor definition. EPA will provide FEDERAL REGISTER notification when changing the total annual sales values of this definition.

(b) *Persons who must report.* Except as provided in paragraph (c) of this section, the following persons are subject to this section:

(1) Persons who manufacture or propose to manufacture HFPO for use as an intermediate in the manufacture of fluorinated substances in an enclosed process.

(2) Persons who import or propose to import HFPO for use as an intermediate in the manufacture of fluorinated substances in an enclosed process.

(3) Persons who process or propose to process HFPO as an intermediate in the manufacture of fluorinated substances in an enclosed process.

(c) *Persons not subject to this rule.* The following persons are not subject to this rule:

(1) Small processors.

(2) Persons described in §704.5(a) through (f).

(3) Persons who have already submitted to EPA a completed copy of the Preliminary Assessment Information Manufacturer's Report (EPA Form

7710-35, as described at §712.28 of this chapter) for HFPO are not required to report under this section with respect to activities previously reported on.

(d) *What information to report.* Persons identified in paragraph (b) of this section must submit a Premanufacture Notice Form (EPA Form 7710-25).

(e) *When to report.* (1) Persons who are manufacturing, importing, or processing, or who propose to manufacture, import, or process HFPO for use as an intermediate in the manufacture of fluorinated substances in an enclosed process as of December 10, 1987, must report by February 8, 1988.

(2) Persons who propose to manufacture, import, or process HFPO for use as an intermediate in the manufacture of fluorinated substances in an enclosed process after December 10, 1987, must report within 30 days after making a firm management decision to commit financial resources for the manufacturing, importing, or processing of HFPO.

(f) *Recordkeeping.* Persons subject to the reporting requirements of this section must retain documentation of information contained in their reports for a period of 5 years from the date of submission of the reports.

(g) *Where to send reports.* Reports must be submitted by certified mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, ATTN: HFPO Reporting.

[52 FR 41299, Oct. 27, 1987, as amended at 58 FR 34204, June 23, 1993; 60 FR 16308, Mar. 29, 1995; 60 FR 31920, June 19, 1995; 60 FR 34463, July 3, 1995; 71 FR 33641, June 12, 2006; 85 FR 31995, May 28, 2020]

§ 704.175 4,4'-methylenebis(2-chloroaniline) (MBOCA).

(a) *Substance subject to reporting.* The chemical substance 4,4'-methylenebis(2-chloroaniline) (CAS No. 101-14-4) is subject to reporting under this section. The substance also is identified as 4,4'-methylenebis(2-chlorobenzeneamine) and MBOCA.

(b) *Persons who must report.* Except as provided in paragraph (c) of this section, the following persons are subject to this rule.

(1) Persons who propose to manufacture MBOCA in the United States on or after June 2, 1986.

(2) Persons who are manufacturing MBOCA in the United States as of June 2, 1986.

(3) Persons manufacturing MBOCA in the United States on or after June 2, 1986 who propose to change their manner or method of manufacturing the substance from a manner or method of manufacturing that previously was reported under this section.

(c) *Persons not subject to this rule.* The following persons are exempt from the reporting requirements of this section:

(1) Persons who import MBOCA into the customs territory of the United States and do not otherwise manufacture the substance in the United States.

(2) Persons who complied with the requirements of this section prior to June 2, 1986 and received written notification of compliance from EPA.

(d) *What information to report.* Persons who are subject to this rule as described in paragraph (b) of this section must report information to EPA by completing the following parts of the notice form contained in appendix A to part 720 of this chapter: Parts I.A., I.B., I.C.1., I.C.3., and II.A.; also, part III as appropriate. Persons subject to the requirements of this section also must submit a narrative description of any processing and packaging of MBOCA that occurs at the manufacturing plant site, including the number of workers potentially exposed to MBOCA during on-site processing and packaging of MBOCA and a description of any personal protective equipment and/or engineering controls that would be used to prevent release of and exposure to MBOCA during on-site processing and packaging. Persons subject to the requirements of this section are not required to submit information on processing or use of MBOCA away from the manufacturing plant site. Respondents to this rule shall report all information that is known to or reasonably ascertainable by the person reporting.

(e) *When to report.* (1) Persons specified in paragraph (b)(1) of this section must report by July 2, 1986 or within 30 days after making a firm management decision to commit financial resources

for the manufacture of MBOCA, whichever is later in time.

(2) Persons specified in paragraph (b)(2) of this section must report by July 2, 1986.

(3) Persons specified in paragraph (b)(3) of this section must report within 30 days of making a firm management decision to commit financial resources to change their manner or method of manufacturing the substance from a manner or method of manufacturing that previously was reported under this section.

[51 FR 13223, Apr. 18, 1986, as amended at 52 FR 20083, May 29, 1987; 58 FR 34204, June 23, 1993]

PART 707—CHEMICAL IMPORTS AND EXPORTS

Subpart A [Reserved]

Subpart B—General Import Requirements and Restrictions

Sec.
707.20 Chemical substances import policy.

Subpart C [Reserved]

Subpart D—Notices of Export Under Section 12(b)

707.60 Applicability and compliance.
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707.65 Submission to agency.
707.67 Contents of notice.
707.70 EPA notice to foreign governments.
707.72 Termination of reporting requirements.
707.75 Confidentiality.

AUTHORITY: 15 U.S.C. 2611(b) and 2612.

SOURCE: 45 FR 82850, Dec. 16, 1980, unless otherwise noted.

Subpart A [Reserved]

Subpart B—General Import Requirements and Restrictions

§ 707.20 Chemical substances import policy.

(a) *Scope.* (1) This statement addresses the policy of the Environmental Protection Agency (EPA) on importation of chemical substances, mixtures, and articles under section 13 of the Toxic Substances Control Act (TSCA; 15 U.S.C. 2601 *et seq.*). In particular, it