BERGESON & CAMPBELL, P.C.
THE ACTA GROUP

GUIDANCE MATERIALS FOR TOXIC SUBSTANCES CONTROL ACT INVENTORY NOTIFICATION RULEMAKING

September 11, 2017

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INTRODUCTION

One month ago today, on August 11, 2017, the U.S. Environmental Protection Agency (EPA) published in the *Federal Register* its final rule on the Toxic Substances Control Act (TSCA) Inventory Notification (Active/Inactive) Requirements. As further discussed in the final rule and in the Bergeson & Campbell, P.C. (B&C®) memorandum EPA Issues Final TSCA Framework Rules, chemical manufacturers and importers are required to submit notifications for chemicals that were manufactured or imported over the ten-year look-back period of June 21, 2006, to June 21, 2016. Pursuant to the final rule, the retrospective reporting period for manufacturers began on August 11, 2017, and ends on **February 7, 2018**. Processors will have until **October 5, 2018**, to submit retrospective activity notifications, if they choose to.

B&C and The Acta Group prepared the appended guidance materials for our clients to assist in determining what chemicals need to be reported, by when, and how.

We hope the information provided is useful.

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Questions and Guidance on Inventory Active-Inactive Notification (the "Inventory Reset")

What is the "Inventory Reset"?
The Toxic Substances Control Act (TSCA) Inventory is not actually being reset. Under new TSCA, the U.S. Environmental Protection Agency (EPA) is required to divide the Inventory into two categories: substances that are active in commerce (or were in the past ten years) and substances that are inactive. Inactive substances are not removed from the Inventory. EPA refers to these actions and the associated rule as "Inventory Notification (Active-Inactive)."

What are the Two Types of Notices of Activity (NOA)?
Retrospective notification (Form A reporting): NOA reporting for substances manufactured (or imported) in a look-back period that covers June 21, 2006, through June 21, 2016.

Prospective notification (Form B reporting): NOA reporting for substances listed on the TSCA Inventory as inactive (only applies after the Inventory Reset is complete).

Where are the regulations codified?
The regulations are codified at 40 C.F.R. Part 710 Subpart B (§ 710.23 through § 710.39)

RETROSPECTIVE (FORM A) REPORTING

Who is impacted under the retrospective notification (Form A) requirements?
Any entity that, during the look-back period, manufactured or imported a substance listed on the Inventory for a non-exempt purpose must submit a Form A or have evidence that the substance is otherwise identified as active.

Processors may submit active notices, but are not required to do so. Processors must ensure that all substances processed are listed as active at the end of the reporting period and/or cease processing inactive substances.

Chemical users are probably processors and must ensure that all substances used for non-exempt purposes are listed as active.

Any entity that wishes to maintain the identity of a substance as confidential business information (CBI) must submit a Form A to maintain the CBI even if the substance is identified as interim active. See CBI information below.

There are three ways for a manufacturer/importer to satisfy an active notice obligation:

1) Submit a Form A;
2) Find the substance listed on the Inventory as interim active; and
3) Obtain a Form A Central Data Exchange (CDX) submission receipt from another submitter (although you must take care to ensure that the other submitter does not subsequently withdraw or otherwise correct the Form A notice).

When is the Reporting Deadline?
Manufacturers and importers are required to file Form As no later than **February 7, 2018.** Processors who choose to file Form As must do so no later than **October 5, 2018**.

What substances are subject to NOA reporting?
Only substances that were listed on the TSCA Inventory as of June 21, 2016, can be notified during the reset. If a substance was not listed on the Inventory as of June 21, 2016, it is exempt from NOA reporting.

A substance that is already identified as "interim active" (based on 2012 and 2016 Chemical Data Reporting (CDR) or that has been subject of a notice of commencement (NOC) after June 22, 2006) is exempt from NOA reporting. EPA has designated the "interim active" chemicals on the publicly available TSCA Inventory at https://www.epa.gov/tsca-inventory.

EPA has aligned what must be reported via NOA with other reporting, such as listing on the Inventory. Note, however, that substances manufactured under a Section 5 exemption, including Low Volume Exemption (LVE), Low-Release/Low-Exposure Exemption (LoREX), and Polymer Exemption, and also are listed on the Inventory must be notified.

Table 1 compares the various exemptions from listing on the Inventory, from CDR reporting, and from NOA reporting.

What if we stopped producing a substance and do not intend to produce it in the future?

Retrospective reporting (Form A) is based on activity that happened in the look-back period, not a manufacturer's intent going forward. If an entity manufactured or imported a substance for a non-exempt commercial purpose, the entity is responsible to ensure that the substance is identified as active. This provision is in the statute.

PROSPECTIVE (FORM B) REPORTING

What substances are subject to Form B reporting?

An entity must submit a Form B notice prior to manufacturing, importing, or processing an inactive substance for a non-exempt commercial purpose. Form B reporting is not required until after the Transition Period ends (in approximately **December 2018**).

What is the "Transition Period"?

The Transition Period begins on June 22, 2016, and ends on the date that EPA designates chemical substances on the Inventory as active or inactive. EPA will publish the final active/inactive list "as soon as practicable" after the processor reporting deadline (**October 5, 2018**). EPA expects it will take about 60 days to publish this list. In the proposed rule, entities that commenced a reportable commercial activity during the Transition Period did not have a mechanism to ensure that substances were listed as active: Form A notices only apply to activity prior to June 22, 2016, and Form B notices only apply after the final list is published.

As a solution, EPA has changed the definition of an inactive substance. Now a substance is inactive 90 days after EPA designates it as inactive on the final active/inactive list. This provides an entity that commences during the Transition Period manufacturing, importing, or processing a substance designated as inactive 90 days to submit a Form B and avoid manufacturing, importing, or processing an inactive substance.

What do I do if I started importing a substance after June 22, 2016 and that substance is not designated as active?

As currently defined in 40 C.F.R. § 710.23, a substance is not inactive until 90 days after EPA formally designates that substance as inactive. This provides entities that commenced a reportable commercial activity after June 22, 2016, 90 days after the final active/inactive list is published to submit a Form B NOA and avoid manufacturing, importing, or processing an inactive substance.

Who is impacted under the prospective notification requirements?
Once the retrospective reporting by manufacturers and processors is completed, a manufacturer, importer, or processor that intends to manufacture, import, or process a substance designated as inactive must submit a Form B no more than 90 days prior to commencing the activity. There is no minimum time, as long as the notice is submitted prior to manufacturing, importing, or processing the substance.

GENERAL NOA QUESTIONS

How is NOA reporting different from CDR reporting? How are NOA reporting exemptions different from CDR exemptions?
All substances that are listed on the Inventory that were manufactured for a non-exempt commercial purpose (*e.g.*, other than impurities, byproducts, R&D, and similar self-executing exemptions) are reportable as NOAs. Stakeholders need to be aware that certain CDR exemptions do not apply for Inventory notification reporting. In particular,

- Most polymers are exempt from CDR; polymers that are listed on the Inventory are not exempt from NOA reporting;
- CDR has reporting thresholds of 25,000 kg and 2,500 kg for chemicals subject to certain TSCA actions; there is no *de minimus* threshold for NOA reporting; and
- Companies meeting the small business exemption do not have to report under CDR; small businesses are not exempt from reporting under the Inventory notification rule.

See Table 1 for a list of common TSCA exemptions and how they apply to NOA reporting.

What if we submit an NOA with an error?
Form A notices may be withdrawn prior to the submission deadline. Form B notices may be withdrawn prior to EPA processing the notice and changing the status of the substance to "active."

Who reports for toll manufacturers?
Responsibility for NOA reporting mirrors EPA's approach to CDR reporting: Either party may submit the NOA, but if neither submits, both are liable for failure to submit the notice. The parties should decide among themselves which will report.

What records must be kept and how long must the records be kept?
Records "relevant to" a Form A report must be kept for five years after the day after the submission period closes. Relevant records include documentation of reportable activity (*e.g.*, manufacturing batch records or import records) and documentation of exempt activity (*e.g.*, records demonstrating R&D). Records relevant to a Form B report must be kept for five years after the notice is submitted.

CONFIDENTIAL BUSINESS INFORMATION

What may be claimed as CBI?
Identities for substances that are listed on the confidential portion of the Inventory may be claimed as CBI, although not required to do so, companies could use the notification process as an opportunity to review carefully their CBI claims. Identities for substances that are listed on the public portion of the Inventory may not be claimed as CBI.

The identity of the NOA submitter and/or technical contact may be claimed CBI even if the substance identity is not CBI.

Identities for substances that are listed on the confidential portion of the Inventory may be claimed as CBI regardless of who made the original CBI claim.

Submitters may submit an NOA for substances on the confidential portion of the Inventory without claiming the identity as CBI (that is, the submitter does not seek to continue protection of the identity). If EPA receives no substantiated NOAs for a CBI substance, EPA will disclose the substance and move the substance to the public portion of the Inventory.

To maintain a confidential identity of a substance listed on the confidential portion of the Inventory, a company must submit an NOA with an indication that the chemical identity be maintained as CBI; the submitter will have to substantiate the CBI claim, either with the Form A submission or under a to-be-issued EPA CBI review plan.

Companies are not required to substantiate CBI for chemical identity during retrospective reporting. EPA will issue a separate rulemaking to establish its CBI review plan, which will include when and what will be required for chemical identity substantiation. Until that occurs, chemical substances claimed as CBI during retroactive review will remain on the confidential portion of the Inventory until EPA issues its rulemaking, companies submit the substantiation as required by said rule, and EPA reviews the claim.

While not required, companies can substantiate chemical identity CBI claims when they submit the NOA Form A. If the proactive substantiation is submitted no more than five years before the due date in the to-be-issued EPA CBI review plan, a company would be exempt from the requirement to submit additional substantiation under the terms of the review plan.

Other information on the NOA may be claimed as CBI (*e.g.*, submitter identity). Such claims must be substantiated at the time of Form A notification. EPA must review 25% of such CBI claims.

PREPARING FOR NOA REPORTING

What should companies do to prepare?

Search manufacturing, import, and purchasing records from the look-back period for records relating to manufacturing or import of chemical substances or mixtures (formulations) of chemical substances. Remember that a formulated product may contain many substances (as represented by Chemical Abstracts Service (CAS) numbers). Maintain supporting records for five years from the end of the reporting period.

See the step-by-step guide below to reviewing substances for Form A reporting.

EPA has created a Comma Separated Value (CSV) file template to enable a submitter to upload many substances into the CDX system in preparation for Form A submission. **Note: If you are preparing a CSV file to upload, be sure to purge your list of substances that are designated as interim active and substances that are not listed on the Inventory.** The eNOA system on CDX only accepts entries for substances that are not designated as interim active. Uploading a list (via the CSV upload function) that includes a substance that is interim active will cause an error and CDX will reject the entire upload file. Attempting to upload a substance that is not listed on the Inventory will cause an identical error. Manual entry (via the Substance Registry Service (SRS)) will return a "0 results" message after a search for an interim active substance or a substance not listed on the Inventory.

What if I do not have an accession number?

Gather documentation, such as premanufacture notice (PMN) number, a copy of the NOC, and *Federal Register* notices of EPA's receipt of both the PMN and NOC for the substance(s); and prepare Inventory correspondence (IC) to request that EPA provide the

accession number(s) for the substances. An entity may request multiple accession numbers in a single IC.

This sort of IC cannot be used to search the confidential portion of the Inventory, only to determine the accession number of a substance for which the requester submitted as a PMN.

I import formulations, what do I have to do?
Ideally, gather the CAS number or accession number for each substance that is intentionally present in the formulation; note that you do not need the percentage of each, just whether or not each substance is intentionally present; there is no *de minimus* threshold. A substance that is intentionally present, even at 0.001%, is subject to reporting. Impurities are exempt from reporting.

If the foreign supplier is unwilling to provide chemical identity information (either as a CAS number or the accession number), an importer may take advantage of joint reporting. The importer would begin the Form A reporting and specify in the submission that the Form A will be a joint notice. In a joint submission, the primary submitter (the importer) specifies the individual (the supplier) who will be the secondary submitter.

If the supplier is unwilling to participate in a joint submission, importers should seek certification from the supplier that the substance is listed on the Inventory as active.

What if I cannot find records?
Entities are only required information that is Known or Reasonably Ascertainable (*see* 40 C.F.R. § 710.23 and § 710.25(a)).

Be aware that companies are required to maintain records for manufacturing and import that occurred in the past five years; companies are also required to maintain records to support 2016 and 2012 CDR reporting.

What if I find a substance that was manufactured that is not listed on the Inventory?

1) Double-check the identity to ensure you have the proper TSCA identity. It is not unusual for a substance to be identified with one CAS number for business purposes and another CAS number for TSCA purposes. Examples include hydrates of substances and substances imported from the European Union (EU) where a different CAS number is used.

2) Determine if the substance was manufactured under an exemption (*e.g.*, R&D Exemption, Byproduct Exemption, Polymer Exemption, or an LVE).
3) Attempt to determine if the substance is listed on the confidential portion of the Inventory.

If a substance was manufactured, but the substance is not listed on the Inventory, the substance is exempt from active notice reporting. A manufacturer should seek guidance on compliance with other sections of TSCA.

What if we only imported a substance for R&D?
The substance is exempt from reporting, even if it is listed on the Inventory. EPA would be of the view that it should not be reported as active.

What if we just started manufacturing a substance in December 2016 and it is not reported as active?
Check the final active/inactive list that will be published about two months after the **October 5, 2018**, deadline for processor reporting. EPA does not have a specific target date for publication of that list; the statute requires that the list be published "as soon as practicable" after the reporting period. EPA estimates that it will publish the final active/inactive list 60 days after the reporting period closes (**early-to-mid December 2018**). If the substance is designated as inactive on that list, submit a Form B NOA within 90 days of publication of the list.

TABLE 1: TSCA REPORTING EXEMPTIONS

	Listing on Inventory or PMN	Reporting to CDR	NOA Reporting
Non-TSCA uses	Excluded	Exempt	Exempt
R&D	Exempt	Exempt	Exempt
Naturally Occurring Substances (NOS)	Automatically included if [1]	Exempt if [1]	Exempt if [1]
Impurities	Exempt	Exempt	Exempt
Byproducts	Exempt if [2]	Exempt if [2]	Exempt if [2]
Small business reporters	Not exempt	Exempt	Not exempt
Polymers that meet 40 C.F.R. § 723.250	Exempt	Exempt unless certain subject of TSCA action	Exempt if [3]
Polymers that do not meet 40 C.F.R. § 723.250	Not exempt	Exempt unless certain subject of TSCA action	Not exempt
Manuf./Import (M/I) <25,000 kg/year	Not exempt	Exempt unless certain subject of TSCA action	Not exempt
M/I under an LVE, TME, or LoREX	Exempt	Exempt if [3]	Exempt if [3]
Imported as part of article	Exempt if [4]	Exempt if [4]	Exempt if [4]
Intermediates (isolated)	Not exempt	Not exempt	Not exempt
Intermediates (non-isolated)	Exempt	Exempt	Exempt
Substances not listed on the Inventory	Not exempt	Exempt	Exempt
Mixtures [5]	Exempt	Exempt	Exempt
Components of mixtures	Not exempt	Not exempt	Not exempt

[1] NOS are exempt from reporting if the substance was manufactured or processed in a way that meets the definition of a NOS in 40 C.F.R. § 710.3.
[2] Byproducts are exempt from reporting if they are used as specified in 40 C.F.R. § 710.4(d)(2).
[3] Substances manufactured under a Section 5 exemption (LVE, LoREX, Polymer Exemption, and Test Marketing Exemption (TME)) are exempt from NOA reporting only if such substances are not listed on the Inventory.
[4] Substances that are intended to be released from an article are not exempt. An ink cartridge is an article; components of the ink are reportable substances.
[5] All components of a mixture that are intentionally present are reportable.

TABLE 2: NOA REPORTING DEADLINES

	The activity occurred (or will occur)		
I am a	**During Look-back Period (June 21, 2006, and June 21, 2016)**	**During Transition Period (Between June 22, 2016, and when EPA published the final active/inactive list, expected in December 2018)**	**After the Transition Period (expected December 2018)**
Manufacturer/importer (required reporting)	Form A. Deadline: February 2, 2018	Form B. Deadline: 90 days after the list is published, approximately early March 2019	Form B. Deadline: Before commencing the activity, but not more than 90 days before
Processor (optional reporting)	Form A. Deadline: October 5, 2018	Form B. Deadline: 90 days after the list is published, approximately early March 2019	Form B, Deadline: Before commencing the activity, but not more than 90 days before

STEP-BY-STEP APPROACH FOR RETROACTIVE REPORTING

Gather records of substances manufactured, imported, or processed (M/I/P) between June 21, 2006, and June 21, 2016, inclusive (the look-back period). Maintain those records documenting activity and exemptions for five years from the end of the NOA reporting period.

See flowchart for a visual depiction of the steps below.

STEP 1. From the gathered records, prepare a list of substances (including CAS number and best available name or accession number and generic name) M/I/P during the look-back period.

- For mixtures, identify all the components of the mixture.
- Include all polymers and chemical substances M/I/P regardless of import or production volume.

STEP 2. Note and set aside substances M/I/P exclusively for a non-TSCA purpose. These substances are excluded from TSCA and exempt from NOA reporting.

- Pesticides. Pesticide inert ingredients are regulated under TSCA up to the point the inert ingredients are incorporated into a pesticide formulation.
- Tobacco/tobacco products.

- Nuclear source materials.
- Firearms, munitions, and ammunition.
- Food, food additives, drugs, medical devices, or cosmetics.

STEP 3. Note and set aside substances M/I/P exclusively for an exempt use.

- R&D.
- Imported solely as part of articles. (Note: Substances intended to be released from articles are not exempt. A toner cartridge is an article; toner is not.)
- Non-isolated intermediates.
- Impurities.
- Byproducts (if used according to 40 C.F.R. § 710.4(d)(2)).
- Export only.

STEPS 4 and 5. Compare list to TSCA Inventory.

- STEP 4. Note and set aside substances that are identified as interim active.
- STEP 5. Note and set aside naturally occurring substances (if manufactured according to 40 C.F.R. § 710.4(b)).

At this point, the list should contain substances that are listed on the Inventory that <u>are</u> subject to Form A reporting (STEP 6); and substances that are not listed on the Inventory (see STEP 7).

STEP 6. For substances listed on the Inventory Submit Form A NOAs. Users may either search for individual chemicals or upload a CSV file that lists the chemicals (*see* Guidance for Preparing CSV File for Upload).

For the substances that are <u>not</u> listed on the Inventory:
STEP 7. Note and set aside any substance that was M/I/P under an existing Section 5(h) exemption. These are exempt from Form A reporting.

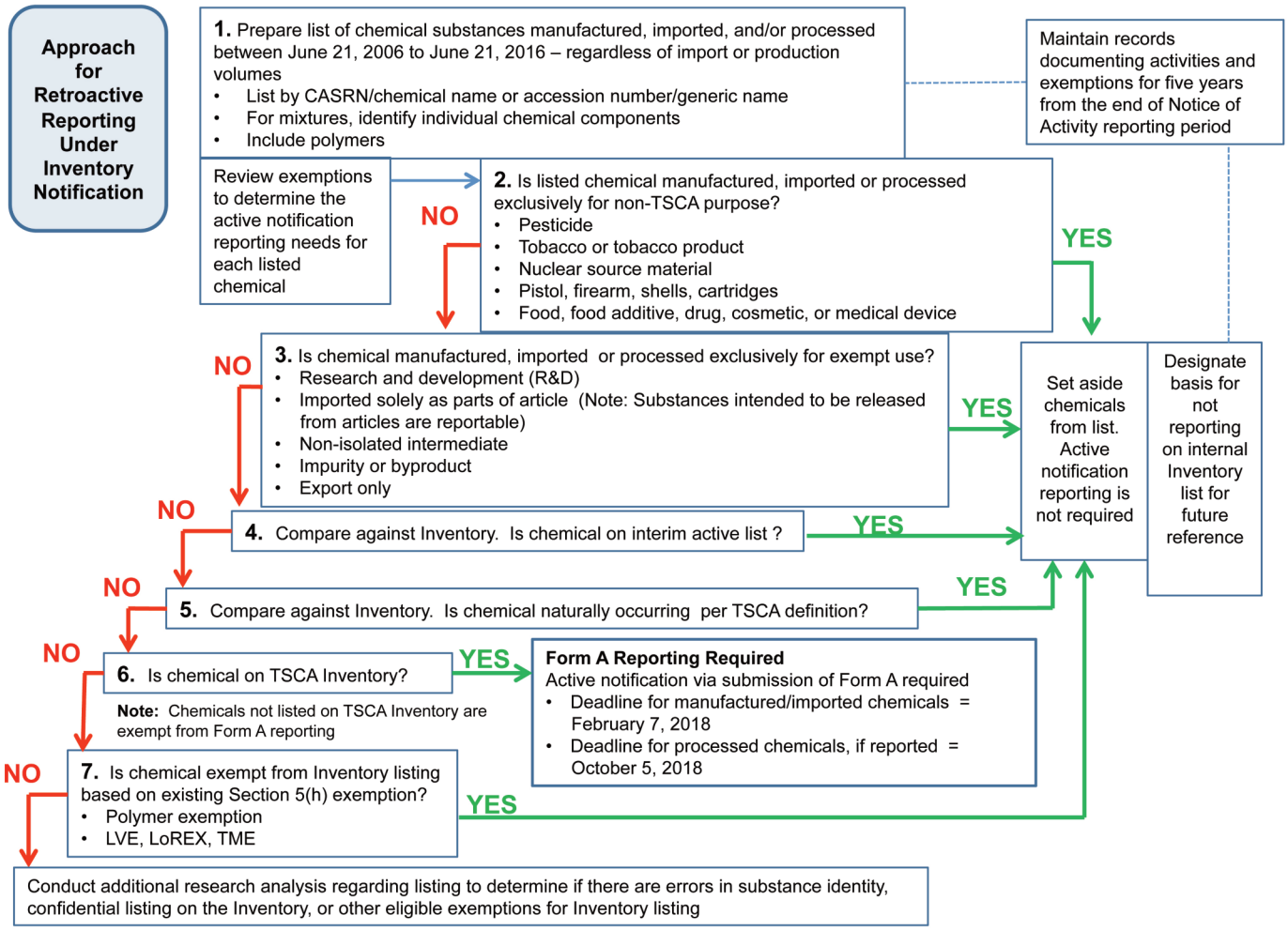
- M/I/P under the Polymer Exemption.
- M/I/P under a LVE, LoREX, or TME.

The remaining substances require more research. We suggest contacting us to discuss. Possible explanations include:

- Incorrect substance identity. Some substances have different CAS numbers in different jurisdictions (*e.g.*, EU Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)). Understanding the correct identity can be subtle.

- The substance may be listed on the confidential portion of the Inventory.
- The substance may be eligible for another exemption.

Note that substances that are not listed on the Inventory are exempt from Form A reporting and the eNOA system will not accept Form A reports for substances that cannot be found on the Inventory. There may be issues with other sections of TSCA, but those issues can and should be resolved separately from the NOA reporting deadline.



GUIDANCE FOR PREPARING CSV FILE FOR UPLOAD

Note: If you are preparing a CSV file to upload, be sure to purge your list of substances that are designated as interim active and substances that are not listed on the Inventory. The eNOA system on CDX only accepts entries for substances that are not designated as interim active. Uploading a list (via the CSV upload function) that includes a substance that is interim active will cause an error and CDX will reject the entire upload file. Attempting to upload a substance that is not listed on the Inventory will cause an identical error. Manual entry (via the SRS) will return a "0 results" message after a search for an interim active substance or a substance not listed on the Inventory.

eNOA Upload Template File

EPA has provided a template (available for download from within the eNOA system on CDX) for users to upload many substance identities in a batch. The template file is CSV-NAA.csv and is readable by most spreadsheet and database programs. The file refers to Parts A and B of the CBI substantiation sections of the data entry system; Part A relates to all confidential information in the submission; part B relates specifically to CBI claims for chemical identity.

You may combine CBI and non-CBI in the file. Each row must have a CAS number or an accession number. If you have both a CAS number and an accession number, the system may not accept both. Include the number that is currently listed on the Inventory (*e.g.*, include the accession number if the substance is currently listed on the confidential portion of the Inventory).

Field name (as it appears in the CSV file)	Field explanation	Comment
CASRN	CASRN with our without dashes.	After upload, dashes will be present
Accession Number	Accession number for substances listed on the confidential portion of the Inventory.	
Chemical Cbi	Submitter seeking to maintain CBI claim for substance identity.	Must be "TRUE" or "FALSE"
Submitter Cbi	Submitter claiming CBI for submitter identity.	Must be "TRUE" or "FALSE"
Company Details Cbi	Submitter claiming CBI for submitting company details.	Must be "TRUE" or "FALSE"
Technical Contanct Cbi	Submitter claiming CBI for technical contact identity. NB: "Contanct" is misspelled in the template.	Must be "TRUE" or "FALSE"
Substantiation CBI	Submitter claiming CBI for substantiation statement(s).	Must be "TRUE" or "FALSE"
ShowCbiQuestions	Set to TRUE to substantiate CBI claims. This is required for sub mitter, company, and technical contact claims.	Must be "TRUE" or "FALSE"
PartA-Q1	Is information exempt under Section 14(c)(2)?	Must be "TRUE" or "FALSE"
PartA-Q1	Explain which information is exempt and which exemption applies.	Free text
PartA-Q2	Will disclosure result in substantial competitive harm?	Must be "TRUE" or "FALSE"
PartA-Q2	Describe the harm with specificity for each element claimed as CBI.	Free text
PartA-Q3-1	Is NDA required prior to accessing the CBI information?	Must be "TRUE" or "FALSE"
PartA-Q3-2	Is access limited to individuals with a need to know?	Must be "TRUE" or "FALSE"
PartA-Q3-3	Is information secured (physically or electronically)?	Must be "TRUE" or "FALSE"
PartA-Q3-4	Are there other internal security control measures?	Must be "TRUE" or "FALSE"
PartA-Q3	Describe internal security control measures.	Free text
PartA-Q4	Does the information appear in any public document?	Must be "TRUE" or "FALSE"
PartA-Q4	If information appears in a public document, explain why it should be kept confidential.	Free text
PartA-Q5	Is the claim intended to last less than ten years; if so, indicate the number of years or the specific date or occurrence after which the claim is to be withdrawn.	Free text
PartA-Q6	Has any federal agency or court made a determination about confi-dentiality related to this substance?	Must be "TRUE" or "FALSE"
PartA-Q6	If yes, provide explanation of the outcome.	Free text
PartA-AC	Additional comments.	Comment related to Part A
PartB-Q1	Are you substantiating a CBI claim for substance identity?	Must be "TRUE" or "FALSE"
PartB-Q1	Additional information related to claiming CBI during submission.	Free text
PartB-Q2	Is the substance publicly known to have been offered for commercial distribution in the U.S.?	Must be "TRUE" or "FALSE"
PartB-Q2	If so, explain why the information should be treated as confidential.	Free text
PartB-AC	Additional comments.	Comment related to Part B

EPA	**U.S. Environmental Protection Agency** **NOTICE OF ACTIVITY OF MANUFACTURE, IMPORT, OR PROCESSING – FORM A**	Submission Date:	
		Revised Date:	

Part I – Submitter Identification

	Name of Authorized Official	Mailing Address (street, city, zip code)	CBI*
Manufacturer, Importer, Processor (in U.S.)	(first) (last)		
	Company Name	Mailing Address (street, city, zip code)	
Technical Contact (in U.S.)	Name	Telephone Number	
	(first) (last)		

* CBI refers to the term “Confidential Business Information.” Mark (X) in the CBI box(es) if the submitter information is to be held confidential.

Part II – Chemical Substance Identity

CASRN	TSCA Inventory Chemical Name (if specific chemical identity is not CBI)	
Accession Number	Generic Chemical Name (if specific chemical identity is CBI)	

Part III – Status of Confidential Chemical Substance Identity

	I am seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory.
	I am not seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory.

Part IV – Certification

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge, is true, accurate, and complete. I also certify that I have manufactured, imported, or processed the above chemical substance between the dates of June 21, 2006 and June 21, 2016. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information, and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

Signature of authorized official:		Date:	

Form A is for retrospective reporting. Domestic manufacturers and importers must submit a completed notice not later than 180 calendar days after August 11, 2017. Processors can voluntarily submit a completed notice not later than 420 calendar days after August 11, 2017. Requests to maintain an existing CBI claim for specific chemical identity must be substantiated according to the Review Plan required under TSCA (not yet published, as of August 11, 2017), but may be substantiated at the time this notice is submitted. Assertions of CBI claims for information other than specific chemical identity must be substantiated at the time this notice is submitted.

The public reporting and recordkeeping burden for this collection of information is estimated to average 5.7 hours per response. Send comments on the Agency’s need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed EPA Form [insert] to this address.

Part V - CBI SUBSTANTIATION

This substantiation contains CBI: Yes ☐ No ☐

Pursuant to TSCA section 14(c)(3), you must substantiate any CBI claims for information elements other than specific chemical identity at the time this notice is submitted. EPA guidance for complying with TSCA section 14(c)(3) may be found at https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission. You may also substantiate a request to maintain an existing CBI claim for a specific chemical identity at the time this notice is submitted, but this is not required. Rather, you must substantiate the existing CBI claim for the specific chemical identity by the deadline established in a forthcoming Review Plan, to be promulgated at a later date in accordance with TSCA section 8(b)(4)(C).

If you do not assert a CBI claim at time of submission of this form, or otherwise fail to assert a proper CBI claim (i.e., by failing to substantiate your CBI claim or not providing a certification statement), the information shall be treated as not subject to a CBI claim, and may be made public without further notice. If a single substantiation response applies for all or a class of 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 A.1. or 2) or in the additional information box at the end of this form.

Information element(s) that you identified as CBI in previous parts:

☐ Name of Authorized Official/Mailing address (Part I)

☐ Company Name/Mailing Address (Part I)

☐ Technical Contact/Telephone Number (in U.S.) (Part I)

☐ Specific Confidential Chemical Identity (as listed on the TSCA Inventory) (Part II/III)

A. APPLICABLE TO ANY CBI CLAIM

1. Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)[i]?

   If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).

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

   ☐ Yes
   ☐ No

Click or tap here to enter text.

2. Will disclosure of the information likely result in substantial harm to your business's competitive position?

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

   If, for example, it is not publicly known that the submitter manufactures, imports or processes the reported chemical, describe with specificity the harmful effects that would result if this information were made available to the public. If you are claiming technical contact name or name of authorized official as CBI, describe with specificity the harmful effects that would result if this information were made available to the public.

   If you are claiming multiple information elements as CBI, please provide information for EACH element you identified above.

   ☐ Yes
   ☐ No

Click or tap here to enter text.

3. To the extent your business has disclosed the 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.*	☐ Yes ☐ No

Click or tap here to enter text.

4. Does the information appear in any public documents, including (but not limited to) safety data sheets, 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.

Click or tap here to enter text.

5. Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B)[ii])? If so, please indicate the number of years (between 1-10 years) or the specific date/occurrence after which the claim is withdrawn.

Click or tap here to enter text.

6. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical 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.

Click or tap here to enter text.

Additional comments:

Click or tap here to enter text.

B. APPLICABLE ONLY TO A SPECIFIC CHEMICAL IDENTITY CBI CLAIM

1. Are you providing a substantiation at this time to maintain a specific confidential chemical identity as CBI? ☐ Yes ☐ No

If you answered yes, please respond to questions below and in Section A.

If you answered no, please leave all questions below blank. You must substantiate by the deadline established in a forthcoming Review Plan, to be promulgated at a later date in accordance with TSCA section 8(b)(4)(C).

2. Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? ☐ Yes ☐ No

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

Click or tap here to enter text.

Additional comments:

Click or tap here to enter text.

C. CERTIFICATION

I certify that all claims for confidentiality made or sought to be maintained with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. I further certify 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.

Signature of authorized official		Date	

[i] **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 Registry 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.

[ii] **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).

EPA	**U.S. Environmental Protection Agency** **NOTICE OF ACTIVITY OF MANUFACTURE, IMPORT, OR PROCESSING – FORM B**	Submission Date:	
		Revised Date:	

Part I – Submitter Identification

Manufacturer, Importer, Processor (in U.S.)	Name of Authorized Official	Mailing Address (street, city, zip code)	CBI*
	(first) (last)		
	Company Name	Mailing Address (street, city, zip code)	
Technical Contact (in U.S.)	Name	Telephone Number	
	(first) (last)		

* CBI refers to the term “Confidential Business Information.” Mark (X) in the CBI box(es) if the submitter information is to be held confidential.

Part II – Chemical Substance Identity

CASRN	TSCA Inventory Chemical Name (if specific chemical identity is not CBI)	
Accession Number	Generic Chemical Name (if specific chemical identity is CBI)	

Part III – Status of Confidential Chemical Substance Identity

	I am seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory.
	I am not seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory.

Part IV – Anticipated Date** of Reintroduction of Chemical Substance in U.S. Commerce***

Date:		

** If the notice is filed prior to the effective date of the chemical substance’s inactive designation, the most recent date of manufacture or processing may be provided in lieu of an anticipated date.
*** Mark (X) in the CBI box if the date is to be held confidential.

Part V – Certification

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge, is true, accurate, and complete. I also certify that I have intent to manufacture, import, or process the above chemical within 90 days of submission. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information, and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

Signature of authorized official		Date	

Form B is for forward-looking reporting. Domestic manufacturers, importers, and processors must submit a completed notice prior to the date that an inactive substance is manufactured, imported, and/or processed, but not more than 90 calendar days prior. Domestic manufacturers, importers, and processors currently manufacturing, importing, or processing a chemical substance or who anticipate manufacturing, importing, or processing the chemical substance within 90 days following submission, may submit a completed notice prior to the effective date of the chemical substance’s inactive designation. Requests to maintain an existing CBI claim for specific chemical identity must be substantiated not later than 30 calendar days after submitting this notice, but may be substantiated at the time this notice is submitted. Assertions of CBI claims for information other than specific chemical identity must be substantiated at the time this notice is submitted.

The public reporting and recordkeeping burden for this collection of information is estimated to average 1.7 hours per response. Send comments on the Agency’s need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed EPA Form [insert] to this address.

Part VI - CBI SUBSTANTIATION

This substantiation contains CBI: Yes ☐ No ☐

Pursuant to TSCA section 14(c)(3), you must substantiate any CBI claims for information elements other than specific chemical identity at the time this notice is submitted. EPA guidance for complying with TSCA section 14(c)(3) may be found at https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission. You may also substantiate a request to maintain an existing CBI claim for a specific chemical identity at the time this notice is submitted, but this is not required. Rather, you must substantiate the existing CBI claim for the specific chemical identity not later than 30 days after providing this notice.

If you do not assert a CBI claim at time of submission of this form, or otherwise fail to assert a proper CBI claim (i.e., by failing to substantiate your CBI claim or not providing a certification statement), the information shall be treated as not subject to a CBI claim, and may be made public without further notice. If a single substantiation response applies for all or a class of 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 A.1. or 2) or in the additional information box at the end of this form.

Information element(s) that you identified as CBI in previous parts:

☐ Name of Authorized Official/Mailing address (Part I)

☐ Company Name/Mailing address (Part I)

☐ Technical Contact/Telephone Number (in U.S.) (Part I)

☐ Specific Confidential Chemical Identity (as listed on the TSCA Inventory) (Part II/III)

☐ Anticipated Date of Reintroduction of Chemical Substance in U.S. Commerce (Part IV)

A. APPLICABLE TO ANY CBI CLAIM

1. Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)[i]?

   If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).

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

   ☐ Yes
   ☐ No

Click or tap here to enter text.

2. Will disclosure of the information likely result in substantial harm to your business's competitive position?

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

   If, for example, it is not publicly known that the submitter manufactures, imports or processes the reported chemical, describe with specificity the harmful effects that would result if this information were made available to the public. If you are claiming technical contact name or name of authorized official as CBI, describe with specificity the harmful effects that would result if this information were made available to the public.

   If you are claiming multiple information elements as CBI, please provide information for EACH element you identified above.

   ☐ Yes
   ☐ No

Click or tap here to enter text.

3. To the extent your business has disclosed the 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 .*	☐ Yes	☐ No

Click or tap here to enter text.

4. Does the information appear in any public documents, including (but not limited to) safety data sheets, 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.

Click or tap here to enter text.

5. Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B)[ii])? If so, please indicate the number of years (between 1-10 years) or the specific date/occurrence after which the claim is withdrawn.

Click or tap here to enter text.

6. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical 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.

Click or tap here to enter text.

Additional comments:

Click or tap here to enter text.

B. APPLICABLE ONLY TO A SPECIFIC CHEMICAL IDENTITY CBI CLAIM

1. Are you providing a substantiation at this time to maintain a specific confidential chemical identity as CBI? ☐ Yes ☐ No

If you answered yes, please respond to questions below and in Section A.

If you answered no, please leave all questions below blank. You must substantiate not later than 30 days after providing this notice in accordance with TSCA section 8(b)(5)(B)(ii)(II).

Click or tap here to enter text.

2. Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? ☐ Yes ☐ No

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

Click or tap here to enter text.

Additional comments:

Click or tap here to enter text.

C. CERTIFICATION			
I certify that all claims for confidentiality made or sought to be maintained with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. I further certify 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.			
Signature of authorized official		Date	

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(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.

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(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).

BERGESON & CAMPBELL, P.C. AND THE ACTA GROUP ARE PLEASED TO PROVIDE THESE GUIDANCE MATERIALS.

Further information is available on our website:

- Memoranda - http://www.lawbc.com/regulatory-developments/tsca
- Articles - http://www.lawbc.com/published-articles/tsca
- Firm news - http://www.lawbc.com/news/tsca
- TSCA Reform News & Information page - http://www.lawbc.com/knowledge-resources/tsca-reform-news-info

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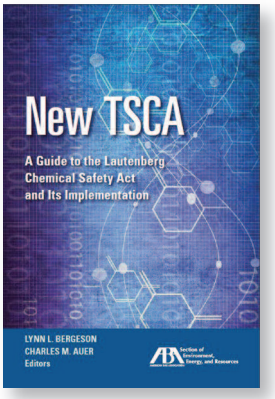

Available now from Bergeson & Campbell, P.C. and the American Bar Association - *New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation*. Readers will gain an appreciation of the fundamental shifts in the requirements and approach to chemical management under new TSCA, and will benefit from thorough analysis of a number of the provisions, including those relating to definitions, testing, review and regulation of new and existing chemicals, information reporting, confidential business information (CBI), preemption, fees, and others.

A 15-page Executive Summary of the book is available on the ABA website. Click on Preface: "Executive Summary." *New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation* is available for purchase via the ABA online bookstore.

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