

(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 dimension, 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 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.

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(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.

(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.

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(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.

EFFECTIVE DATE NOTE: At 82 FR 3653, Jan. 12, 2017, § 740.20 was added. At 82 FR 22088, May, 12, 2017, the effective date was delayed to Aug. 14, 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.

(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.