

# CBI SUBSTANTIATION

## *General filing*

Use of this form is recommended, but not required.

This Document Contains CBI: Yes  NO

Technical Contact: [REDACTED]

Technical Contact Phone Number: [REDACTED]

Submission number (if known): [Click here.](#)

Submitting Company Name: [REDACTED]

**Information element(s) claimed as CBI \*:** Please identify the information element(s) that you are substantiating from the list below.

*You are responsible for substantiating each information element claimed as CBI (unless that item is exempt from the substantiation requirement—see endnote 1). Any information element that is not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter, it shall be determined that you have waived your CBI claim. If a single substantiation response applies for all information claimed as CBI, you should indicate this in your substantiation response. If different substantiation responses are necessary to support CBI claims for different information types, you should provide separate substantiation responses for each information type, clearly identifying the information for which each substantiation applies in the free text boxes (e.g. Question B) or in the additional information box at the end of this form.*

*\*The generic template information elements and their descriptions were sourced from the Office of Pollution Prevention and Toxics' Confidential Business Information Tracking System (CBITS), a legacy Oracle database, and EPA Form No. 7710-58, "TSCA Health and Safety Study Coversheet".*

<input checked="" type="checkbox"/> Submitter	<input type="checkbox"/> Export Date
<input type="checkbox"/> Chemical	<input type="checkbox"/> Country
<input type="checkbox"/> Volume	<input type="checkbox"/> Release
<input type="checkbox"/> Use	<input type="checkbox"/> Site
<input checked="" type="checkbox"/> Plant Site	<input type="checkbox"/> Mixture
<input type="checkbox"/> Process	<input type="checkbox"/> Financial
<input type="checkbox"/> Properties	<input checked="" type="checkbox"/> Privacy
<input type="checkbox"/> Exposure	<input type="checkbox"/> Report/Study Title
<input type="checkbox"/> Envir-Release	<input type="checkbox"/> Report Study Information

**Other information elements claimed as CBI** (Please list any other CBI claim or any TSCA Section 14(c)(2) assertion not listed above):

We are specifically claiming the following information as CBI:

- technical contact name and details (as associated with submitter company name)
- submitter company name, address, plant sites and associated details
- name of other companies named in the report and their plant site information.

This information will not be subject to the disclosure requirements of section 14(b) of TSCA.

We are NOT claiming the specific chemical identity or CASRN of the chemical as CBI.

**I. REQUIRED FOR ANY IDENTIFIED CBI CLAIM**

A. Do you believe that any information element claimed as CBI is exempt from substantiation pursuant to TSCA section 14(c)(2)<sup>1</sup>?  Yes  No

*If you answered yes, you must identify the specific information element(s), provide the specific exemption(s) and answer no further questions. For any information element that is not exempt, please respond to all of the questions below.*

If the Agency disagrees with this assertion, you may be asked to provide additional information to support your claim.

[Click or tap here to enter text.](#)

B. Will disclosure of any information element claimed as CBI likely result in substantial harm to your business's competitive position?  Yes  No

*(If you answered yes, please describe with specificity the substantial harmful effects that would result to your competitive position if the CBI information element is made available to the public.)*

*If you are claiming multiple information elements, please make sure to provide information for EACH element you identified above. If a single substantiation response applies for all information claimed as CBI, you should indicate this in your substantiation response.*

This information applies to all CBI claims for this submission.

Due to the historical nature of the full report, we assert an assert a claim of confidentiality for information related to all company names in the report and associated details. We are unable to determine if the other companies named in the report are aware of its existence, or the relevant contacts in these companies related to the substance. Due to privacy issues, we believe the identities of these companies should not be disclosed without express permission of an authorized company representative.

The name and contact details of the technical contact for the notifying company is claimed as CBI along with the submitting company. Associated contact information (email; phone and fax number; mailing address) is also claimed as CBI for privacy reasons. If name is disclosed, link to company identity (also claimed as confidential) is easily discoverable via a simple internet search.

The sanitization of the report to remove the identified CBI information does not alter the health-related data discussed in the report.

This information will not be subject to the disclosure requirements of section 14(b) of TSCA.

C. To the extent your business has disclosed any information to others (both internally and externally), what precautions has your business taken? Please identify the measures or internal controls your business has taken to protect the information claimed as confidential.

1. Non-disclosure agreement required prior to access.  Yes  No

2. Access is limited to individuals with a need-to-know.  Yes  No

3. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.).  Yes  No

4. Other internal control measure(s). *(If yes please explain below.)*  Yes  No  
This information applies to all CBI claims for this submission.

Any employees or contractors who may have knowledge or access to this toxicological report or the company systems (computer and hard copy files) housing this data are under confidentiality obligations to the company. Access to this type of confidential information is limited to those employees and contractors whose duties necessitate their having such information.

This type of information (full report) would not be made available to any person or persons outside the company in the absence of a written confidentiality agreement or contract. The agreement or contract prohibits the company information designated as CBI to any person or persons not expressly designated as eligible to receive this information.

Additionally, access to CBI identified information is not made available to all employees within the company. Security protocols are in place regarding access to company facilities, offices and computer systems. Access to computer systems containing this information must be approved by a management official, and logs are maintained documenting personnel who have access to these systems. Not all company employees have authorization or are able to access these systems.

Company facilities are not open to the general public and the information related to this submission is located in employee-restricted areas. Any employee or non-employee who is not under a specific confidentiality obligation is denied access to any location within a facility where confidential information may be disclosed. All prospective publications which may disclose confidential information are screened by an attorney to delete any such information prior to publication.

D. Does any of the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public?  Yes  No

*(If you answered yes, please explain why the information should be treated as confidential.)*

This information applies to all CBI claims for this submission.

The full report submitted by the company is not available in any promotional or technical documentation available for public review. As far as we can determine, the full report is not readily accessible via search in public or academic libraries, or in local or federal agency files. Furthermore, outside of the specific companies named in the report, the company does not believe the full report has been disclosed to the public, or other third parties, through technical journals or other publications.

The information contained in the full report is not disclosed on a distributed Safety Data Sheet (SDS), label, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public.

- E. Does any of the information you are claiming as CBI contain (a) trade secret(s)<sup>2</sup>?  Yes  
 No
- (If you answered yes, please explain the reason for your belief and attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).)*

Click or tap here to enter text.

- F. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(e)(1)(B)<sup>3</sup>), then please indicate the number of years (between 1-10 years) or specific date of which the claim is withdrawn<sup>4</sup>?

This information applies to all CBI claims for this submission.

Due to the historical nature of the full report, we assert an assert a claim of confidentiality of at least 10 years. We are unable to determine if the other companies named in the report are aware of its existence, or the relevant contacts in these companies related to the substance. We believe the identities of these companies should not be disclosed without express permission of an authorized company representative.

The sanitization of the report to remove the identified CBI information does not alter the health-related data discussed in the report.

- G. Has the EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance?  Yes  
 No
- (If you answered yes, please explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.)*

This information applies to all CBI claims for this submission.

To the best of my knowledge or our records search, neither EPA, nor any other federal agency or US court has not made any confidentiality determination regarding information associated with this report.

**Additional comments:**

Click or tap here to enter text.

**II. REQUIRED ONLY FOR CHEMICAL IDENTITY CBI CLAIMS**

- A. Are you claiming a specific chemical identity as CBI?  Yes  
 No
- (If you answered yes, please respond to questions below.  
If you answered no, please leave all questions below blank.)*

<p>B. Is the chemical substance (or mixture) on the confidential portion of TSCA Inventory?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
<p>C. Has the chemical substance (or mixture) been offered for commercial distribution?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Click or tap here to enter text.</p>	
<p>D. Is the chemical substance known to be in US commerce?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Click or tap here to enter text.</p>	
<p>E. Would disclosure of the specific chemical name release confidential process information?</p> <p><i>(If you answered yes, please explain what process information would be released.)</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Click or tap here to enter text.</p>	
<p>F. In the case of a mixture, would disclosure of the chemical name disclose a portion of the mixture comprised by any of the chemical substances in the mixture?</p> <p><i>(If you answered yes, please explain what information would be released.)</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Click or tap here to enter text.</p>	
<p>G. Does this particular chemical substance leave the site of manufacture (including import) in any form, e.g., as a product, effluent, emission?</p> <p><i>(If yes, please explain what measures have been taken to guard against the discovery of its identity.)</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Click or tap here to enter text.</p>	
<p>H. If the chemical substance leaves the site in a form that is available to the public or your competitors, can the chemical identity be readily discovered by analysis of the substance (e.g., product, effluent, emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies?</p> <p><i>(Please explain why or why not.)</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Click or tap here to enter text.</p>	
<p><b>Additional comments:</b></p>	
<p>Click or tap here to enter text.</p>	

### III. SUBSTANTIATION CERTIFICATION

Do you wish to claim this substantiation as CBI?

Yes

*TSCA section 14(c) requires that persons asserting a CBI claim shall certify to the validity of the claims. By the marking of a yes, you are certifying to the truth of the below statements.*

No

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- (i) My company has taken reasonable measures to protect the confidentiality of the information;
- (ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
- (iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

September 29, 2021

<sup>1</sup> **“TSCA Section 14(c)(2) states:**

Information generally not subject to substantiation requirements

Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(B) Marketing and sales information.

(C) Information identifying a supplier or customer.

(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

(F) Specific production or import volumes of the manufacturer or processor.

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

<sup>2</sup> **“Trade secret”** is defined as “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.” Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

<sup>3</sup> **“TSCA section 14(e)(1)(B) States”**

(B) in the case of information other than information described in subsection (c)(2)—

(i) for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator; or

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(ii) if applicable before the expiration of such 10-year period, until such time as—

(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or

(II) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g).

<sup>4</sup> Information with withdrawn CBI claims may be made available to the public without further notice.