

Applicability of the Toxic Substances Control Act to Chemicals made from Petroleum and Renewable Sources Used as Fuels and Fuel Additives and Distillates

- Purpose: EPA is reaffirming in this Compliance Advisory that chemical substances used as fuels and fuel additives and distillates made from either petroleum or renewable sources are subject to the Toxic Substances Control Act (TSCA). Anyone who plans to manufacture (including import) a chemical made from petroleum or renewable sources must comply with the statutory and regulatory new chemical requirements under TSCA section 5.

Why is EPA issuing an advisory now?

EPA has recently received stakeholder inquiries as to whether fuel and fuel additives made from renewable sources (such as renewable naphtha) are subject to the TSCA new chemicals requirements under section 5. EPA is issuing this advisory to affirm that fuel and fuel additives either made from petroleum or renewable sources are subject to TSCA and have been subject to its requirements since 1976.

What is renewable naphtha?

Naphtha is a light distillate oil that is a byproduct in the production of petroleum sourced diesel or jet fuel. It can be blended into gasoline or used as a chemical solvent. Renewable naphtha is produced from feedstocks like crop/fats/waste oil.

What are the TSCA section 5 new chemical requirements?

Section 5 of TSCA requires anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose to provide EPA with notice before initiating the activity (see 40 CFR Part 720). Any substance that is not on the TSCA Inventory is a new chemical under section 5(a)(1)(A) of TSCA. Prior to manufacture (including import) of a new chemical for commercial use, a notice, called a Premanufacture Notice ("PMN") must be filed with EPA under section 5 of TSCA.

What is the TSCA Inventory?

The TSCA Inventory contains chemical substances manufactured, processed, or imported in the U.S. that do not qualify for an exemption or exclusion under TSCA.

Section 8(b) of TSCA requires EPA to compile, keep current and publish a list of chemical substances that are manufactured or processed, including import, in the United States for uses under TSCA. Also called the "TSCA Inventory" or simply "the Inventory," it plays a central role in the regulation of most industrial chemicals in the United States. The Inventory was initially published in 1979, and a second version, containing about 62,000 chemical substances, was published in 1982. The TSCA Inventory has continued to grow and now has more than 86,000 chemicals.

Information on TSCA Inventory can be located on EPA's public website at <https://www.epa.gov/tsca-inventory>

How can you be certain if your chemical substance made from renewable sources is listed on the Inventory?

If a person with a valid commercial intent to manufacture or import a renewable sourced substance is uncertain if their chemical is listed on the TSCA Inventory, they can submit a Bona Fide Intent to Manufacture or Import Notice (“bona fide notice”). For more information, see 40 CFR section 720.25. EPA will consider the information submitted in a bona fide notice and will provide a determination on the TSCA Inventory status for the chemical substance.

In response to a bona fide notice, EPA will also inform you if the substance is subject to regulation under TSCA section 5 including if the substance is subject to a Significant New Use Rule (SNUR) under 40 CFR part 721.

What is a SNUR?

TSCA Section 5(a) Significant New Use Rules (SNURs) require notice to EPA before chemical substances and mixtures are manufactured or processed for a significant new use. TSCA section 5(a) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use.

Information on how to submit a SNUN can be located at EPA’s public website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-significant-new-use-notice>

Information on SNURS can be located in EPA’s regulations at 40 CFR 721 Subpart E and EPA’s public website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/recent-activities-new-chemicals>

How many naphtha are listed on the TSCA Inventory?

There are about 142 “naphthas” and 178 “distillates” (that compositionally can qualify as naphthas) currently on the TSCA Inventory and are considered Unknown, Variable composition, Complex or Biological (UVCB) substances. Most of the naphthas or distillates are made from petroleum sources and some are made from renewable sources.

Example of naphthas made from petroleum sources include naphtha (shale oil), hydrocracked, hydrotreated light, naphtha (petroleum), hydrotreated light, distillates (coal tar), and distillates (shale oil), hydrocracked, alkylate.

Examples naphtha made from renewable sources include naphtha (lignocellulosic), distillates (hydrocracked tallow), coconut oil, mixed with tallow, deodorizer distillates and fats and glyceridic oils, animal, mixed with vegetable oils, deodorizer distillate.

What is a UVCB substance?

Unknown, Variable composition, Complex or Biological (UVCB) substances are a broad class of chemical substances. Complex reaction product UVCBs are often characterized with additional information such as source and/or process. The TSCA Inventory has listings for petroleum-based oils, such as Naphthenic oils described as “Liquid naphthenic hydrocarbons from petroleum,” and plant-based oils such as Coconut oil described as “Extractives and their physically modified derivatives consisting primarily of the glycerides of the fatty acids capric, lauric, myristic, oleic and palmitic (Cocos nucifera).”

Can you manufacture or import a chemical substance made from a renewable source if it is not listed on the TSCA Inventory?

No. Anyone who intends to manufacture (including import) a new chemical substance that is subject to TSCA for a non-exempt commercial purpose is required to submit a PMN at least 90 days prior to the manufacture of the chemical. Manufacturers (importers) are in violation of TSCA if they fail to comply or are late in complying with TSCA notice requirements. If you are required to submit a PMN, failure to do so is a violation of TSCA Section 15 and you may be subject to penalties. PMN submissions must include all available data, pursuant to 40 CFR 720.45 and 720.50. TSCA requires EPA to review the notice and make a determination; and, if appropriate, regulate the proposed activity.

How are chemical substances added to the Inventory?

Following EPA's review and determination regarding a PMN, the company must provide a Notice of Commencement of Manufacture or Import (NOC, EPA Form 7710-56) to EPA within 30 calendar days of the date the substance is first manufactured or imported for nonexempt commercial purposes. Once a complete NOC is received by EPA, the reported substance is considered to be on the TSCA Inventory and becomes an "existing chemical." See 40 CFR Part 720.102.

Information on how to file a notice of commencement (NOC) can be located on EPA's website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa#NOC>

Disclaimer

This Compliance Advisory addresses select provisions of EPA regulatory requirements using plain language. Nothing in this Compliance Advisory is meant to replace or revise any EPA regulatory provision, or any other part of the Code of Federal Regulations, the Federal Register, or TSCA.