

**CBI SUBSTANTIATION**  
***For PMN, SNUN, TMEA, LVE-and LOREX filings***

Use of this form is recommended, but not required.  
***PMN***

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Submitting Company Name	Designer Molecules, Inc.
Submission Number (if known):	

***Important:*** You are responsible for substantiating ***each*** information element you claim as CBI, ***including any additional claim(s) made in any attachment to your submission***, unless that item/information is exempt from the substantiation requirement according to TSCA section 14(c)(2), 15 U.S.C. § 2613(c)(2). This template identifies the information that EPA considers to generally be exempt in this submission type. EPA expects that it will generally deny non-exempt CBI claims that are not substantiated, so recommends that the submitter carefully review the TSCA submission to assure that the substantiation addresses all CBI claims that require substantiation. The substantiation must also clearly indicate which CBI claim(s) it is intended to cover. In this template, similar information elements have been grouped together to permit substantiation of multiple such elements at one time.

EPA expects that some types of CBI claims will be more difficult to support than others or are in some cases restricted by TSCA or its implementing regulations. Health and safety studies and information from such studies, with limited exceptions, may not be withheld by EPA as confidential (see TSCA section 14(b), 15 U.S.C. § 2613(b)). TSCA and its implementing regulations recognize that the following information may be claimed as CBI: (1) Processes used in the manufacture or processing of a chemical substance or mixture; (2) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture; and (3) Information which is not in any way related to the effects of a substance on human health or the environment, such as the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans. Claims beyond these types of information may be denied if not supported by appropriate substantiation.

***Overly broad CBI claims, such as indicated in blank or largely blank public versions of a health and safety study, may also cause the Section 5 filing to be declared incomplete. Safety Data Sheets (SDSs) contain health and safety information--CBI claims in SDSs should be limited to information unrelated to the effects of a substance on human health or the environment. When creating sanitized versions of attachments, redact only***

***the information claimed as CBI-- REDACTION INDICATES A CBI CLAIM SO REDACTED INFORMATION MUST BE SUBSTANTIATED.***

*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 information claimed as CBI may result in a denial of the CBI claim for that information. For more information, please visit: <https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations>.*

*The second column (CBI Claim) on this substantiation document is intended to be used to indicate that a CBI claim has been made for the corresponding information in the PMN submission. Please verify that the information you indicate is claimed as CBI on this substantiation document is in fact claimed as CBI in the PMN form and/or attachments. This template cannot be used to assert a CBI claim that is not asserted in the PMN submission.*

*Instructions for using this template:*

- 1. A complete substantiation includes both the questions in Part A (competitive harm) and the questions in Part B (additional questions).*
- 2. The template has been updated to clarify how substantiation should be provided for CBI claims made in attachments. Many CBI claims made in attachments are also made in the relevant submission form. As you are providing substantiation for claims made in the form, you should indicate (using the far righthand column in Part A) whether a claim has been made for the same information in an attachment, and where. For any claims noted in this column in Parts A.I or A.II, you will not need to provide duplicate substantiation in Part A.III.*
- 3. Part A.III is for substantiating CBI claims in that were not substantiated in Part A.I or A.II. In the CBI claim column the submitter should indicate whether there are additional CBI claims in the attachments that were not identified and substantiated in Part A.I or A.II. The substantiation column should list each such additional claim, where it is located in the attachment, and include a description of the competitive harm anticipated if that data were to be disclosed. An example of a claim likely not previously identified and substantiated would be the name of a laboratory that conducted a health and safety study submitted with a PMN. The substantiation must be included in the box provided for such substantiations.*

A. COMPETITIVE HARM QUESTIONS			
Part I Section A Submitter Identification	CBI Claim	Substantiation <i>(Explain how public disclosure of this information is likely to cause substantial harm to your business's competitive position.)</i>	Is this information claimed in an attachment? <i>If so, please list the name of the attachment(s) as noted in the List of Attachments (Part III, PMN Page 12, form 17)</i>
Signature and Date of Authorized Official (Page 2)	<input type="checkbox"/>	Click or tap here to enter text.	
Signature and Date of Agent (Page 2)	<input type="checkbox"/>		
Person Submitting Notice (Part I Section A.1.a)	<input type="checkbox"/>		
Agent (Part I Section A.1.b)	<input type="checkbox"/>		
Joint Submitter (Part I Section A.1.c)	<input type="checkbox"/>	Click or tap here to enter text.	
Technical Contact (Part I Section A.2)	<input type="checkbox"/>	Click or tap here to enter text.	
Pre-notice Communication (PC) (Part I Section A.3)	<input type="checkbox"/>	Click or tap here to enter text.	
Previously Submitted Exemption Application (Part I Section A.4)	<input type="checkbox"/>		
Previously Submitted Bona Fide (Part I Section A.5)	<input type="checkbox"/>		

<b>Part I Section B Chemical Identity Information</b>	<b>CBI Claim</b>	<b>Substantiation</b> <i>(Explain how public disclosure of this information is likely to cause substantial harm to your business's competitive position.)</i>	<b>Is this information claimed in an attachment?</b> <i>If so, please list the name of the attachment(s) as noted in the List of Attachments (Part III, PMN Page 12, form 17)</i>
Chemical Class (Part I Section B.1.a)	<input type="checkbox"/>	<a href="#">Click or tap here to enter text.</a>	
Chemical Name (Part I Section B.1.b)	<input type="checkbox"/>	<p>Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement.</p> <p><a href="#">Click or tap here to enter text, if applicable.</a></p>	
Molecular Formula (Part I Section B.1.d)	<input type="checkbox"/>	<p>Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement.</p> <p><a href="#">Click or tap here to enter text, if applicable.</a></p>	
Chemical Structure Diagram for Class I (Part I Section B.1.e)	<input type="checkbox"/>	<p>Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement.</p> <p><a href="#">Click or tap here to enter text, if applicable.</a></p>	

Precursor Substances Class II (Part I Section B.1.e.1)	<input type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Reaction or Process for Class II (Part I Section B.1.e.2)	<input type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Range of Composition and Typical Composition for Class II (Part I Section B.1.e.3)	<input type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Polymer Information (Part I Section B.2.a)	<input type="checkbox"/>	<p>Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement.</p> <p><a href="#">Click or tap here to enter text, if applicable.</a></p>	
Monomer or Other Reactant Specific Chemical Name (Part I Section B.2.b.1)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Monomer or Other Reactant Specific Chemical Name Typical Composition (Part I Section B.2.b.3)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Monomer or Other Reactant Specific Chemical Name Include in Identity (Part I Section B.2.b.4)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Monomer or Other Reactant Specific Chemical Name Max Residual (Part I Section B.2.b.6)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	

<p>Current Chemical Abstracts (CA) Name and Number for Polymer (Part I Section B.2.d)</p>	<input type="checkbox"/>	<p>Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement.</p> <p>Click or tap here to enter text, if applicable.</p>	
<p>Chemical Structure Diagram (Part I Section B.2.e)</p>	<input type="checkbox"/>	<p>Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement.</p> <p>Click or tap here to enter text, if applicable.</p>	
<p>Impurities (Part I Section B.3)</p>	<input checked="" type="checkbox"/>	<p>Exempt – No substantiation required for this specific information claim</p>	
<p>Synonyms (Part I Section B.4)</p>	<input type="checkbox"/>	<p>Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement.</p> <p>Click or tap here to enter text, if applicable.</p>	

Trade Identification (Part I Section B.5)	<input type="checkbox"/>	Exempt prior to the substance first being offered for commercial distribution – for PMN, LVE, TMEA, and LOREX submissions, no substantiation is required for CBI claims on this specific information. Submitters of SNUNs and requests to modify an LVE or LOREX may not be exempt from this substantiation requirement. <a href="#">Click or tap here to enter text, if applicable.</a>	
Byproducts (Part I Section B.7)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
<b>Part I Section C. Production, Import and Use Information</b>	<b>CBI Claim</b>	<b>Substantiation</b> <i>(Explain how public disclosure of this information is likely to cause substantial harm to your business's competitive position.)</i>	<b>Is this information claimed in an attachment?</b> <i>If so, please list the name of the attachment(s) as noted in the List of Attachments (Part III, PMN Page 12, form 17)</i>
Production Volume (Part I Section C.1)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Category of Use (Part I Section C.2.a.1)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Use Production (Part I Section C.2.a.4)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
% in Formulation (Part I Section C.2.a.6)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
% of Substance Expected Per Use (Part I Section C.2.a.8)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	

<b>Part II Section A</b> <b>Industrial Sites Controlled</b> <b>by the Submitter</b>	<b>CBI</b> <b>Claim</b>	<b>Substantiation</b> <i>(Provide a detailed substantiation explaining how/why of this information is likely to cause substantial harm to your business's competitive position.)</i>	<b>Is this information claimed in an attachment?</b> <i>If so, please list the name of the attachment(s) as noted in the List of Attachments (Part III, PMN Page 12, form 17)</i>
Site Identity (Part II Section A.1.a)	<input type="checkbox"/>	Click or tap here to enter text.	
Number of Sites (Part II Section A.1.a)	<input type="checkbox"/>	Click or tap here to enter text.	
Site Operations (Part II Section A.1.b)	<input type="checkbox"/>	Click or tap here to enter text.	
Amount and Duration (Part II Section A.1.c)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Process Description (Part II Section A.1.d)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Worker Activity (Part II Section A.2.1)	<input type="checkbox"/>	Click or tap here to enter text.	
Physical Form(s) & % New Substance (Part II Section A.2.5)	<input type="checkbox"/>	Click or tap here to enter text.	
# of Workers Exposed (Part II Section A.2.8)	<input type="checkbox"/>	Click or tap here to enter text.	



Maximum Duration (Part II Section A.2.10-11)	<input type="checkbox"/>	Click or tap here to enter text.	
Release Number and Amount of New Substance Released (Part II Section A.3.1-2)	<input type="checkbox"/>	Click or tap here to enter text.	
Medium of Release and Control Technology and Efficiency (Part II Section A.3.4-5)	<input type="checkbox"/>		
Destinations of Releases to Water (Part II Section A.3.7)	<input type="checkbox"/>		
<b>Part II Section B Industrial Sites Controlled by Others</b>	<b>CBI Claim</b>	<b>Substantiation</b> <i>(Explain how public disclosure of this information is likely to cause substantial harm to your business's competitive position.)</i>	<b>Is this information claimed in an attachment?</b> <i>If so, please list the name of the attachment(s) as noted in the List of Attachments (Part III, PMN Page 12, form 17)</i>
Operation Description (Part II Section B.1)	<input checked="" type="checkbox"/>	Exempt – No substantiation required for this specific information claim	
Letter of Activity and # of Workers Exposed (Part II Section B.2.1-2)	<input type="checkbox"/>	Click or tap here to enter text.	
Duration of Exposure (Part II Section B.2.4)	<input type="checkbox"/>	Click or tap here to enter text.	

Protective Equipment/Engineering Controls/Physical Form/ % New Substance/% in Formulation (Part II Section B.2.6-7)	<input type="checkbox"/>	Click or tap here to enter text.	
Release Number and Amount of New Substance Released (Part II Section B.2.9-10)	<input type="checkbox"/>		
Media of Release & Control Technology (Part II Section B.2.12)	<input type="checkbox"/>		
Byproducts (Part II Section B.2.14)	<input type="checkbox"/>		
<b>Additional Information</b>	<b>CBI Claim</b>	<b>Substantiation</b> <i>(Explain how public disclosure of this information is likely to cause substantial harm to your business's competitive position.)</i>	<b>Are information elements found solely in these documents claimed as CBI in an attachment?</b> <i>If so, please list the name of the attachment(s) as noted in the List of Attachments (Part III, PMN Page 12, form 17)</i>
Pollution Prevention Information (PMN page 11, Form page 16)	<input type="checkbox"/>	Click or tap here to enter text.	
Physical and Chemical Properties Worksheet (PMN page 13, Form page 18)	<input type="checkbox"/>	Click or tap here to enter text.	
Other information elements claimed as CBI	<input type="checkbox"/>	Click or tap here to enter text.	

Part III. Attachments.	CBI Claim	<b>Substantiation</b> (Explain how public disclosure of this information is likely to cause substantial harm to your business's competitive position. <u>Be sure to identify and substantiate any additional claims</u> made in attachments that are not covered above. <b>Please note that most health and safety information in attachments cannot be withheld as CBI and should not be redacted from sanitized versions of attachments.</b> . If a claim is covered above, then identify where. If it is not substantiated above, then provide substantiation here. <b>REDACTIONS INDICATE CBI CLAIMS SO ALL REDACTED INFORMATION MUST BE SUBSTANTIATED (unless exempt from the substantiation requirement).</b>
Additional CBI claims made in any attachment that are not covered above.	<input type="checkbox"/>	Click or tap here to enter text.

## B. ADDITIONAL QUESTIONS

I. To the extent the submitter has disclosed information to others (both internally and externally), what precautions has the business taken to protect the information? Please identify the measures or internal controls the 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

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

II. Does 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

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

III. Does any of the information you are claiming as CBI contain (a) trade secret(s)<sup>1</sup>? *(If yes, please identify what information is being claimed as (a) trade secret(s).)*

☐ Yes  
☒ No

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

IV. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? *(If 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.](#)

VI. *(Applicable only to SNUNs or to requests to modify a granted LVE or LOREX submission AND only if chemical identity is claimed as confidential.)* 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.](#)

**Additional comments:**

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

## III. SUBSTANTIATION CERTIFICATION

Do you wish to claim this substantiation as CBI?

☐ Yes

*TSCA section 14(c), 15 U.S.C. § 2613(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.

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<sup>1</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).