

Fact Sheet: TSCA Inventory Guidance Regarding Isotopes

This fact sheet provides guidance on reporting chemical substances that have different isotopes of the same element or the isotopic composition of a constituent element has been intentionally changed from the naturally-occurring isotopic composition. The primary goal of this document is to help the regulated community comply with the requirements of the TSCA Section 5 Premanufacturing Notice (PMN) Program for chemical substances that contain deliberate isotopic modification to an element in the substance.

1. What is an isotope?

Isotopes are sets of nuclides having the same number of protons, but different number of neutrons. In other words, they have the same atomic number but a different atomic mass. Each individual isotope is a separate nuclide. Isotopes that are unstable and undergo radioactive decay are called radioisotopes. A change in the number of neutrons does not affect the charge of the atom.

Every known element has isotopic forms (although some natural elements only have artificially-created isotopes), and heavier elements tend to have more isotopes than lighter elements. Naturally-occurring elements have one isotope that is most common. In some cases, the dominant isotope accounts for all, or nearly all, of that element found in nature. In other cases, the proportion may be nearly equal among two or more isotopes.

The atomic mass assigned to the element in the periodic table usually represents an average of the masses of its isotopes. The average has been adjusted (weighted) to reflect the relative abundance of the different isotopes in nature. Sometimes the mass of the most stable (longest-lived) isotope is listed. So, even though carbon-12 is the basis for the Atomic Mass Unit, the atomic mass of carbon is usually listed as 12.011, because of its isotopes.

[Definition from EPA/OAR website: <http://www.epa.gov/radiation/understand/isotopes.html>].

2. Is a substance which is chemically identical to one on the Inventory, except that one of the elements present has been isotopically changed (depleted, enriched, or purified to contain a single isotope) covered by the Inventory listing of the material made with the corresponding unchanged (naturally occurring isotopic ratio) element?

No, EPA considers chemical substances to have different molecular identities for the purposes of TSCA when they contain different isotopes of the same element or the isotopic composition of a constituent element has been intentionally changed from the naturally-occurring isotopic

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composition. For such substances, the isotopic depletion, enrichment, or purification process is generally accomplished chemically. Consequently, it is differences in chemical properties which allow the depletion/enrichment/purification to occur. Different isotopes have different atomic weights; therefore, using a different isotope in a chemical compound changes the molecular weight. Substances having different molecular weights would be considered different molecular identities under TSCA, and thus, different chemical substances. Consequently, EPA considers a chemical substance of which the isotopic composition for a constituent element has been deliberately modified to be a different chemical substance regardless of how similar its chemistry is to that of the naturally-occurring-ratio (isotopically non-depleted, non-enriched, non-purified) substance. If this different chemical substance is not included in the TSCA Inventory, it would be subject to reporting as a new chemical substance under section 5 of TSCA.

3. Examples of listings on the TSCA Inventory for substances enriched, depleted or purified for specific isotopes.

The Inventory contains a number of listings for substances that are intentionally enriched, depleted, or purified for specific isotopes (e.g., Zinc oxide (ZnO), Zn-64 depleted [CASRN 175449-32-8].) There are also a number of elemental isotopes which are separately listed on the Inventory (e.g., hydrogen, deuterium, tritium), as well as chemical compounds which differ only in the isotopes used to make them (deuteriosulfuric acid, D₂O₄S as compared to sulfuric acid H₂SO₄, deuterotrifluoroacetic acid, C₂DF₃O₂ compared to trifluoroacetic acid C₂HF₃O₂).

4. If a manufacturer has questions regarding whether a specific isotope or an isotopically enriched, depleted, purified compound is subject to TSCA section 5 reporting requirements, who in EPA should be contacted?

The Agency recommends that affected manufacturers consult with the OPPT New Chemicals Management Branch at 202-564-8469 to schedule a pre-notice communication meeting or conference call with OPPT staff. The Agency believes that manufacturers should be able to compile the information necessary for a TSCA section 5 new chemical notification, if needed, and to submit that notification (i.e., a PMN or exemption request) within a one-year timeframe. EPA's review of submitted PMNs should be completed within the 90-day statutory review period (30 days for exemption requests).