|  |
| --- |
| **CBI SUBSTANTIATION*****for non-chemical identity claims made in a******Notice of Commencement (NOC)*** 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. |
| **Premanufacture notice (PMN) number:** | 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). (EPA does not believe that any of the section 14(c)(2) exemptions generally apply to information provided in this submission type.)* *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.*  |

|  |
| --- |
| 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 claiming “**Submitter Information** (Part I)” as CBI?If yes, 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 claiming “**Technical Contact** (Part I)” as CBI?If yes, 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 claiming “**Plant Site** (Part IV)” as CBI?If yes, 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. 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.
 |
| B.1 Non-disclosure agreement required prior to access. | [ ]  Yes [ ]  No  |
| B.2 Access is limited to individuals with a need-to-know. | [ ]  Yes [ ]  No |
| B.3 Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.). | [ ]  Yes [ ]  No |
| B.4 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 general public?

*(If you answered yes, please explain why the information should be treated as confidential.)*  |  |
| 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).)* |  |
| 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.)* |  |
| 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 of which the claim is withdrawn[[3]](#endnote-3)?
 |
| Click or tap here to enter text**.** |
| **Additional comments:** |
| Click or tap here to enter text. |

|  |
| --- |
| **SUBSTANTIATION CERTIFICATION**  |

|  |  |
| --- | --- |
| **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.*  |  |
| 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 that1. 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)