

## **TSCA Chemical Data Reporting Fact Sheet: Non-Isolated Intermediates**

This fact sheet provides information on the reporting exemption applicable to non-isolated intermediate chemical substances for purposes of the Chemical Data Reporting (CDR) rule (40 CFR 711).

The primary goal of this document is to help the regulated community comply with the requirements of the CDR rule. This document does not substitute for that rule, nor is it a rule itself. It does not impose legally binding requirements on the regulated community or on the U.S. Environmental Protection Agency (EPA).

The CDR rule, issued under the Toxic Substances Control Act (TSCA), requires manufacturers (including importers) to give EPA information on the chemicals they manufacture domestically or import into the United States. EPA uses the data, which provides important screening-level exposure related information, to help assess the potential human health and environmental effects of these chemicals and makes the non-confidential business information it receives available to the public.

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### **What is an intermediate?**

The CDR rule defines an intermediate as “any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions.” See 40 CFR 704.3, referenced by 40 CFR 711.3.

### **What is a non-isolated intermediate?**

A non-isolated intermediate is “any intermediate that is not intentionally removed from the equipment in which it 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. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers isolates the substance by removing it from process equipment in which it is manufactured.” See 40 CFR 704.3, referenced by 40 CFR 711.3.

## How do I determine if my chemical substance is a non-isolated intermediate that is exempt from CDR reporting requirements?

The manufacture of a non-isolated intermediate is exempt from reporting requirements under CDR. See 40 CFR 711.10(c) and 40 CFR 720.30(h)(8).

You must consider the entire process sequence from manufacture to use of an intermediate to determine whether or not an intermediate chemical substance is a “non-isolated intermediate.” Evaluating the following questions can help you make this determination.

### *a. Does the chemical substance function as an intermediate?*

If the chemical substance is not partially or totally consumed for the intentional manufacture of another chemical substance or a mixture (or intentionally present for the purpose of altering the rate of such a chemical reaction), then it is not an intermediate. See 40 CFR 704.3, referenced by 40 CFR 711.3. If it is not an intermediate, it cannot be a non-isolated intermediate.

### *b. Was the intermediate “intentionally removed from the equipment in which it was manufactured”?*

A non-isolated intermediate is an intermediate that is not intentionally removed from the equipment in which it was manufactured. The “equipment in which [the intermediate] was manufactured” is defined to include the following (40 CFR 704.3, referenced by 40 CFR 711.3):

- the reaction vessel in which the intermediate is manufactured,
- equipment which is ancillary to the reaction vessel, and
- any equipment through which the substance passes during a continuous flow process (not including tanks or other vessels in which the substance is stored after its manufacture).

If a particular volume portion of an intermediate is isolated, it is possible that the remaining volume portion of the intermediate may still be considered a non-isolated intermediate. The volume portion that is isolated is subject to CDR reporting requirements, while the remaining volume portion that is non-isolated is exempt from reporting.

### *c. Was the intermediate “stored after its manufacture”?*

A chemical substance is considered to be stored if it has been “intentionally removed from the equipment in which it is manufactured” (such as a reaction vessel) and transferred into equipment where it is “stored after being manufactured.” Such intentional storage of a chemical intermediate is considered isolation, regardless of the length of storage and whether the storage is termed “holding,” and even if the transfer into the storage equipment is enclosed.

However, EPA generally would not consider an intermediate to have been isolated or stored when it is being temporarily held solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process – such as heating, cooling, filtration, or reaction. Other examples of holding that EPA would generally consider to have a clear technical relationship to the needs of the overall manufacturing process are:

- holding to accommodate different reaction rates and varying flow rates or transfer times;
- holding during repair or maintenance of the intermediate’s manufacturing equipment; and
- holding that is necessary for analytical sampling.

In evaluating the particular facts of such cases, the absence of any storage purpose (see 40 CFR 704.3) is the key determining factor: if the chemical substance is being held for storage purposes, it has been isolated. Conversely, if the material is being held solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process, that is an indication that there is not a storage purpose and that the chemical substance has not been isolated.

*d. Which pieces of equipment can be considered “ancillary to the reaction vessel”?*

EPA interprets the phrase “ancillary” as consisting of equipment that is auxiliary or supplemental to the reaction vessel and is used for performing necessary or important parts of the manufacturing process involving the intermediate, such as filtration, distillation, drying, size (volume) reduction, heating or cooling. Equipment that provides primary operational support to the reaction vessel itself, such as equipment for metering or controlling the reaction within the vessel, also would be considered as ancillary. See 40 CFR 710.3 (emphasizing that such equipment must be “strictly ancillary”). EPA does not consider equipment to be ancillary merely because it is located adjacent to or within the same process sequence as the reaction vessel. For example, EPA does not consider pipes and pumps used to transfer a chemical from the reactor to a storage vessel as equipment “ancillary to the reaction vessel.” These pieces of equipment serve the purpose of storage and transfer; not the manufacturing purpose of the reaction vessel.

**Examples of isolated and non-isolated intermediates**

Example	Isolated, Reportable	Non-isolated, Not Reportable
An intermediate sent off-site for reclamation.	X	
An intermediate that is transferred into an open or closed tank for long-term storage.	X	
An intermediate that is transferred to a closed container for shipment or sale.	X	
An intermediate that is temporarily transferred to a closed vessel while the equipment in which it was manufactured is being repaired.		X
Quality control samples taken of an intermediate during the manufacturing process, or the intermediate being held in the reaction vessel in which it was manufactured during and solely for a quality control analysis of that intermediate.		X
Portion of an otherwise non-isolated chemical intermediate that is accidentally released due to equipment failure or necessary maintenance.		X
Portion of an otherwise non-isolated chemical intermediate that is left as a residue in the reaction vessel.		X
Intermediate is consumed in the same reaction vessel in which it was manufactured (provided that it hasn't been held there for storage purposes).		X
Intermediate is manufactured in a reaction vessel and subsequently transferred in an enclosed loop system to an enclosed processing unit (such as a drum filter used to remove impurities) and then to a reaction vessel to be consumed in a reaction.		X
Portion of an otherwise non-isolated chemical intermediate that is incidentally caught in the catalysts when the reaction catalysts are annually removed and replaced.		X
Portion of an otherwise non-isolated chemical intermediate that is incidentally caught in the filter media when the filters are exchanged during routine maintenance (i.e., removal of intermediate is limited to the quantities incidentally caught in the filter media).		X
Chemical intermediate that is recovered for subsequent commercial purposes such as a filter cake and then manually transferred to another piece of equipment.	X	
Chemical intermediate that is held in a flow-through storage tank or other intermediate storage (e.g., silo) for a continuous process, provided the storage residence time isn't limited to the time required to complete an activity with a clear technical relationship to the overall manufacturing process (e.g., dissolution in water, heating, cooling, filtration, or reaction)	X	

## Specific Case Studies

### Case Study A

***Company A manufactures Chemical Intermediate X in Reactor 1. After manufacture, Chemical Intermediate X is transferred via mechanical means inside a closed system to a tank. From this tank, Chemical Intermediate X is then transferred to Reactor 2 where it is consumed in a subsequent reaction. The tank, reactors and connecting lines are all enclosed. Is the mechanical transfer from Reactor 1 to the tank considered an isolation step?***

To determine whether or not the transfer to the tank is an isolation step, Company A must determine whether Chemical Intermediate X is being stored between being manufactured in Reactor 1 and being consumed in Reactor 2.

Suppose there is a closed vessel between Reactor 1 and Reactor 2 that temporarily accommodates the newly formed intermediate during its continuous flow from Reactor 1 to Reactor 2, solely to allow space for surges of intermediate-containing material out of Reactor 1. If that is the only hold, the transfer between Reactor 1 and Reactor 2 is not an isolation step, since any hold between Reactor 1 and Reactor 2 is solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process.

Alternatively, suppose there is a closed vessel between Reactor 1 and Reactor 2 that is being used solely to heat, cool, or filter Chemical X before transfer to Reactor 2. These are the sole purposes of the hold and they have a clear technical relationship to the needs of the overall manufacturing process. The hold would not be viewed as storage and isolation. If that is the only hold, the transfer between Reactor 1 and Reactor 2 is not an isolation step.

Finally, suppose there is a closed vessel between Reactor 1 and Reactor 2 that is being used to temporarily hold Chemical X for plant operation convenience or non-technical business reasons. This is viewed as storage and the transfer between Reactor 1 and Reactor 2 isolates the intermediate.

### Case Study B

***Company B operates a distillation column, which produces an intermediate stream in the overheads identified as “Distillates (petroleum), straight-run light.” This overheads stream is then fed directly, through a closed system, to an enclosed unit in the plant that is used for alkylation reactions. Would the overheads stream that is the feed to this unit be considered a non-isolated intermediate?***

The transfer of this overheads stream distillates from the distillation column to the alkylation reaction chamber occurs through enclosed equipment, without any holding steps, via a continuous flow process. Therefore, the intermediate stream produced in the distillation column and transferred to the reaction chamber is considered to be a non-isolated intermediate.

### **Case Study C**

***Company C operates a distillation column, which produces an intermediate stream in the overheads identified as “Distillates (petroleum), straight-run light.” This overheads stream is then fed directly, through a closed system, to a drop tank until there is a volume of intermediate that is convenient to use in that plant’s alkylation unit. Would the overheads stream that is the feed to this unit be considered a non-isolated intermediate?***

Whether the intermediate stream is considered isolated or non-isolated is dependent on factors that were not included in the description. Depending upon the situation, the use of the drop tank could be for storage or it could be solely for purposes that have a clear technical relationship to the needs of the overall manufacturing process.

Isolated intermediate: If the alkylation unit is intended to only be run occasionally, such as when an order for product is placed, then the drop tank would be used to store the intermediate stream until the alkylation unit is running. Although the transfer is accomplished through a closed system, the normal operation of the system includes a storage step and the intermediate is considered isolated in the drop tank.

Non-isolated intermediate: If the alkylation unit is run continuously, but the distillation column is run intermittently because the rate of reaction of the intermediate in the alkylation unit is lower than the rate of manufacture of the intermediate in the distillation column, there may be some intermediate that accumulates in the drop tank. Even though some intermediate may be held in the drop tank, this is done for reasons that have a clear technical relationship to the needs of the overall manufacturing process; the hold is not for business reasons or for plant operation convenience. The intermediate is considered to be non-isolated.

### **Case Study D**

**Company D manufactures chemical substance A, which will be reacted with other chemicals to manufacture product B. Chemical substance A, therefore, is an intermediate. The equipment used to manufacture A and B is enclosed and can be operated in a continuous flow manner. The process to manufacture A is slow, so that portion of the process runs continuously. The process to manufacture B is much faster, and therefore, the company typically waits until it has orders for product B before running the second half of the process. Is chemical substance A a non-isolated intermediate?**

Although chemical substance A is held in part because of the different rates of reaction, it is also being held for reasons that do not have a clear technical relationship to the needs of the overall manufacturing process (i.e., the desire to not run the reactor to manufacture product B until Company D has orders). Therefore, the hold on chemical substance A constitutes storage and chemical substance A is isolated.

### **Case Study E**

**A reactor in which an intermediate substance is manufactured is equipped with a surge tank that temporarily and reversibly accommodates some of the reaction mixture that surges out of the reactor when there is an exothermic expansion, excessive foaming, or some other type of pressure build-up in the reaction mixture that forces some of it (already containing a portion of the newly-formed intermediate) to flow into the surge tank until the reaction conditions stabilize. All of the vessels and lines are enclosed and the transfer or flow of reaction mixture occurs by mechanical or gravitational means or as a spontaneous flow as part of releasing pressure in the reactor. After the surging reaction mixture returns to the reactor and the manufacture of the intermediate is completed, the intermediate will be consumed in the same reactor to manufacture the final product. Is the intermediate in the reaction mixture that flows into the surge tank considered non-isolated?**

This surge tank performs a holding function for one purpose only, which bears a clear technical relationship to the needs of the overall manufacturing process (i.e., addressing pressure build-up in the course of the reaction). The intermediate is not isolated by being held in the surge tank.

### **Case Study F**

**Company F manufactures substance C and transfers a portion through an enclosed, continuous flow system to a second reactor to manufacture chemical substance D, which is subsequently used for a commercial purpose. The remaining portion of substance C is transferred to a storage tank for later use for a different commercial purpose. Is any portion of substance C considered a non-isolated intermediate?**

The portion of substance C that is transferred through an enclosed, continuous flow system to a *second reactor* (where it is used to manufacture chemical substance D) is considered to be a non-isolated intermediate. The portion of substance C that is transferred to a storage tank is isolated. Reporting under CDR for the isolated portion of substance C would be required if the isolated portion of substance C meets the other reporting requirements.

### **Case Study G**

**Company G manufactures Chemical Y in Reactor 1 as part of a continuous flow process. After manufacture, Chemical Y is held in an in-line, flow-through tank where it is dissolved in water. From this tank, Chemical Y is then transferred to Reactor 2 where it is consumed in a subsequent reaction. Is the hold in the flow-through storage tank considered an isolation step?**

Whether the residence time in the tank is considered isolated or non-isolated is dependent on factors that were not included in the process description. Depending upon the situation, the flow-through tank could be used for storage or used solely for purposes with a clear technical relationship to the needs of the overall manufacturing process.

**Isolated intermediate:** If the residence time in the tank exceeds the duration needed for dissolution of Chemical Y with water and the additional residence time in the tank does not have a clear technical relationship to the needs of the overall manufacturing process, then Chemical Y is considered isolated in the tank and reportable. For example, holding sufficient volume to maintain process operation in the event of a shutdown is considered storage that is not a clear technical relationship to the needs of the process. Therefore, Chemical Y would be considered isolated with respect to the flow-through tank

**Non-isolated intermediate:** If the residence time in the tank is limited only to the time required for dissolution of Chemical Y with water, then the use of the in-line, flow-through tank would be considered to have a clear technical relationship to the needs of the overall manufacturing process. Therefore, Chemical Y would be considered non-isolated with respect to the flow-through tank.

**For further information:**

To access copies of additional fact sheets and other CDR information, visit [www.epa.gov/cdr](http://www.epa.gov/cdr).

If you have questions about CDR, you can contact the TSCA Hotline by phone at 202-554-1404 or e-mail your question to [eCDRweb@epa.gov](mailto:eCDRweb@epa.gov).