

# CBI SUBSTANTIATION

## *Premanufacture notice*

Use of this form is recommended, but not required.

**This Document Contains CBI:** Yes  NO

**Technical Contact:** Saadia Eltayeb

**Technical Contact Phone Number:** 202-828-8965

**Submission number (if known):** P-17-0256

**Submitting Company Name:** Kao Specialties Americas LLC

**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.*

<input type="checkbox"/> Signature and Date of Authorized Official (Page 2)	<input checked="" type="checkbox"/> Production Volume (Part I Section C.1)*
<input type="checkbox"/> Signature and Date of Agent (Page 2)	<input checked="" type="checkbox"/> Category of Use (Part I Section C.2.a.1)*
<input type="checkbox"/> Person Submitting Notice (Part I Section A.1.a)	<input checked="" type="checkbox"/> Use Production (Part I Section C.2.a.4)*
<input type="checkbox"/> Agent (Part I Section A.1.b)	<input checked="" type="checkbox"/> % in Formulation (Part I Section C.2.a.6)*
<input type="checkbox"/> Joint Submitter (Part I Section A.1.c)	<input checked="" type="checkbox"/> % of Substance Expected Per Use (Part I Section C.2.a.8)*
<input type="checkbox"/> Technical Contact (Part I Section A.2)	<input type="checkbox"/> Site Identity (Part II Section A.1.a)
<input type="checkbox"/> Prenotice Communication (PC) (Part I Section A.3)	<input type="checkbox"/> Number of Sites (Part II Section A.1.a)
<input type="checkbox"/> Previously Submitted Exemption Application (Part I Section A.4)	<input type="checkbox"/> Site Operations (Part II Section A.1.b)
<input type="checkbox"/> Previously Submitted Bona Fide (Part I Section A.5)	<input type="checkbox"/> Amount and Duration (Part II Section A.1.c)*
<input type="checkbox"/> Chemical Class (Part I Section B.1.a)	<input type="checkbox"/> Process Description (Part II Section A.1.d)*
<input type="checkbox"/> Chemical Name (Part I Section B.1.b)**	<input type="checkbox"/> Worker Activity (Part II Section A.2.1)
<input type="checkbox"/> Molecular Formula (Part I Section B.1.d)**	<input type="checkbox"/> Physical Form(s) & % New Substance (Part II Section A.2.5)
<input type="checkbox"/> Chemical Structure Diagram for Class I (Part I Section B.1.e)**	<input type="checkbox"/> # of Workers Exposed (Part II Section A.2.8)
<input type="checkbox"/> Precursor Substances Class II (Part I Section B.1.e.1)*	<input type="checkbox"/> Maximum Duration (Part II Section A.2.10-11)
<input type="checkbox"/> Reaction or Process for Class II (Part I Section B.1.e.2)*	<input type="checkbox"/> Release Number and Amount of New Substance Released (Part II Section A.3.1-2)
<input type="checkbox"/> Range of Composition and Typical Composition for Class II (Part I Section B.1.e.3)*	<input type="checkbox"/> Medium of Release and Control Technology and Efficiency (Part II Section A.3.4-5)
<input checked="" type="checkbox"/> Polymer Information (Part I Section B.2.a)**	<input type="checkbox"/> Destinations of Releases to Water (Part II Section A.3.7)
<input checked="" type="checkbox"/> Monomer or Other Reactant Specific Chemical Name (Part I Section B.2.b.1)*	<input checked="" type="checkbox"/> Operation Description (Part II Section B.1)*
<input type="checkbox"/> Monomer or Other Reactant Specific Chemical Name Typical Composition / Include in Identity (Part I Section	<input type="checkbox"/> Letter of Activity and # of Workers Exposed (Part II Section B.2.1-2)

B.2.b.3-4)	
<input type="checkbox"/> Monomer or Other Reactant Specific Chemical Name Max Residual (Part I Section B.2.b.6)	<input type="checkbox"/> Duration of Exposure (Part II Section B.2.4)
<input checked="" type="checkbox"/> Current Chemical Abstracts (CA) Name and Number for Polymer (Part I Section B.2.d)**	<input type="checkbox"/> Protective Equipment/Engineering Controls/Physical Form/ % New Substance/% in Formulation (Part II Section B.2.6-7)
<input checked="" type="checkbox"/> Chemical Structure Diagram (Part I Section B.2.e)**	<input type="checkbox"/> Release Number and Amount of New Substance Released (Part II Section B.2.9-10)
<input type="checkbox"/> Impurities (Part I Section B.3)	<input type="checkbox"/> Media of Release & Control Technology (Part II Section B.2.12)
<input type="checkbox"/> Synonyms (Part I Section B.4)	<input type="checkbox"/> Byproducts (Part II Section B.2.14)
<input type="checkbox"/> Trade Identification (Part I Section B.5)	<input type="checkbox"/> Pollution Prevention Information (PMN page 11, form page 16)
<input checked="" type="checkbox"/> Byproducts (Part I Section B.7)	<input checked="" type="checkbox"/> Physical and Chemical Properties Worksheet (PMN page 13, Form page 18)***
<input checked="" type="checkbox"/> <b>Other information elements claimed as CBI</b> (Please list any other CBI claim or any TSCA Section 14(c)(2) assertion not listed above): CAS IES Report Physical Chemical Properties-IR Spectrum and Water Solubility GPC Report SDS Attachment for Process Diagram-Processing at Sites Controlled by Others-Section 14(c)(2)(A) Attachment for Process Diagram-Use at Sites Controlled by Others-Section 14(c)(2)(A) Attachment for Algal Growth Inhibition Test Report Acute Toxicity in Fish Report Acute Immobilization Study in Daphnia magna Report Additional Information-PMN page 5-Section 14 (c)(2)(A)	

**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.

Monomer or Other Reactant Specific Chemical Name (Part I Section B.2.b.1)-Section 14(c)(2)(A)  
Production Volume (Part I Section C.1)-Section 14(c)(2)(F)  
Category of Use (Part I Section C.2.a.1)-Section 14(c)(2)(E)  
Use Production (Part I Section C.2.a.4)-Section 14(c)(2)(E)  
% in Formulation (Part I Section C.2.a.6)-Section 14(c)(2)(E)  
% of Substance Expected Per Use (Part I Section C.2.a.8)-Section 14(c)(2)(E)  
Operation Description (Part II Section B.1) for both Processing and Use Operations-Section 14(c)(2)(A)  
Attachment for Process Diagram-Processing at Sites Controlled by Others-Section 14(c)(2)(A)  
Attachment for Process Diagram-Use at Sites Controlled by Others- Section 14(c)(2)(A)  
Additional Information-PMN page 5-Section 14 (c)(2)(A)

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.*

We are claiming Polymer Information (Part I Section B.2.a), Current Chemical Abstracts (CA) Name and Number for Polymer (Part I Section B.2.d), Chemical Structure Diagram (Part I Section B.2.e), CAS IES Report, IR spectrum, and GPC report as CBI and offer the following substantiation:

We are claiming the Byproducts (Part I. Section B.7) as CBI and offer the following substantiation:

We are claiming the SDS as CBI and offer the following substantiation:

We are claiming the Water solubility study as CBI and offer the following substantiation:

We are claiming the following test reports as CBI: Algal Growth Inhibition Test Report; Acute Toxicity in Fish Report; Acute Immobilization Study in Daphnia magna Report for the following reasons:

<p>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.</p>	
1. Non-disclosure agreement required prior to access.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2. Access is limited to individuals with a need-to-know.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.).	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4. Other internal control measure(s). <i>(If yes please explain below.)</i> Click or tap here to enter text.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>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?</p> <p><i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p> <p>Click or tap here to enter text.</p>	
<p>E. Does any of the information you are claiming as CBI contain (a) trade secret(s)<sup>2</sup>?</p> <p><i>(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).)</i></p> <p>Click or tap here to enter text.</p>	
<p>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>?</p> <p>Click or tap here to enter text.</p>	
<p>G. Has the EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance?</p> <p><i>(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.)</i></p> <p>Click or tap here to enter text.</p>	
<p><b>Additional comments:</b></p> <p>Click or tap here to enter text.</p>	

## II. REQUIRED ONLY FOR CHEMICAL IDENTITY CBI CLAIMS

<p>A. Are you claiming a specific chemical identity as CBI?</p> <p><i>(If you answered yes, please respond to questions below.</i> <i>If you answered no, please leave all questions below blank.)</i></p>	
<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	

<p>B. Is the chemical substance (or mixture) on the confidential portion of TSCA Inventory?</p>	<input checked="" 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? <i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>D. Is the chemical substance known to be in US commerce? <i>(If you answered yes, please explain why the information should be treated as confidential.)</i></p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>E. Would disclosure of the specific chemical name release confidential process information? <i>(If you answered yes, please explain what process information would be released.)</i></p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<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? <i>(If you answered yes, please explain what information would be released.)</i></p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p><b>Additional comments:</b> Click or tap here to enter text.</p>	

<p><b>III.SUBSTANTIATION CERTIFICATION</b></p>	
<p><b>Do you wish to claim this substantiation as CBI? Yes</b></p> <p><i>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></p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.</p>	

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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\* EPA believes this information element to be exempt from substantiation for this activity.

\*\* EPA believes this information element to be exempt from substantiation for this activity (this exemption only applies prior to the date on which a chemical substance is first offered for commercial distribution).

\*\*\* EPA believes Spectra claims to be exempt from substantiation for this activity (this exemption only applies prior to the date on which a chemical substance is first offered for commercial distribution).

<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

(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.