

Questions and Answers for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database

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PREFACE

EPA intends this document and the answers provided to be used for guidance only. This guidance is not a substitute for the Toxic Substances Control Act (TSCA) Chemical Inventory regulations, also known as the Inventory Update Reporting (IUR) rule. You should carefully review the IUR regulations located at 40 CFR part 710, subpart C for specific information on how to comply with IUR requirements.

This document addresses specific questions related to reporting for the 2006 IUR. Additional questions specifically related to reporting inorganic chemicals can be found in the *Questions and Answers for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database: Inorganic Chemicals Addendum*. Information on the mechanics of IUR reporting is located in *Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database* (Instructions for Reporting). Detailed examples of completing Form U are provided in *Case Studies for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database* (Case Studies Document). The purpose of these four documents is to help the regulated community comply with the requirements of the IUR regulation. These documents are available on the internet at <http://www.epa.gov/oppt/iur>.

The questions and answers in this document are organized in sections as listed in the table of contents.

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General IUR Questions

1. What types of reporting assistance will be available?

In addition to this *Questions and Answers Document*, an EPA guidance document, *Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database* (Instructions for Reporting), will answer most questions concerning reporting under the rule. The purpose of the Instructions for Reporting is to help the regulated community comply with the requirements of the IUR rule. In addition to the Instructions for Reporting, the *Case Studies for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database* presents sample reporting scenarios and examples to help you with the reporting requirements. Additional answers to questions on reporting inorganic chemical substances can be found in the *Questions and Answers for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database: Inorganic Chemicals Addendum*. These documents are not a substitute for the IUR regulations found at 40 CFR part 710 subpart C. These documents, along with other useful information, can be found on the IUR Web site at www.epa.gov/oppt/iur. You may also contact the TSCA Hotline for assistance at (202) 564-3011.

2. Is the purpose of the IUR to make additions or deletions to the list of substances included on the TSCA Chemical Substances Inventory?

No. The purpose of the IUR is to collect recent information on the manufacture (including importation), processing, and industrial, commercial, and consumer uses of certain chemical substances currently on the TSCA Inventory. Additions to the TSCA Inventory are made through EPA's New Chemicals Program (See 40 CFR part 720).

3. What is the difference between the IUR and the Toxic Release Inventory (TRI)?

The IUR rule, promulgated under the authority of section 8(a) of TSCA, requires chemical manufacturers (including importers) to report manufacturing data and industrial, commercial, and consumer processing and use information for a portion of the substances on the TSCA Inventory. The TRI focuses on chemical substances specified under the Emergency Planning and Community Right-to-Know Act (EPCRA). Under TRI, regulated facilities must report information on the releases and other waste management of EPCRA Section 313 chemicals.

4. What should I do if I manufacture a chemical substance that is not included on the TSCA Inventory?

If you discover that you are manufacturing or importing a substance which is not on the TSCA Inventory but which should have been reported to EPA, such manufacture or importation is in violation of Section 5 of TSCA and could subject you to administrative or criminal penalties. If you find that you have or may have manufactured or imported a chemical substance in violation of TSCA, contact the Agency at the following address:

Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
Ariel Rios Building (Mail Code 2245A)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Significant reductions in penalties are typically given to persons who voluntarily disclose such information. Note, however, that continued manufacture or importation of such chemical substances remains in violation of Section 15 of TSCA, even after you have contacted EPA, until the reporting requirements of TSCA have been met.

Definitions

5. What is a “chemical substance” for purposes of IUR?

Under TSCA sec. 3(2), and 40 CFR 710.3, a chemical substance is any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical. In summary, “chemical substance” does *not* include:

- (1) Any mixture;
- (2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide;
- (3) Tobacco or any tobacco product, but not including any derivative products;
- (4) Any source material, special nuclear material, or byproduct material;
- (5) Any pistol, firearm, revolver, shells, or cartridges; and
- (6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

6. How does TSCA define “manufacture?”

Manufacture means to manufacture, produce, or import for commercial purposes (40 CFR 710.3).

7. What is meant by “manufacture or import for commercial purposes” for purposes of IUR?

Manufacture or import for commercial purposes means to manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, for example, the manufacture or import of any amount of a chemical substance or mixture:

- (1) For commercial distribution, including test marketing, or
- (2) For use by the manufacturer, including for use in product research and development, or as an intermediate. (40 CFR 710.3)

8. What is the definition of “importer” for purposes of IUR?

An importer is any person who imports any chemical substance, either by itself or as part of a mixture or article, into the customs territory of the United States and includes: (1) the person primarily liable for the payment of any duties on the merchandise, or (2) an authorized agent acting on his/her behalf. (40 CFR 710.3)

9. What is the definition of “byproduct” for purposes of IUR?

A byproduct is a chemical substance produced without a separate commercial intent during the manufacture or processing of another chemical substance or mixture. (40 CFR 710.3)

10. What is the definition of “impurity” for purposes of IUR?

An impurity is a chemical substance which is unintentionally present with another chemical substance. (40 CFR 710.3)

11. What is the definition of “intermediate” for purposes of IUR?

An intermediate is any chemical substance which is (1) intentionally removed from the equipment in which it is manufactured, and (2) either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s). (40 CFR 710.3)

12. What is the definition of “non-isolated intermediate” for purposes of IUR?

A non-isolated intermediate is any intermediate that is not intentionally removed from the equipment in which the intermediate 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.

13. What is a “naturally occurring substance” for purposes of IUR?

A naturally occurring substance is a chemical substance that is naturally occurring and which are: (1) unprocessed; or (2) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or (3) extracted from air by any means. (40 CFR 710.4(b)) Chemicals produced according to these conditions are considered naturally occurring substances and need not be reported under the IUR regulation. (40 CFR 710.46(a)(3))

Examples of substances that are typically naturally occurring materials are raw agricultural commodities, water, air, naturally occurring gases, crude oil, rocks, ores, and minerals. The naturally occurring substance exclusion is a process-specific exclusion rather than a chemical-specific one; therefore, persons who produce any substance in a manner other than as described in 40 CFR 710.4(b) are required to report unless otherwise excluded. For this reason, substances such as water, minerals, and certain agricultural products are sometimes considered not to be naturally occurring and are thus potentially subject to reporting because of their method of production.

14. What is the definition of “article” for purposes of IUR?

An article is any manufactured item which: (1) is formed to a specific shape or design during manufacture, (2) has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) has either no change of chemical composition during its end use or only those changes of composition that have no commercial purpose separate from that of the article and that may occur as described in 40 CFR 710.4(d)(5). Fluids and particles are not considered articles regardless of shape or design. (40 CFR 710.3)

15. What is the definition of “site” for purposes of IUR?

A site is a contiguous property unit. Property divided only by a public right-of-way will be considered one site. There may be more than one manufacturing plant at a single site (40 CFR 710.3). For the purposes of reporting imported chemical substances under IUR, the site is the site of the operating unit within the organization of the person reporting which is directly responsible for importing the chemical substance and which controls the import transaction. (40 CFR 710.48(b))

16. What is meant by “site-limited” for purposes of IUR?

Site-limited means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. Imported substances are never site-limited. Although a site-limited chemical substance is not distributed for commercial purposes outside the site at which it is manufactured and processed, the substance is considered to have been manufactured and processed for commercial purposes. (40 CFR 710.43)

17. What is the difference between information that is “known to or reasonably ascertainable by” and “readily obtainable?”

Known to or reasonably ascertainable by a person means all information in that person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know (40 CFR 710.43).

Under TSCA section 8(a), the Agency may collect information associated with chemical substances to the extent that it is known to or reasonably ascertainable by the submitter.

This is information possessed or expected to be possessed, controlled, or known, by employees or other agents of the company submitting Form U, including persons involved in the research, development, manufacturing, or marketing of a chemical substance. This information includes knowledge gained through discussions, symposia, and technical publications. For purposes of IUR reporting, the “known to or reasonably ascertainable by” standard applies to the information listed in 40 CFR 710.52(c)(1), 710.52(c)(2), and 710.52(c)(3), which corresponds with Parts I and II of Form U.

Readily obtainable information is information known by management and supervisory employees of the submitter company who are responsible for manufacturing, processing, technical services, or marketing the reportable chemical substance (40 CFR 710.43). The readily obtainable standard applies to processing and use information required by 40 CFR 710.52(c)(4) and reported in Part III of Form U. This standard for reporting processing and use information is intended to require less effort on the part of the submitter than the known to or reasonably ascertainable by standard that applies to all other IUR reporting. The readily obtainable standard limits the burden associated with processing and use reporting by making extensive file searches and customer surveys unnecessary. It is identical to the standard currently in effect under EPA's TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) rule (See 40 CFR 712.7).

18. What is the definition of “process” for purposes of IUR?

Process is the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture; or (2) as part of a mixture or article containing the chemical substance or mixture.

19. What is meant by “process for commercial purposes” for purposes of IUR?

Process for commercial purposes means to process (1) for distribution in commerce, including for test marketing purposes; or (2) for use as an intermediate (40 CFR 710.3).

20. What is meant by the term “use” for purposes of IUR?

Use is any utilization of a chemical substance or mixture that is not otherwise covered by the terms “manufacture” or “process.” Relabeling or redistributing a container holding a chemical substance or mixture where no repackaging of the chemical substance or mixture occurs does not constitute use or processing of the chemical substance or mixture. (40 CFR 710.43)

21. What is the definition of “repackaging” for purposes of IUR?

Repackaging is the physical transfer of a chemical substance or mixture, as is, from one container to another container or containers in preparation for distribution of the chemical substance or mixture in commerce. (40 CFR 710.43)

22. What is an “industrial use” for purposes of IUR?

Industrial use means use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed. (40 CFR 710.43)

23. What is a “commercial use” for purposes of IUR?

Commercial use means the use of a chemical substance or mixture in a commercial enterprise providing saleable goods or services (e.g., dry cleaning establishment, painting contractor). (40 CFR 710.43)

24. What is a “consumer use” for purposes of IUR?

Consumer use means the use of a chemical substance that is directly, or as part of a mixture, sold to or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in or around recreational areas. (40 CFR 710.43)

Determining What Chemicals Must be Reported

25. How do I determine my reporting requirements?

Carefully review the regulations located at 40 CFR part 710 subpart C to determine your reporting requirements. 40 CFR 710.46 identifies chemicals for which some or all of the IUR information is not required. The regulations at 40 CFR 710.48 identify the persons who must report, while the regulations at 40 CFR 710.49 identify those persons who are not subject to IUR reporting requirements. Activities for which reporting is not required are set out in 40 CFR 710.50. Section 2.0 of the Instructions for Reporting also explains the reporting requirements. Section 2.0 contains flow diagrams and examples to help you determine if your chemical substance is reportable and if you are required to report.

Regulated Chemical Substances

26. For what chemical substances must IUR information be submitted?

Under the IUR regulation, information must be submitted for a chemical substance included on the TSCA Inventory at the beginning of the submission period if your site manufactures 25,000 pounds or more of the substance during a reporting year. The exception to this general rule is chemicals listed in 40 CFR 710.46(a) which are exempt from reporting requirements. For the 2006 submission period, the reporting year is calendar year 2005. Information for calendar year 2005 must be submitted between August 25 and December 23, 2006.

27. How can I obtain a copy of the non-confidential portion of the TSCA Inventory?

The public portion of the TSCA Inventory is available on computer tape, diskettes, and CD-ROM from the National Technical Information Service (703-487-4650 or 1-800-553-NTIS). You may also write to NTIS at the following address: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. Information is provided only on substances which are not on the confidential portion of the TSCA Inventory.

28. Are chemical analyses needed to report IUR information?

No, the IUR regulation does not require submitters to perform chemical analyses. The information required by EPA is limited to information that is “known to or reasonably ascertainable” or that is “readily obtainable.” The first standard is applicable to information reported in accordance with 40 CFR 710.52(c)(2) and 710.52(c)(3) while the latter standard is applicable information reported in accordance with 40 CFR 710.52(c)(4).

Full Exemptions

29. Are all substances on the TSCA Inventory subject to the IUR reporting requirements?

No, some substances are fully exempt or partially exempt from the IUR regulation.

30. Which chemical substances on the TSCA Inventory are generally exempt from IUR requirements and do not need to be reported?

Four groups of chemicals listed on the TSCA Inventory are largely exempt from IUR requirements. These four groups are described at 40 CFR 710.46 and include polymers, microorganisms, naturally occurring chemical substances, and certain forms of natural gas. However, polymers, microorganisms, and certain forms of natural gas must be reported under IUR if they are the subject of a final or proposed rule under TSCA section 4, 5(a)(2), 5(b)(4), or 6, an order issued under TSCA sections 5(e) or 5(f), or relief under TSCA section 5 or 7.

31. Are there other circumstances in which reporting under IUR is not required?

Yes, there are certain situations under which an otherwise reportable chemical would not be subject to the reporting requirement. These situations include the following: (1) the chemical is produced in small quantities for research and development; (2) the chemical is imported as part of an article; (3) the chemical is manufactured as an impurity, byproduct (under certain circumstances), non-isolated intermediate, or in another manner described in 40 CFR 720.30(h); and (4) the person manufacturing the chemical substance qualifies as a small manufacturer as that term is defined in 40 CFR 704.3. (40 CFR 710.49 and 710.50) Note, however, that a person who qualifies as a small manufacturer is subject to the IUR requirements with respect to any chemical substance that is the subject of a rule proposed or promulgated under section 4, 5(b)(4) or 6 of TSCA, or is the subject of an order in effect under section 5(e) of TSCA, or is the subject of relief that has been granted under a civil action under section 5 or 7 of TSCA.

Polymers and Microorganisms

32. Many polymers are exempt from IUR reporting. How is “polymer” defined under the IUR regulation?

The IUR definition of polymer found in 40 CFR 710.46(a)(1). Examples of polymers include but are not limited to siloxanes and silicones, polysaccharides, rubber, lignin, and proteins. However, substances that result from hydrolysis, depolymerization, or chemical modification of polymers, regardless of the extent of these processes, so that the final products are no longer polymeric (e.g., a mixture of amino acids that is the result of hydrolysis of a polypeptide) are not considered to be polymers and must be reported if they are not otherwise excluded.

33. Microorganisms are usually exempt from IUR reporting. How does the IUR regulation define microorganism?

Microorganism is defined as an organism classified, using the 5-kingdom classification system of Whittaker, in the kingdoms Monera (or Procaryotae), Protista, Fungi, and the Chlorophyta and the Rhodophyta of the Plantae, and a virus or virus-like particle (40 CFR 725.3). Any combination of chemical substances that is a living organism and meets this definition is exempt from IUR reporting requirements unless it is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of TSCA, or is the subject of an order issued under section 5(e) or 5(f) of TSCA or is the subject of relief that has been granted under a civil action under section 5 or 7 of TSCA. Note that any chemical substance produced from a living microorganism is reportable unless otherwise excluded.

Naturally Occurring Substances

34. Is a chemical substance subject to IUR reporting requirements if it is a naturally occurring substance?

A “naturally occurring substance” is defined for purposes of IUR in 40 CFR 710.4(b) as any chemical substance that is naturally occurring and that is (1) unprocessed; or (2) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or (3) extracted from air by any means. Examples of substances that are typically naturally occurring are raw agricultural commodities, water, air, naturally occurring gases, crude oil, rocks, ores, and minerals. The naturally occurring substance exclusion is a process-specific exclusion rather than a chemical-specific one. Thus, distillates or substances extracted from naturally-occurring substances by solvents other than water are not considered naturally occurring. Naturally occurring substances are exempted from reporting requirements of the IUR regulation (40 CFR 710.46(a)(3)).

Other Questions Regarding Full Exemptions

35. Will EPA update the flags in the TSCA Inventory that note which chemical substances are exempted from reporting under the IUR regulation?

The TSCA Inventory includes an ‘XU’ flag if the chemical substance is exempted from reporting. The flags in the current edition have been updated to reflect the 2006 reporting requirements. Note that you are advised to use the flags only as a guide; you are responsible for verifying whether a chemical substance contained in the TSCA Inventory is exempt from reporting.

36. How can I learn whether a chemical substance is the subject of a rule, proposed or promulgated, an order issued, or relief granted under certain sections of TSCA?

Appendix C in the Instructions for Reporting contains a list of substances which are the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of TSCA, or are the subject of an order issued under section 5(e) or 5(f) of TSCA or are the subject of relief that has been granted under a civil action under section 5 or 7 of TSCA. You are encouraged to carefully review *Federal Register* notices related to your chemical or contact EPA for further information on this issue.

Partial Reporting Exemptions

37. What are partial reporting exemptions?

If your chemical substance is subject to reporting but qualifies for a partial exemption, you must report the information required by 40 CFR 710.52(c)(1)-(3) which corresponds to Parts I and II of Form U); you are not required to report the information described in

40 CFR 710.52(c)(4) (which corresponds to Part III of Form U). Chemical substances in the following three groups qualify for a partial exemption from reporting requirements:

- 1) “Petroleum process streams” listed in 40 CFR 710.46(b)(1);
- 2) Specific chemical substances listed in 40 CFR 710.46(b)(2)(iv); and
- 3) Inorganic substances. For the 2006 submission period only, submitters do not need to complete Part III of Form U for inorganic chemicals.

Note that these partial exemptions are negated if the chemical substance is the subject of (1) a rule proposed or promulgated under sections 4, 5(a)(2), 5(b)(4), or 6 of TSCA, (2) an order under section 5(e) or 5(f) of TSCA, or (3) relief granted under section 5 or 7 of TSCA.

38. My site manufactures more than 300,000 pounds of a chemical substance listed as a petroleum process stream at 40 CFR 710.46(b)(1). Which sections of Form U am I required to complete?

If your chemical substance is listed in 40 CFR 710.46(b)(1), you need to complete only Part I (site identification) and Part II (manufacturing information) of Form U unless the chemical is subject to any of certain TSCA actions as noted in the previous question. For these “petroleum process streams,” Part III of Form U would be designated as “not applicable” (N/A).

39. My site manufactures more than 300,000 pounds of an inorganic chemical substance. Which sections of Form U am I required to complete?

You need to complete only Part I (site identification) and Part II (manufacturing information) of Form U in 2006 unless the inorganic chemical substance is subject to any of certain TSCA actions as noted in question 37. Inorganic substances are partially exempt from IUR requirements for the 2006 submission period and therefore Part III of Form U would generally be designated as “not applicable” (N/A) to these substances. After the 2006 submission period, this partial exemption will not apply and you would complete Parts I, II, and III of Form U. Additional information on reporting inorganic chemical substances can be found in the Inorganic Chemicals Addendum to this document. Also, several of the examples in the IUR Case Studies document illustrate the reporting of inorganic chemical substances.

Reporting Requirements for Mixtures

40. Are mixtures listed on the TSCA Inventory?

The TSCA Inventory is intended to list chemical substances. With the exception of a very limited number of listings, the TSCA Inventory does not include mixtures.

As defined in 710.3(d), a mixture is any combination of two or more chemical substances if the combination does not occur in nature and is not the result of a chemical reaction, except that “mixture” does include:

- 1) Any combination that occurs as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined; and
- 2) Hydrated forms of a chemical substance or hydrated ions formed by association of a chemical substance with water.

41. How do I report on a mixture consisting of different chemicals?

Individual chemical substances which comprise a mixture may have to be reported under the IUR rule. If you manufacture the substances as part of a mixture, you should determine whether the production volume for each substance in the mixture was 25,000 pounds or more during the reporting year. Similarly, if you import a mixture, you should determine whether the imported volume for each substance in the mixture was 25,000 pounds or more during the reporting year. Note, however, that if you purchase chemicals domestically and process them, with no chemical reaction, to produce a mixture, you are not a manufacturer of those substances and do not have to report those substances under the IUR regulation.

42. My company imported one million pounds of a mixture during the reporting year containing 80% Chemical A, 19% Chemical B, and 1% Chemical C. How do I report for this mixture?

You should evaluate your reporting requirements for each constituent of the mixture. For Chemical A, you imported 800,000 pounds (1,000,000 pounds x 80%) of this substance during the reporting year; assuming that Chemical A isn't fully or partially exempt from reporting, you should complete Parts I, II, and III of Form U for Chemical A. For Chemical B, you imported 190,000 pounds of this substance during the reporting year; assuming Chemical B is not fully exempt from reporting, you only need to complete and submit Parts I and II of Form U for this chemical because you do not meet the 300,000 pound threshold that triggers Part III reporting. You imported 10,000 pounds of Chemical C during the reporting year; therefore, you are not required to report the importation of Chemical C under the IUR rule because you do not meet the 25,000 pound threshold that triggers reporting.

43. How do I report for IUR if I import a solid solution?

Report solid solutions in the same manner in which you report liquid solutions or other mixtures; i.e., report the amount of each chemical substance in the mixture you import.

Determining Whether You Must Report

Production Volume Thresholds (Triggering the Requirement to Report)

44. My company manufactured 31,000 pounds of a reportable chemical at one site and 20,000 pounds at another site. Does my production volume meet or exceed the threshold for reporting?

You need only report for those sites at which you manufactured (including imported) 25,000 pounds or more of a chemical substance. Therefore, you would report the 31,000 pounds manufactured at the first site, but you are not required to report the 20,000 pounds manufactured at the second site.

45. What if I both manufacture and import a chemical substance at a plant site?

You should aggregate the total amount of the chemical substance manufactured and imported at the site to determine if the 25,000-pound threshold has been met.

Exemptions from IUR Requirements

46. I have determined that my chemical substance is on the Inventory and is not exempted from IUR requirements. Are there any other reporting requirements I should evaluate before completing Form U?

Even if you manufacture or import a chemical substance that is subject to the IUR regulation, you may be exempt from the reporting requirements for that substance. The following questions may help you determine if you must report:

- (1) Did you manufacture or import less than 25,000 pounds a chemical substance on the Master Inventory File at the beginning of a submission period at any site during the reporting year? If so, then you are not required to report under the IUR regulation for that chemical substance at that site.
- (2) Are you a small manufacturer? A small manufacturer as defined in 40 CFR 704.3 is exempt from IUR requirements? See 40 CFR 710.49.
- (3) You are not subject to the IUR requirements if you solely manufacture or import a reportable chemical substance under the following circumstances (40 CFR 710.50):
 - a. The chemical is imported only as part of an article;

- b. The chemical substance is manufactured solely as described in 40 CFR 720.30(g) or in certain forms that are not distributed in commerce as the chemical substance per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part (see 40 CFR 720.30(h)); or
- c. The chemical is manufactured solely in small quantities for research and development.

Small Manufacturers

47. Is there an exemption from IUR reporting requirements for small manufacturers?

In accordance with 40 CFR 710.49, a person who qualifies as a small manufacturer as defined in 40 CFR 704.3 is not subject to IUR requirements. In order to qualify as a small manufacturer, you must satisfy either of the following tests:

- a. Your total annual sales, when combined with those of your parent company, domestic or foreign, are less than \$40 million and your annual production (including importation) volume does not exceed 100,000 pounds of a reportable substance at any plant site you own or control; or,
- b. Your total annual sales, when combined with those of your parent company, domestic or foreign, are less than \$4 million, regardless of the quantity of substances produced or imported.

The small manufacturer exemption from IUR requirements does not apply if the substance being manufactured is the subject of a rule proposed or promulgated under section 4, 5(b)(4) or 6 of TSCA, or is the subject of an order in effect under section 5 (e) of TSCA, or is the subject of relief granted under a civil action under section 5 or 7 of TSCA. (See 40 CFR 710.49)

Articles

48. If a chemical substance is part of an article when it is imported, is the substance reportable under the IUR regulation?

No. If the chemical substance is imported solely as part of an article, the substance is exempt from IUR reporting. An article is any manufactured item that: (1) is formed to a specific shape or design during manufacture, (2) has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) has either no change of chemical composition during its end use or only those changes of composition that have no commercial purpose separate from that of the article and that may occur as described in 40 CFR 710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design. (See 40 CFR 710.3(d) and 710.50(b))

Impurities and Byproducts

49. Am I required to report impurities under the IUR regulation?

No, impurities are exempted from IUR requirements. An impurity is a chemical substance which is unintentionally present with another chemical substance (40 CFR 710.3(d)). Impurities are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.

50. Am I required to report byproducts under the IUR regulation?

A byproduct is a chemical substance produced without a separate commercial intent during the manufacture or processing of another chemical substance or mixture. Persons who do not manufacture a chemical substance for commercial purposes are not subject to IUR reporting for that chemical. You do not need to report byproducts under the IUR regulation unless the byproduct is used for a commercial purpose other than those specified in 40 CFR 720.30(g). If you manufacture a chemical substance on the Master Inventory File as a byproduct and use the byproduct for a separate commercial purpose in a quantity sufficient to trigger the IUR reporting requirements, then you must report it if the substance does not otherwise qualify for an exemption from IUR requirements. Note that while a substance listed in the TSCA Inventory may be a byproduct because it was produced without a separate commercial intent by the manufacturer, and is not used for a commercial purpose by that manufacturer, other manufacturers may produce that same substance with a separate commercial intent or may use it for a separate commercial purpose so that it is not considered to be a byproduct..

51. Reactants A and B are charged to a reaction vessel where they react to form Chemical X. Chemical C is subsequently added to the reaction vessel where it reacts with Chemical X to form Chemical Y, which is isolated and packaged into shipping containers. Small amounts of Chemical X may be unintentionally present in the packaged product. Is Chemical X subject to IUR requirements at this site?

In this example, Chemical X is considered an impurity because it is unintentionally present in the final product. Quantities of an otherwise reportable chemical substance which are impurities in the final product are exempt from IUR requirements.

Non-Isolated Intermediates

52. Reactants C and D are charged to a vessel where they react to form Chemical P. Chemical substance E is then added to the reaction vessel and Chemical P is completely consumed in the formation of Chemical Q, which is then drummed for shipment. Is the manufacture of Chemical P subject to IUR requirements?

In this example, EPA considers Chemical P to be a “non-isolated intermediate” because it is not stored in or intentionally removed from the process equipment of manufacture and it is reacted in that vessel to form another chemical substance. Persons who manufacture chemical substances solely as non-isolated intermediates are exempt from IUR requirements for those chemicals (40 CFR 710.50(c) which references 40 CFR 720.30(h)). Form U should be completed for Chemical Q if 25,000 pounds or more of this chemical substance are manufactured at the site during the reporting year.

53. Does the sampling for quality control purposes negate the non-isolated intermediate status of Chemical X?

No. Sampling for quality control does not negate the non-isolated intermediate status of a chemical substance.

Research and Development Chemicals

- 54. I manufacture a small quantity of a chemical solely for research and development. Do I need to report?**

No, you do not need to report. A chemical manufactured solely in small quantities for research and development need not be reported under the IUR regulation (40 CFR 710.50(a)). Be sure that you can verify that this chemical substance is used solely for research and development.

- 55. I manufacture 26,000 pounds of a chemical and then use 2,000 pounds for research and development. I sell the remaining chemical for industrial uses. Do I need to report?**

Yes, you must report. A person is exempt from IUR requirements for a chemical substance manufactured for research and development only if they do not also manufacture the chemical for other uses (40 CFR 710.50(a)). The total amount of the chemical manufactured must be reported because, in this scenario, the reporting threshold is exceeded.

Non-TSCA Uses

- 56. I manufacture a chemical substance for a non-TSCA use. Am I required to submit IUR information for this chemical substance?**

Chemical substances that are manufactured solely for non-TSCA uses, as identified in TSCA section 3(2)(B), are exempt from all TSCA requirements and therefore are not subject to the IUR rule. Substances exempted in TSCA section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act; any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code. Therefore, information on substances intended at the time of manufacture to be used solely for non-TSCA purposes need not be reported.

- 57. I manufacture a chemical substance which may be used for purposes regulated by TSCA and for uses which are excluded from regulation under TSCA by section 3(2)(B). Should the entire quantity that I manufacture be reported on my IUR submission?**

No. The quantity of a chemical substance intended at the time of manufacture to be used for a commercial purpose that is excluded from regulation by TSCA should not be included in the quantity reported under IUR. If it is not known at the time of manufacture if the chemical will be used for a TSCA or a non-TSCA purpose, the entire quantity of a chemical substance should be included in the quantity reported under IUR.

- 58. I manufacture Chemical C. My customers use Chemical C for a variety of uses including the manufacture of a chemical substance to be used as a pesticide active ingredient. Pesticides are exempt from regulation by TSCA. Do I need to report industrial processing and use data for this chemical substance?**

Persons manufacturing chemicals for a variety of uses are not required to report processing and use information on the non-TSCA uses of the TSCA chemicals they manufacture. A person manufacturing a chemical which is not an active ingredient in a pesticide formulation should report the amount of the chemical manufactured but need not report processing and use information for activities occurring after it is incorporated into the pesticide formulation.

Exporting a Chemical

- 59. I manufacture a chemical on the TSCA Inventory solely for export. Am I subject to the IUR regulations?**

Yes. Persons who manufacture chemicals solely for export are considered manufacturers for the purposes of IUR. You need to comply with the IUR regulations.

Note, however, that the information required by 40 CFR 710.52(c)(4) is restricted to domestic activities, i.e. within the customs territory of the United States. If all processing and use occurs outside the United States, check the box labeled "N/A" in the upper right-hand corner of Sections A and B of Part III on Form U.

Manufacturers Responsible for Reporting

- 60. I am a toll manufacturer (i.e., contract manufacturer) of a reportable substance for another company. Am I required to report?**

Yes, the company that actually manufactures the chemical substance is required to report under the IUR for all chemicals manufactured at its site. Please remember that, as the toll or contract manufacturer, you should be listed as the manufacturer on Form U, and the location of your manufacturing plant should be identified as the site.

Reporting Requirements for Importers

61. If I import a chemical substance, am I required to report under the IUR rule?

Under TSCA, manufacturing and importing a chemical substance are equivalent. Any person who manufactured (including imported) for commercial purposes 25,000 lbs. or more of a chemical substance at any single site during calendar year 2005 is subject to reporting requirements (40 CFR 748(a)).

62. My company imported 30,000 lbs. of a chemical substance during a reporting year. Fifteen thousand pounds of the chemical were delivered from a foreign source to each of two domestic sites owned by my company. Is my company required to report?

It depends. When importing chemical substances, the import site for purposes of IUR 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. The import site may in some cases be the organization's headquarters in the United States. (40 CFR 710.48(b))

If a single operating unit within your company is directly responsible for and controls the import transaction, the site of that operating unit is the import site for purposes of IUR. In this instance, you must aggregate the total amount imported at that site (30,000 lbs.); this amount exceeds the threshold (25,000 lbs.) for reporting.

If each of the operating units receiving the chemical substance is separately responsible for and independently controls the import of the chemical substance to their location, then, under the IUR regulation, the location of each operating unit is a site importing 15,000 lbs of the chemical substance. For this example, each site imported less than 25,000 pounds of the chemical substance and would not need to report.

Reporting Responsibility

63. If I import a chemical substance using a broker, who is responsible for reporting?

Under the IUR regulation, the importer is the party primarily liable for the payment of any duties or an authorized agent acting on his/her behalf and is responsible for reporting.

When two or more persons are involved in a particular import transaction and each person meets the Agency's definition of "importer" as set forth in 40 CFR 704.3, they may determine among themselves who will submit the required report. If no one reports an import transaction when required, EPA can hold all persons who qualify as importers of the chemical liable for failure to report (40 CFR 710.55(b)).

64. Is a company operating in a foreign trade zone subject to the IUR rule?

Yes, a company is subject to the IUR rule if it manufactures (including imports) a chemical substance on the TSCA Inventory at the beginning of the submission period in a Foreign Trade Zone in quantities of 25,000 lbs. or more during an IUR reporting year.

Reporting the Identity of Imported Chemicals

65. I am importing a chemical whose identity is not known to me because the foreign company selling the chemical to me claims the chemical identity to be proprietary. Do I need to report this chemical in accordance with the IUR rule?

Yes, as an importer you are required to comply with the IUR regulation. If the quantity of the chemical imported exceeds the IUR reporting threshold and the chemical is not otherwise exempt from reporting, contact your chemical supplier and request the specific chemical identity and CAS number of the imported chemical substance. If your foreign manufacturer/supplier continues to claim the chemical identity as confidential, the manufacturer/supplier can send the confidential information directly to EPA.

66. I receive a chemical substance from a foreign source and use it as a reactant. The reaction completely consumes the chemical. Is this chemical considered to be site-limited?

For purposes of IUR, imported chemical substances are never site-limited. (40 CFR 710.43) A chemical is site-limited only if it is domestically produced and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site.

67. I transport a chemical substance via pipeline from outside the customs territory of the United States to my plant site. Am I required to report in accordance with the IUR regulation for this chemical?

You are importing a chemical substance and therefore you are potentially subject to IUR regulations. The mode of transporting the chemical to your site is not relevant when determining your reporting requirements under the IUR regulation.

Completing Form U

68. Should I report known values and estimated values differently on Form U?

No. Report all information requested in Parts I and II of Form U to the extent it is known to or reasonable ascertainable by you. EPA expects that the information in Parts I and II of Form U is information that you know or could reasonably ascertain. Report all readily obtainable information on Part III.

69. Can EPA clarify how the percent of production volume figures should be rounded for purposes of IUR reporting?

When rounding a number to the closest ten percent for IUR reporting, round a number ending in 5 percent or greater up to the next higher 10 percent. For example, 5 percent is rounded up to 10 percent, 15 percent is rounded up to 20, and, 25 percent is rounded up to 30. Round a number ending in less than 5 percent down to the next lower 10 percent. For example, 14 percent is rounded down to 10 percent, 24 percent is rounded down to 20 percent, and so forth.

An exception to this rule applies where a particular combination of industrial processing or use operation, NAICS code, and industrial function category accounts for 5% or less of the submitter's site's total production volume of a reportable chemical substance; in this case, the percentage must not be rounded off to zero percent if the production volume attributable to that industrial processing or use operation, NAICS code, and industrial function category combination is 300,000 lbs or more during the reporting year. Instead, in such an instance, submitters must report the percentage, rounded to the closest 1% of the submitter's site's total production volume of the reportable chemical substance associated with the particular combination of industrial processing or use operation, NAICS code, and industrial function category (40 CFR 710.52(c)(4)(i)(D)). A similar exception pertains to commercial and consumer use information (40 CFR 710.52(c)(4)(ii)(C)).

Estimating Number of Workers Reasonably Likely to be Exposed to a Chemical Substance

70. What does “reasonably likely to be exposed” to a chemical substance mean?

EPA defines “reasonably likely to be exposed” as exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use, is more likely to occur than not occur. Such exposures would normally include, but are not limited to activities such as charging reactor vessels, drumming, bulk loading, cleaning equipment, maintenance operations, materials handling and transfers, and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact, absorption, etc.), but excludes accidental or theoretical exposures. *See* 40 CFR 710.43.

71. Should the number of workers reasonably likely to be exposed to a chemical substance be reported as full-time equivalents or the actual number of workers?

Do not report full-time equivalents. EPA requires that you report the total number of individuals reasonably likely to be exposed to each reportable chemical substance (40 CFR 710.52(c)(3)(v) and 710.52(c)(4)(i)(F)). When a site employs temporary, seasonal, or contract workers in the manufacture of a reportable chemical substance, those workers should be included in the number of workers reasonably likely to be exposed if they work in areas where the chemical is manufactured. Those employees whose jobs are not associated with potential exposures to a chemical or mixture (e.g., administrative staff who never enter areas where the chemical is manufactured and persons working

elsewhere on site who are not reasonably anticipated to be exposed to the chemical for even a brief period of time) should not be included in the reported number of workers reasonably likely to be exposed to a chemical substance.

72. Should administrative staff be included in the estimate for number of workers?

There may be instances in which administrative staff working at the site are reasonably likely to be exposed to the chemical and thus should be included in the number of workers reported. However, if the administrative workers do not enter areas where the chemicals are manufactured and are not reasonably likely to be exposed to a chemical substance for even a brief period of time, they should not be counted among the number of workers.

73. I have determined that I need to complete Parts I, II, and III of Form U for a chemical I manufacture and process at my site. I am aware that this chemical is present in the air in non-manufacturing areas of the plant site at measurable concentrations. How should I estimate the number of workers reasonably likely to be exposed to the chemical? Are all workers employed at the site reasonably likely to be exposed?

The IUR regulation requires that you report the number of workers reasonably likely to be exposed to a reportable chemical substance (40 CFR 710.52(c)(3)(vi) and 40 CFR 710.52(c)(4)(i)(F)). There is no minimum level of exposure to a chemical substance in IUR reporting below which a worker need not be counted among the number reasonably likely to be exposed to a chemical substance. Therefore, if you are aware that a chemical substance manufactured at the site is present in the air throughout the site, all workers at the site must be included in the number of workers reasonably likely to be exposed to the chemical substance.

74. Should contractors and temporary employees be included in the number of workers likely to be exposed?

Yes, include temporary, seasonal, or contract workers in the number of workers estimate if they are reasonably likely to be exposed.

75. Does EPA provide guidance on how the frequency and duration of exposure should be considered when estimating the number of workers reasonably likely to be exposed to a chemical substance? Is there a minimum duration of exposure that does not need to be reported (e.g., one minute)?

Under the IUR rule, there is no minimum duration or frequency of exposure for determining the number of workers reasonably likely to be exposed to a chemical substance. If you determine that a worker is reasonably likely to be exposed at any time during the year for any length of time, include this worker in your estimate.

- 76. I employ 12 workers to operate manufacturing lines for three different chemical substances, X, Y, and Z. The workers rotate among the different manufacturing lines. Only four workers work on the manufacturing line for Chemical X at any given time. However, any of the 12 workers may be assigned to Chemical X production. How do I report the number of workers reasonably likely to be exposed during the manufacturing of Chemical X?**

Because any of the 12 workers may have worked on the Chemical X production line during the reporting year, you should report code W2 in Part II of IUR Form U to reflect at least 10 but fewer than 25 workers.

- 77. How do I make judgments about the number of workers reasonably likely to be exposed to a chemical substance at processing and use sites?**

Report the number of workers reasonably likely to be exposed to a chemical substance at processing and use sites to the extent the information is readily obtainable by you. Readily obtainable information may include estimates that use your best professional judgment based on past experience for similar chemical substances in the same or similar markets.

If you manufacture multiple substances that have similar use operations and you know the number of workers reasonably likely to be exposed to the chemical at one of the downstream sites, you can use best professional judgment to estimate the same number of workers at the other downstream sites. For example, you sell 25% of your production volume to each of 4 sites, each of which uses the chemical in a similar manner. You know one site has 25 workers who are reasonably likely to be exposed to the chemical. You can use best professional judgment to estimate the remaining three sites have at least 25 workers reasonably likely to have exposed to the chemical and report a range code of W5 representing at least 100 but less than 500 workers. If the information is not readily obtainable, enter 'NRO' in the number of workers block.

- 78. Am I required to perform a mathematical probability analysis for each exposure scenario to determine if worker exposure is 'more likely to occur than not to occur'?**

No. In Part II of Form U, enter the number of workers reasonably likely to be exposed at your site if the information is known or reasonably ascertainable. EPA expects the information in Part II will generally be known to or reasonably ascertainable by persons submitting IUR information. In Part III of Form U, report the number of workers reasonably likely to be exposed to the chemical to the extent the information is readily obtainable. Neither the known to or reasonably ascertainable by standard nor the readily obtainable standard requires extensive testing or modeling.

79. Why are engineering controls and personal protective equipment (PPE) not considered when estimating the number of workers reasonably likely to be exposed?

Engineering controls and personal protective equipment (PPE) may reduce but do not preclude exposure to a chemical substance. Examples of engineering controls include ventilation systems, nitrogen blankets, and dust collectors. Examples of PPE include chemical gloves, respirators, goggles, and protective clothing. Based on EPA's experience, the definition and use of engineering controls and PPE varies from site to site. In addition, the effectiveness of engineering controls and PPE is limited by possible equipment malfunction and improper use. When reporting the number of workers reasonably likely to be exposed to a chemical substance, no allowance should be made for the possible protection provided by engineering controls and PPE.

80. Should workers that may be exposed to a chemical substance during accidental releases be included in the estimate of number of workers reasonably likely to be exposed?

No, workers that may be exposed during accidental releases should not be included in the number of workers reasonably likely to be exposed to a chemical substance. Only workers reasonably likely to be exposed to a chemical substance during normal manufacturing, processing, and use of a chemical substance, as well as ancillary activities such as equipment cleaning and maintenance, must be included in IUR reporting.

Part I - Site Identification Information

Company Ownership

81. During the first 6 months of 2005, Company X manufactured 30,000 pounds of a chemical substance included in the TSCA Inventory and not otherwise exempted from the IUR at a particular site. On July 1, 2005, Company X sold its assets at this site including the chemical manufacturing facility, inventory, and equipment to Company Y. Company X continued in business. During the last six months of 2005, Company Y manufactured 40,000 pounds of the same chemical substance at the site. Who should report the amounts of the chemical substance manufactured during calendar year 2005?

Company X is required to report the 30,000 pounds of the chemical substance that it manufactured during the first 6 months of reporting year 2005. Company Y is required to provide a separate report for the 40,000 pounds of the chemical that it manufactured during the last six months of calendar year 2005.

- 82. During the first six months of 2005 Company X manufactured 30,000 pounds of a chemical substance included on the TSCA Inventory and not otherwise excluded from the IUR at a particular site. On July 1, 2005, Company Y purchased Company X, acquiring all the assets of company X and assuming all of the liabilities of Company X. During the last six months of 2005, Company Y manufactured 40,000 pounds of the same chemical substance at the site. Who should report the amounts of the chemical substance manufactured during calendar year 2005?**

Because all of the assets and liabilities of Company X were merged into Company Y during 2005, and Company Y continued as a going concern, Company Y is required to report the entire 70,000 pounds of the chemical substance manufactured at the site during calendar year 2005.

- 83. Which company should report if a chemical is being manufactured by a joint venture?**

Participants in the joint venture may determine among themselves who should report. If no report is submitted when required, EPA may hold each party in the joint venture liable for the failure to report.

Technical Contact

- 84. Who can be the technical contact listed on the IUR submission?**

The technical contact should be a person capable of answering questions about the information submitted to EPA. The technical contact does not have to physically work at the site reported on Form U.

- 85. Can two different plant sites within the same company that are both reporting under the IUR have different technical contacts?**

Yes. Form U would be completed for each plant site, and each form would list one technical contact able to answer questions about the information in the report. You may report a different technical contact for each site.

Part II Section A - Chemical Identification

- 86. How can I determine the Chemical Abstracts Service Registry Number (CAS Number) for a chemical?**

Each chemical has a unique CAS Number. This number is often listed in the Material Safety Data Sheet (MSDS) for a chemical. CAS Numbers are listed in the TSCA Inventory and can also be found on many Internet sites. You can also obtain information about the CAS Registry on the CAS Web site <http://www.cas.org/EO/regsys.html>.

87. What identifying number should be reported if I am unable to obtain a CAS Number?

An EPA-designated Accession Number for substances listed on the confidential portion of the TSCA Inventory or a premanufacture notice (PMN) case number may be reported if a CAS Number is not known and cannot reasonably be ascertained (*See* 40 CFR 710.52(c)(3)).

88. If I know the Accession Number or a PMN case number for a chemical I report, can I report it? For example, importers may be given the Accession Number or PMN case number by a foreign supplier.

If the CAS Number is known or can be reasonably ascertained, it must be used in IUR submissions. If the CAS Number is unknown and cannot reasonably be ascertained, an EPA-designated Accession Number for a chemical substance on the confidential TSCA Inventory or a PMN case number can be used in IUR submissions to identify a chemical substance.

Part II Section B - Manufacturing Information

Site Limited Status

89. I manufacture a site-limited chemical that is on the TSCA Inventory. Do I need to report under the IUR rule?

Yes, a report must be submitted for site-limited chemicals on the TSCA Inventory, if 25,000 lbs. or more of the chemical is manufactured at the site and you are not otherwise excluded from reporting. Enter "Y" for yes in Block 2.B.4 of IUR Form U to signify that the chemical substance is site-limited. See 40 CFR 710.52(c)(iii).

90. Can imported chemicals be site-limited (Block 2.B.4)?

No. Imported chemicals are transported beyond the bounds of your site and, therefore, are not site-limited (40 CFR 710.43). Always report "N" in Block 2.B.4 of IUR Form U if your chemical is imported, even if your chemical is imported and is totally consumed as a reactant at the site receiving the imported chemical.

91. At my site, we produce over 25,000 pounds of a reportable chemical substance. Most of this production is for on-site use but a small amount is sent to another site. Is my chemical site-limited?

Because some portion of this substance leaves the plant site, the chemical is not site-limited. Report "N" in Block 2.B.4 of IUR Form U for this chemical substance.

- 92. At my site, we produce over 25,000 pounds of a chemical substance on the TSCA Inventory which is not exempt from IUR requirements. The chemical is reacted on-site in the production of another chemical substance. The only amount of this chemical leaving this site is in the form of a laboratory sample for off-site analysis. Should I report the chemical as site-limited on IUR Form U?**

Yes, laboratory samples sent off-site for monitoring of the production process or quality control do not affect the site-limited status of the chemical.

- 93. At my site, we produce 300,000 lbs. or more of a chemical substance which is used solely to produce other chemical products. When the products are packaged and distributed to my customers, residual amounts of the chemical may still be unintentionally present in distributed products which do not affect the commercial value of the product. Is the chemical considered to be site-limited? Do I need to report processing and use information on Part III of Form U for my chemical substance?**

As described, the chemical substance remains in the reaction product as an unreacted starting material. Regardless of the amount of the starting material remaining in the product, if the starting material does not have a separate commercial purpose, then your production of this chemical would be considered site-limited. Due to its site-limited status, you would only report your site's use of the chemical as an intermediate on Part III of Form U for this chemical substance; information on the uses of the reaction products would be separately reported, if required, under the CAS Registry Nos. for the reaction products. Conversely, some prepolymers intentionally contain unreacted monomeric material that is important in the functioning of the partially polymerized product and contributes to the commercial value of the product; these monomers are not site-limited and subsequent processing and use of these monomers must be reported.

Production Volume

- 94. How precisely must the manufactured (including imported) volume be reported?**

You must report the total amount (in pounds) for each subject chemical substance manufactured (including imported) at each site. Report this amount to two significant figures of accuracy. See 40 CFR 710.52(c)(3)(iv).

Maximum Concentration during Manufacturing

- 95. I manufacture a chemical that is sent off-site in products containing from 3% to 33% by weight of the chemical. What code should I use to report the maximum concentration?**

The maximum concentration leaving your site is 33%. Therefore, report code M3, which represents a concentration of 31 to 60% by weight.

96. How do I report the maximum concentration if a chemical substance never leaves the site where it is produced?

For site-limited chemicals, report the maximum concentration at the time the chemical is reacted on-site to produce a different chemical substance.

97. If samples are sent off-site for analysis, should these samples be included when reporting the maximum concentration of the chemical leaving the site?

Analytical samples for purposes of certification and quality control are presumed not to be distributed for a separate commercial purpose and do not impact the reporting status of a chemical substance. Therefore, analytical samples do not need to be considered when reporting the maximum concentration. Note, however, that if the chemical substance was sent off-site for research and development purposes, the maximum concentration of the chemical substance leaving the site for these purposes would be reported.

98. I manufacture a chemical substance at 100 percent concentration, but I blend the substance with other chemicals, which results in a final product at 60 percent concentration. This product is drummed and distributed to my customers. How should I report the maximum concentration in Block 2.B.9?

You would report the maximum concentration of the chemical substance as it leaves your site. For this example, the code is M3 which corresponds to the 60% concentration leaving the manufacturing site.

99. I produce a chemical substance at 98 percent concentration and then react the substance to form other chemical products. When the products are packaged and distributed to my customers, small amounts of the original substance may be unintentionally present in these products. How should I report the maximum concentration in Block 2.B.9 of Form U?

Regardless of the amount of the original chemical substance present in the product, if it is not distributed for commercial purposes, then the original substance is considered to be site-limited. Assuming the chemical is not present in products for a commercial purpose and is thus site-limited, you are required to report the maximum concentration of the original chemical substance when it is reacted on-site. Therefore, report M5 for the maximum concentration code, corresponding to 98 percent.

Physical Form

100. How do I report the physical form of a slurry or a solid/liquid suspension?

For purposes of IUR, slurries, colloidal suspensions, and other solids-liquid mixtures should be reported as a “water- or solvent-wet solid.”

101. What is the difference between water- or solvent-wet solid and liquid?

For purposes of IUR, water- or solvent-wet solids include mixtures of liquids and solids, such as slurries and colloidal suspensions. Liquids include liquid-liquid mixtures and liquid solutions containing dissolved solids.

102. Does EPA differentiate between pellets and granules when reporting the physical form?

No. For purposes of IUR, pellets and granules should be reported as “pellets or large crystals.”

103. What physical form do I report for a chemical substance that is manufactured at elevated temperatures as a liquid but then a portion is cooled and pelletized? The substance may leave the site in either form.

Report the physical form of the chemical when it leaves the site. In this case, you should report both “liquid” and “pellets or large crystals” because the chemical may leave the site in either form.

Part III - Processing and Use Information

104. Does EPA intend for submitters to send questionnaires to customers requesting information about downstream uses?

No. Persons reporting IUR processing and use information reported on Part III of Form U are required to provide only information that is readily obtainable. This does not require persons reporting IUR information to conduct surveys of customer users.

105. My site manufactures 500,000 pounds of Chemical A during the reporting year. Some of the Chemical A is stored and sold during the subsequent year. How should I complete Part III of Form U?

When reporting IUR information, you are required to report the processing and use of chemical substances manufactured for a commercial purpose during the reporting year to the extent that the information is readily obtainable. Therefore, report the uses of the 500,000 pounds of Chemical A manufactured during the reporting year including the portion sold during the subsequent year if readily obtainable. If a fraction of Chemical A remains in inventory at the time Form U is submitted, information on processing and use of that fraction of Chemical A would not be readily obtainable.

- 106. My site manufactures and sells Chemical B to three different companies (X, Y, and Z). My site is aware that Company X and Company Y are in NAICS code 32592 and use Chemical B as a reactant to produce Chemical C. I also know that Company Z (NAICS code 32519) uses Chemical B in a product formulation and sells this product formulation to one downstream customer, KLM Incorporated (NAICS code 32599), who packages and distributes the product to consumers. What information must be reported on Part III Section A of IUR Form U?**

Complete the following lines under Part III Section A of Form U for Chemical B:

Block	a. Type of Process or Use	b. (5-digit) NAICS	c. Industrial Function Category
3.A.1	PC	32592	U16
3.A.2	PF	32519	U15 or other appropriate code
3.A.3	PK	32599	U15 or other appropriate code

PC = Processing as a reactant.

PF = Processing – incorporation into formulation, mixture, or reaction product.

PK = Processing – repackaging.

U15 = Functional Fluids.

U16 = Intermediates.

Note that you need to include downstream uses of Chemical A by entities that are not your direct customers if such information is readily obtainable (i.e., in the example, you must report processing and use information for ABC Incorporated). Select the Industrial Function category that represents the function of Company Z’s formulation product. You do not need to report the downstream users for Chemical C, but your customer who manufactures Chemical C may be subject to IUR reporting with respect to their manufacture of Chemical C.

- 107. Company A manufactures an additive for polymer resins and sells it to Formulator F. Formulator F formulates a can coating and sells its product, which contains the additive, to Can Coater C. Can Coater C applies the coating to steel and aluminum cans. The additive is completely reacted when the coating is cured. Can Coater C sells the cans to Paint Formulator P, who fills the coated cans with paint and sells its formulated paint product to the public (consumers). Which company is responsible for reporting for the additive for polymer resins?**

As the manufacturer of the additive, Company A is responsible for meeting all reporting obligations for this chemical substance. If the reporting threshold for processing and use information (300,000 pounds) is met or exceeded, Company A would report information on Part III of Form U reflecting the formulation activities of Formulator F and the coating activities of Can Coater C. Reporting downstream uses for the additive ceases when the coating is cured (i.e., the additive is reacted to form another chemical).

Note that a different chemical substance is created when the additive is cured, but this chemical substance (cured can coating) is exempt from IUR reporting (40 CFR 710.50(c) which references 40 CFR 720.30(h)).

Process or Use, NAICS, and IFC Codes

108. Which NAICS codes should I report for processing and use of chemical substances which I manufacture?

Report the NAICS code(s) that correspond to the processing and use activities for your chemical substance. The U.S. Census Bureau provides a Web site listing the NAICS codes, <http://www.census.gov/epcd/naics02/>. They are also included in the eIUR software for electronic reporting of IUR information.

109. How should I determine the top 10 combinations of type of process/use, NAICS, and IFC codes if I do not know the amount of chemical dedicated to each use?

Use readily obtainable information to select the 10 highest volume uses of the chemical and report the combinations of process/use, NAICS, and IFC codes for those uses. If information on processing and use, NAICS code, or IFC is not readily obtainable, enter 'NRO' in the block for that data element on the appropriate line.

Intermediates

110. How do I complete Part III of Form U for a chemical substance that is used as an intermediate to manufacture another chemical?

If a chemical substance is used solely as a chemical intermediate to manufacture another chemical substance, enter the Process or Use code PC, representing processing as a reactant. The NAICS code may vary depending upon the industry that uses the chemical. The IFC code is U16, representing intermediates.

111. I manufacture 300,000 lbs. or more of an organic chemical substance, which is used as an intermediate to manufacture other chemical substances. A portion of the organic chemical is not consumed by the reaction and is separated and burned as a fuel; a small amount of the organic chemical substance may be unintentionally present in the reaction product and does not have a separate commercial purpose. The reaction product is sold for commercial and/or consumer use. How should I complete Part III of Form U? Am I required to enter codes to report the burning of the organic chemical as a fuel? Do I need to report commercial and consumer uses for original chemical substance because there may be a small amount of the chemical present in the reaction product?

Complete Part III, Section A of Form U to reflect the use of the organic chemical substance as a chemical intermediate. You do not need to report use of the organic chemical as a fuel or the commercial and/or consumer use of the reaction product containing the original substance.

- 112. I manufacture Chemical P and distribute it to several customers who consume Chemical P in the production of Chemicals Q and R. Chemicals Q and R are then used in the metal plating industry. Under the IUR regulation, if I must report Chemical P, must I also report the uses for Chemicals Q and R on Part III of Form U?**

You are only required to report the uses for Chemical P. Once Chemical P is converted into other chemical substances, in this case Chemicals Q and R, it no longer exists as a chemical substance and there are no further reportable uses of Chemical P. Note that your customers who use Chemical P to produce Chemicals Q and R may be subject to IUR reporting for their manufacture of Chemicals Q and R and may be required to report their use in the metal plating industry.

Fertilizers and Fungible Commodities

- 113. How do I report the use of an organic fertilizer in Part III of IUR Form U?**

The industrial, commercial, and /or consumer uses of organic fertilizers should be reported up to the point at which they are applied as fertilizers. Therefore, the final use that a fertilizer manufacturer would need to report would be the application of the fertilizer. (40 CFR 710.52(c)(4)(ii)(A))

- 114. How should I report industrial, commercial, and consumer uses of fungible commodities?**

Treat the chemical you manufacture as a discrete entity and provide estimates for the intended use(s) of that discrete entity. For example, if you produce 100,000 tons of ammonia that is transported via a pipeline with ammonia produced by other manufacturers to various distribution points along the pipeline, you should treat your site's 100,000 tons as a discrete entity and assume that the ammonia you produced is extracted from the pipeline by your customer. That is, you do not have to account for all potential downstream processing and use scenarios for the entire quantity of ammonia in the pipeline even though you are unsure whether your customer received the ammonia that you injected into the pipeline or received ammonia produced by another manufacturer. In other words, provide processing and use information based on the assumption that the ammonia that you injected into the pipeline is delivered to your customer.

Consumer Uses

115. How do I report IUR information for a chemical my company manufactures and sells directly to consumers?

If you manufacture (including import) 300,000 lbs. or more of a chemical substance and sell it for direct consumer use, mark the 'NA' box in the upper-right corner of Part III Section A of IUR Form U to denote that there is no industrial processing of the chemical substance you manufacture. Complete Section B of Part III to reflect the manner in which consumers use the chemical.

116. How is “intended for use by children” defined for purposes of IUR?

For purposes of reporting in accordance with the IUR regulation, “intended for use by children” means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers “yes” to at least one of the following questions for the product into which the submitter’s chemical substance or mixture is incorporated: (1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?; (2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended or will be used by children age 14 or younger?; or (3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

117. How do I report a chemical that is used as a plasticizer in plastic pellets or articles?

A plasticizer is an additive chemical that is mixed with a polymer prior to forming an article composed of the polymer and associated polymer additives. If you manufacture (including import) 25,000 lbs. or more of the plasticizer, either alone or as a component of a mixture with other chemicals in compounded pellets, you must evaluate your reporting requirements under the IUR regulation. Note that you do not need to report the plasticizer if you imported the plasticizer solely as part of an article (*See* 40 CFR 710.50(b)).

- 118. Site A manufactures 300,000 pounds of a nonreactive plasticizer at a single site. The plasticizer is sold to a polymer compounder who combines the plasticizer with a polymer and other polymer additives and forms pellets containing the polymer and additives. These pellets are sold to a molder/fabricator to be molded into plastic parts used in making bassinets for infants. Site A knows that the concentration of the plasticizer in the pellets is 2% or less by weight, but cannot readily obtain more specific information regarding the maximum concentration in the consumer product. How does Site A report commercial and consumer use information for the plasticizer under the IUR regulation?**

Assuming Site A is not excluded from the requirement to report IUR processing and use information for the plasticizer, Site A should report the following information in Part III, Section B of IUR Form U:

Block	Field	Response	Definition
3.B.1.a	Commercial and Consumer Product Category	C15	Rubber and plastic products
3.B.1.b	Used in Products Intended for Children	Y	
3.B.1.c	Percent Production Volume Associated with Each Category	100%	
3.B.1.d	Maximum Concentration Associated with Each Category	M2	From 1 to 30% by weight.

Confidentiality Claims and Certification Statements

119. What must I generally consider in making a claim of confidentiality under TSCA?

When claiming information confidential, you must ensure that your information meets the regulatory criteria found at 40 CFR 2.208. Under this regulation, business information is entitled to confidential treatment if:

- (a) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived, nor withdrawn;
- (b) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information and that it intends to continue to take such measures;
- (c) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);
- (d) No statute specifically requires disclosure of the information; and,
- (e) Either (1) The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position, or (2) The information is voluntarily submitted information and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future.

Additional requirements apply when the identity of a chemical substance or the site of its manufacture is claimed to be confidential (*See* 40 CFR 710.58).

120. How do I claim the link between the identity of my company and the information I submit under the IUR to be confidential?

To claim the link between your company and the information you report on IUR Form U as confidential, check the CBI box next to the Company Information field (Block 2.B.1). Also mark as confidential any correspondence that may link your company name or site to the reported chemical substance.

121. Can I claim my site information as CBI?

Yes. Under the IUR, you may assert a confidential claim for the identity of your site ("site information") if this information meets the general criteria for confidentiality found at 40 CFR 2.208. Claiming site information confidential protects the release of the site name, address, city, county, state, zip code, and Dun & Bradstreet number. Confidentiality claims should be limited to circumstances in which they are absolutely necessary and legally justified. Note that claiming site identity confidential does not alone protect the link between the specific chemical identity and your company's identity. It does protect the identity of the site where the chemical was manufactured (including imported).

To claim your site address as confidential, check the site information CBI box (Block 2.B.2) on Form U. Note that written substantiation is required to claim site information as CBI.

122. Can the identity and contact information for the person listed as the technical contact for a site be claimed as confidential?

Yes. Check the CBI box adjacent to item 2.B.3 on IUR Form U.

123. If I have previously reported production volume, plant site, or other information for the Original Inventory (1977 data) or for the 1986, 1990, 1994, 1998, or 2002 IUR reporting periods, and did not claim the information as confidential at the time, can I make a confidentiality claim now?

You can claim information submitted in response to the IUR regulation in 2006 to be CBI if the information is actually confidential (as determined through applying the regulatory criteria at 40 CFR 2.208). You may not, however, amend past submissions to assert CBI claims for information submitted in previous years. Note that you may not claim as confidential the identity of any chemical substance currently listed on the public portion of the TSCA Inventory.

124. Can I claim as confidential the fact that a substance is not site-limited?

Yes, provided that this information meets the regulatory criteria for confidentiality outlined in 40 CFR 2.208.

125. What is the difference between claiming Company Information as confidential and claiming Site Information as confidential? Do I need to provide written substantiation for claiming Company Information confidential?

Checking the CBI box for Company Information asserts a confidentiality claim for the link between your company and the chemical substance. You do not need to provide written substantiation to claim Company Information as confidential.

Checking the CBI box for Site Information protects the link between the site of manufacture and the chemical identity. Claiming Site Information confidential protects the release of plant site name, address, city, county, state, zip code, and Dun & Bradstreet number. You must provide written substantiation if you claim Site Information to be confidential. Note that confidentiality claims that require written substantiation are marked with an asterisk (*) on Form U. When using the eIUR software, the substantiation questions are activated when the Site Information CBI box is selected.

Because a person can report information for multiple chemicals manufactured at the same site using a single copy of the first page of Form U, the CBI claims for both company and site information are linked to each individual chemical on the chemical-specific second page of Form U. For instance, if you report four chemical substances using the eIUR software, you would be given the opportunity to individually determine for each chemical

substance whether you need to claim CBI for your site information. You can claim the site information for one chemical substance as CBI while, on the same Form U, you do not claim the site information as CBI for the other three chemicals. Likewise, if you report four chemical substances by photocopying the second page of Form U containing Parts II and III and filling in the information for each chemical on a separate page, you would be able to claim CBI for the site information for one chemical by checking the “CBI” box on that chemical’s page while releasing this information for the other three by not checking the equivalent box on the pages for each of those chemicals.

126. If the identity of my site is claimed confidential, should I also claim the name of my company confidential?

You may claim Company Information as non-confidential (Block 2.B.1) and Site Information as confidential (Block 2.B.2), but not the reverse; if Company Information is claimed as confidential, it follows that the Site Information must also be claimed confidential to fully protect the Company Information.

127. When is written substantiation required for claiming confidentiality?

Your IUR submission must include written substantiation which answers the questions set out in 40 CFR 710.58(b) or (c) when confidentiality is claimed for either the chemical identity or site identity, respectively. In addition to signing the Certification on page one of IUR Form U, your responses to the substantiation questions claiming the chemical identity or site identity to be confidential must be signed and dated by an authorized official.

128. Must the authorized official who signs any responses to confidentiality claim substantiation questions on behalf of a site be the same individual who signs the Certification statement on behalf of a site?

No. EPA has not promulgated criteria for determining who is an official authorized to sign either the IUR Certification statement or the statements which accompany claims of confidentiality for either the identity of a chemical substance or the site of manufacture (or import). The person authorized to sign the statements which accompany confidentiality claims for the identity of the chemical and of the site need not be the same person who signs the certification statement on Form U.

129. How will the confidentiality of IUR data submitted electronically to EPA be maintained?

EPA has taken great care to assure the confidentiality of information being transmitted electronically. Submissions through the Internet are double encrypted – first by the eIUR software, and second by the transmission method. The eIUR software uses a Federal Information Processing Standards (FIPS) compliant encryption module, the government standard of encryption. Once your file is encrypted by the eIUR software, only authorized EPA staff can decrypt your file. Because of this, the IUR software contains several warnings for you to save your file before encrypting it; once the file is encrypted, you will not be able to decrypt the file.

During transmission through the Internet to EPA's Central Data Exchange (CDX), your file is again encrypted using open Secure Socket Layer (SSL) (FIPS 140 certified). This second layer of encryption protects your information while it is being transmitted from your desktop to EPA. Once received by EPA's CDX, the SSL encryption is removed, but the initial encryption remains. Your file is then transmitted from CDX to EPA's data repository for IUR information. Your file remains encrypted until it is received into the IUR data repository, a protected database that exists inside EPA firewalls, at which point it is decrypted by authorized EPA staff.

Electronic submissions are considered safer than mailed-in submissions, even when CBI procedures are used, because the private key held only by EPA is needed to open and decrypt your electronic submission.

Submitting Your Report

130. When do I submit Form U to EPA?

IUR information generated during the reporting year must be sent to EPA during the subsequent submission period. Information gathered during the reporting year, calendar year 2005, should be submitted during the subsequent submission period, August 25, 2006 through December 23, 2006. For future IUR reporting years (i.e., 2010, 2015, 2020, etc.) the submission period will be from June 1 through September 30 of the following year.

131. In the past, report numbers were preprinted on all reporting forms. How will I know the number that is assigned by EPA to my 2006 Form U?

EPA will assign the official form numbers to IUR submissions; the Agency will provide these to you if EPA requests that your report be revised or amended. EPA will use the assigned number to link your original and revised reports.

132. Can I photocopy Form U and submit the photocopies?

Yes, you may photocopy IUR Form U and use the photocopied forms to report your IUR information. A single copy of page one of Form U must be included with each report submitted for a site along with a copy of page two for each chemical substance included in that report. A site may submit more than one report but should report each chemical substance manufactured (including imported) at that site only once.

133. What final checks should I perform before submitting Form U?

Make sure that you respond to all the information elements required on the form or enter 'NRO' if the information in Part III is not readily obtainable. Have an authorized official of your company sign the certification statement and any written responses to substantiate confidentiality claims. If you are reporting on a magnetic disk, a signed paper copy of the certification statement and substantiation of confidentiality claims must accompany your report.

Recordkeeping Requirements

134. Are we required to keep our records related to IUR reporting?

You must maintain records that document any IUR information reported to EPA for a period of 5 years beginning on the last day of the submission period (40 CFR 710.57). Persons submitting IUR information are encouraged to retain their records longer than 5 years to refer to when preparing reports for subsequent submission periods.

135. What must our retained records include?

A person reporting information under the IUR rule must maintain records that document any information reported to EPA. It is up to each person to determine the appropriate level of detail.

136. If our annual production is less than 25,000 pounds of a substance must we still keep records?

Although the IUR regulation does not require you to maintain information upon which you base your decision not to report, EPA believes that this type of information is routinely retained by companies in the normal course of business.

Penalties for Not Submitting a Report

137. What are the consequences if: (a) I fail to report when required to do so or fail to report on time; (b) I report production volumes under 25,000 pounds or report substances that are not required to be reported; or (c) I make obvious but unintentional errors in filing?

- a) You would be in violation of TSCA if you fail to comply or are late in complying with the IUR regulation and may be subject to enforcement action.
- b) If EPA detects an error or omission on Form U, the Agency may send a letter requiring you to correct the error within a specified time. If a timely correction is not received, you may be subject to an enforcement action.