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| **CBI SUBSTANTIATION**  ***8(e) submission***  Use of this form is recommended, but not required. | | | | |
| **Technical Contact Name:** | Click or tap here to enter text. | | | |
| **Technical Contact Phone Number:** | Click or tap here to enter text. | | | |
| **Technical Contact Email:** | Click or tap here to enter text. | | | |
| **Submitting Company Name:** | Click or tap here to enter text. | | | |
| **Submission Number (if known):** | Click or tap here to enter text. | | | |
| ***Important:*** *You are responsible for substantiating* ***each*** *data element claimed as CBI unless that item is exempt from the substantiation requirement according to TSCA section 14(c)(2).  (With the exception of chemical identity information discussed in Section II, below, EPA does not believe that any of the section 14(c)(2) exemptions generally apply to information provided in this submission type.)*  *Where a substantiation explanation applies to more than one information type that you have claimed as CBI, you may substantiate them as a group. However, your substantiation must also clearly indicate which CBI claim(s) it is intended to cover.*  *40 CFR § 2.208 specifies the substantive criteria that are used to determine whether information is entitled to confidential treatment. Among these criteria is the substantial competitive harm(s) that would be caused by public disclosure of the information that you have claimed as CBI. Failure to sufficiently explain this harm in the substantiation for any data element claimed as CBI may result in a denial of the CBI claim for that data element.* | | | | |
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| 1. **APPLICABLE TO ANY CBI CLAIM** | | | |
| 1. Please identify each information element being claimed as CBI and the likely substantial harm to your business’s competitive position if the information were publicly disclosed: | | | |
| A.1: Are you are claiming **“Submitter Information”** as CBI?  Please explain how public disclosure of this information is likely to cause substantial harm to your business’s competitive position. | | | Yes  No |
| Click or tap here to enter text. | | | |
| A.2: Are you are claiming **“Technical Contact”** as CBI?  Please explain how public disclosure of this information is likely to cause substantial harm to your business’s competitive position. | | | Yes  No |
| Click or tap here to enter text. | | | |
| A.3 Are you are claiming other information as CBI?  If so, please list the information type and explain how public disclosure of this information is likely to cause substantial harm to your business’s competitive position. | | | Yes  No |
| Click or tap here to enter text. | | | |
| 1. 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. | | | |
| Non-disclosure agreement required prior to access. | | Yes No | |
| Access is limited to individuals with a need-to-know. | | Yes No | |
| Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.). | | Yes No | |
| Other internal control measure(s). *(If yes please explain below.).* | | Yes No | |
| Click or tap here to enter text. | | | |
| * + 1. 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 public?   *(If you answered yes, please explain why the information should be treated as confidential.)* | | Yes  No | |
| Click or tap here to enter text. | | | |
| * + 1. Does any of the information you are claiming as CBI contain (a) trade secret(s)[[1]](#endnote-1)?   *(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).)* | | Yes  No | |
| Click or tap here to enter text. | | | |
| * + 1. Has this substance been issued a [Unique Identifier](https://www.epa.gov/sites/production/files/2018-06/documents/epa-hq-oppt-2017-0144-0024.pdf) (UID)? The current list of Unique Identifiers can be found [here](https://chemview.epa.gov/chemview/proxy?filename=Public_UID_list_11-29-18.htm). If so, please provide below. | | Yes  No  Don’t Know | |
| Click or tap here to enter text. | | | |
| * + 1. Has the EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance?   *(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.)* | | Yes  No | |
| Click or tap here to enter text**.** | | | |
| * + 1. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(e)(1)(B)[[2]](#endnote-2)), then please indicate the number of years (between 1-10 years) or specific date on which the claim is withdrawn[[3]](#endnote-3). | | | |
| Click or tap here to enter text**.** | | | |
| **Additional comments:** | | | |
| Click or tap here to enter text. | | | |

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| **II. APPLICABLE ONLY TO CHEMICAL IDENTITY CBI CLAIMS**  ***Note:*** *Section 14(c)(2) of TSCA provides that certain information in TSCA submissions is exempt from up-front substantiation requirements. If the substance that is the subject of your section 8(e) report has not been offered for commercial distribution in the United States, the following substantiation exemption may apply: “Information generally not subject to substantiation requirements . . . (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.”* | | | |
| A: Are you claiming a **specific chemical identity** as CBI? If not, you need not answer  any further questions in this section. If so, please explain how public disclosure of this information is likely to cause substantial harm to your business’s competitive position. | | Yes  No | |
| Click or tap here to enter text. | | | |
| 1. Is the test substance a discreet chemical or part of a mixture/formulation? | | | Discreet Chemical  Mixture or Formula |
| 1. Is the test substance an R&D chemical, a pesticide, or part of a pesticide product? | | | Yes  No |
| 1. What is the current TSCA Inventory status of the test substance? | On the public TSCA Inventory  On the confidential TSCA Inventory  Not on the Inventory  Don’t know | | |
| 1. When this chemical substance leaves the site of manufacture in any form, *e.g.,* as product, effluent, emission, what measures are taken to guard against the discovery of its identity? When the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product? | | | |
| Click or tap here to enter text. | | | |
| 1. Would disclosure of the specific chemical name release confidential process information?   *(If you answered yes, please explain what process information would be released.)* | | | Yes  No |
| Click or tap here to enter text. | | | |
| 1. 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?   *(If you answered yes, please explain what information would be released.)* | | | Yes  No  Don’t Know |
| Click or tap here to enter text. | | | |
| **Additional comments:** | | | |
| Click or tap here to enter text. | | | |

No



No



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| 1. **SUBSTANTIATION CERTIFICATION** |

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| **Do you wish to claim this substantiation as CBI?**  *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.* | Yes  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   1. My company has taken reasonable measures to protect the confidentiality of the information; 2. I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law; 3. 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 4. 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. | |

1. **“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). [↑](#endnote-ref-1)
2. **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

   (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). [↑](#endnote-ref-2)
3. Information with withdrawn CBI claims may be made available to the public without further notice. [↑](#endnote-ref-3)