
40 C.F.R. § 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.

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