

## TSCA HEALTH & SAFETY STUDY COVER SHEET

Use of this form is voluntary, but recommended by EPA as a cover sheet for TSCA section 4, 8(d), and 8(e) submissions to expedite and improve the management, processing, quality, review, and public availability of data in TSCATS

**TSCA CBI STATUS:**

• **CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)**

Clearly mark the confidential information with bracketing and check the box in the appropriate section ( *Contains CBI*).  
 Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

<b>1.0 SUBMISSION TYPE</b> <input type="checkbox"/> <i>Contains CBI</i> <input type="checkbox"/> 8(d) <input type="checkbox"/> 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify _____ <input type="checkbox"/> Initial Submission <input type="checkbox"/> Follow-up Submission <input type="checkbox"/> Final Report Submission Previous EPA Submission Number or Title if update or follow-up: _____ Docket Number, if any: # _____  ITC Submission <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> continuation sheet attached											
<b>2.1 SUMMARY/ABSTRACT ATTACHED</b> (may be required for Sec. 8(e); optional for Secs. 4, 8(d) & FYI) <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID</b>	<b>2.3 FOR EPA USE ONLY</b>	<b>2.4 Study</b> ____ of ____								
<b>3.0 CHEMICAL/TEST SUBSTANCE IDENTITY</b> <input type="checkbox"/> <i>Contains CBI</i> <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> _____ CAS# _____ - _____ - _____ Purity _____ % <input type="checkbox"/> Single Ingredient <input type="checkbox"/> Commercial/Tech Grade <input type="checkbox"/> Mixture <i>Trade Name:</i> _____ <i>Common Name:</i> _____ <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <span><u>CAS Number</u></span> <span><u>NAME</u></span> <span><u>% WEIGHT</u></span> </div> Other chemical(s) present in tested mixture <input type="checkbox"/> continuation sheet attached											
<b>4.0 REPORT/STUDY TITLE</b> <input type="checkbox"/> <i>Contains CBI</i>  <input type="checkbox"/> continuation sheet attached											
<b>5.1 STUDY/TSCATS INDEXING TERMS</b> [CHECK ONE] HEALTH EFFECTS (HE): _____ ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____											
<b>5.2 STUDY/TSCATS INDEXING TERMS</b> (see instructions for 4 digit codes) <table style="width: 100%; border: none;"> <tr> <td style="width: 25%;">STUDY TYPE: _____</td> <td style="width: 25%;">SUBJECT ORGANISM (HE, EE only): _____</td> <td style="width: 25%;">ROUTE OF EXPOSURE (HE only): _____</td> <td style="width: 25%;">VEHICLE OF EXPOSURE (HE only): _____</td> </tr> <tr> <td><i>Other:</i> _____</td> <td><i>Other:</i> _____</td> <td><i>Other:</i> _____</td> <td><i>Other:</i> _____</td> </tr> </table>				STUDY TYPE: _____	SUBJECT ORGANISM (HE, EE only): _____	ROUTE OF EXPOSURE (HE only): _____	VEHICLE OF EXPOSURE (HE only): _____	<i>Other:</i> _____	<i>Other:</i> _____	<i>Other:</i> _____	<i>Other:</i> _____
STUDY TYPE: _____	SUBJECT ORGANISM (HE, EE only): _____	ROUTE OF EXPOSURE (HE only): _____	VEHICLE OF EXPOSURE (HE only): _____								
<i>Other:</i> _____	<i>Other:</i> _____	<i>Other:</i> _____	<i>Other:</i> _____								
<b>6.0 REPORT/STUDY INFORMATION</b> <input type="checkbox"/> <i>Contains CBI</i> <input type="checkbox"/> Study is GLP Laboratory _____ Report/Study Date _____ Source of Data/Study Sponsor (if different than submitter) _____ Number of pages _____ <input type="checkbox"/> continuation sheet attached											
<b>7.0 SUBMITTER INFORMATION</b> <input type="checkbox"/> <i>Contains CBI</i> Submitter: _____ Title: _____ Phone: ( ) _____ Company Name: _____ Company Address: _____ _____ _____ Submitter Address (if different): _____  Technical Contact: _____ Phone: ( ) _____ <input type="checkbox"/> continuation sheet attached                      e-mail address _____											
<b>8.0 ADDITIONAL COMMENTS</b> <input type="checkbox"/> <i>Contains CBI</i>  <input type="checkbox"/> continuation sheet attached <b>Submitter Signature:</b> _____ <b>Date:</b> _____											

# TSCA HEALTH & SAFETY STUDY COVER SHEET

## 9.0 CONTINUATION SHEET

**TSCA CBI STATUS:**

- **CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)**

Clearly mark the confidential information with bracketing and check the box in the appropriate section ( *Contains CBI*). Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

**Submitter Tracking Number/Internal ID**

**CONTINUED FROM COVER SHEET SECTION # \_\_\_\_\_**

*Contains CBI*

## TSCA HEALTH & SAFETY STUDY COVER SHEET - INSTRUCTIONS

(Note: Do not mail these instructions with your submission)

### Paperwork Reduction Act Notice

The annual public burden for this collection of information is estimated to average 30 minutes per response, including the time needed for reading the instructions and completing the necessary information contained in this form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division, Environmental Protection Agency (2822T), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460. Include OMB number 2070-0156 in any correspondence. Do not send the completed form to this address. The actual information or form should be submitted in accordance with the instructions specified in the corresponding regulations

### General Instructions

- This voluntary cover sheet was designed to serve as a tool for industry and EPA in the preparation, processing, review, and availability of TSCA information, and as an alternative for cover letters to TSCA submissions.
- As with all EPA submissions, follow applicable EPA regulations and guidance in submitting the information.
- A check box at the top has been provided to indicate if there is confidential business information (CBI). Check this box if the page contains information that is confidential. For information what can be claimed confidential under TSCA refer to TSCA section 14, 40 CFR Part 2 Sub-Part B and other applicable EPA and TSCA guidance. If the page contains CBI, clearly mark the information with bracketing. Check the box "Contains CBI" in the appropriate section. Submit another cover sheet with the CBI deleted and mark "Public Display Copy" in the heading.
- Under TSCA reporting requirements, a submission may contain multiple studies. A cover sheet should be completed for **each study** in the submission and go to box 2.4 and add Study 1 of 1 for a submission having a single study, Study 1 of x, Study 2 of x, etc. (for a submission having multiple or x number of studies).
- A cover sheet is unnecessary for submissions containing **no health and safety data**. Examples of submissions with no health and safety data include: section 4-related correspondence on issues of different test protocols; section 8(e) or FYI voluntary actions of submitters to reduce exposures; information on chemical use or commercial status; substantiation for submitting FYI vs. 8(e). If a submission is related to a previous submission, please reference the EPA assigned Document ID for PMN, 8(e) and FYI submissions (PMN, 8EHQ and FYI numbers). For other submissions, please reference the EPA Document Control Number (DCN) or Study title with submission date. The EPA will provide the Document ID as well as the DCN when acknowledging PMNs, 8(e)s and FYIs.

If additional space is needed in any of the sections of the Cover Sheet, please check the "continuation sheet attached" box in the appropriate section and attach a Continuation Sheet (a standardized continuation sheet has been provided; it is titled 9.0 Continuation Sheet).

## INSTRUCTIONS - continued page 2

- It is important to indicate if a study/submission is initial, follow-up or final. An initial submission is for a given chemical/case identified or initiated by a company. A follow-up or a supplement is a submission which contains information specifically requested by EPA (Follow-up) or information related to a previous submission but not specifically requested by EPA (Supplement).
- Please attach to the cover sheet package an abstract or summary for each study prepared by or for the submitter, **if available**, and check the box "YES" under section 2.1. Otherwise check the box "NO". **[Note: a summary/abstract is required under 8(e).]**
- Space is provided in section 8.0 for the submitter to provide any additional study interpretation, comments, etc which could immediately assist in EPA's screening and review of the study/submission. A continuation sheet may be attached.
- If any information in the cover sheet is unknown, write "unknown." If it is not applicable write "N.A." Provide written explanation if appropriate.

### **Detailed Instructions For Completing Cover Sheet**

**TSCA CBI (Confidential Business Information) Status** - Check this box if the page contains information that is confidential. For information what can be claimed confidential under TSCA refer to TSCA section 14, 40 CFR Part 2 Sub-Part B and other applicable EPA and TSCA guidance. If the page contains CBI, clearly mark the information with bracketing. Check the box "Contains CBI" in the appropriate section. Submit another cover sheet with the CBI deleted and mark "Public Display Copy" in the heading.

**1.0 Submission Type** - Check one of the boxes for the TSCA section that the submission is being made under- 8(d), 8(e), FYI, 4 or OTHER. Check the appropriate box to indicate if a study/submission is initial, follow-up or final. An initial submission is for a given chemical/case identified or initiated by a company. A follow-up or a supplement is a submission which contains information specifically requested by EPA (Follow-up) or information related to a previous submission but not specifically requested by EPA (Supplement).

**2.1 Summary/Abstract Attached** - Please attach to the cover sheet package an abstract or summary for each study prepared by or for the submitter, if available, and check the box "YES" under section 2.1. Otherwise check the box "NO". [Note: a summary/abstract may be required under 8(e).]

**2.2 Submitter Tracking Number or Internal ID** - Enter an internal company id number; also, **write this ID** on the complete submission for easy linkage to and retrieval of the entire study/submission for EPA processing, review, and public availability.

**2.3 For EPA Use Only** - Please leave this section blank. This is for EPA purposes such as assignment of submission tracking numbers.

**2.4 Study \_\_\_ of \_\_\_** -

## **INSTRUCTIONS - continued page 3**

**3.0 Chemical/Test Substance Identity** - If additional space is required for any chemical identity data element, check the continuation box and attach a continuation sheet appropriately identifying the relevant specific data element and referencing the study/submission. Enter the CAS# of the chemical for the specific study of the cover sheet. Enter the chemical name; specify nomenclature if other than CAS name. Enter the % purity if impurities are present, leave blank if unknown. Check one of three boxes indicating if the chemical is a single ingredient (e.g., 100% NaCl), technical grade product (e.g., 50% NaOH solution), or mixture (e.g., perfume formula with many ingredients). Enter the trade names and common names for the material if applicable. If the test substance contains more than one chemical, list the components by CAS number, name, and % weight in the mixture. Submitters are requested to provide informative generic chemical names for substances whose chemical identity has been claimed TSCA confidential business information.

**4.0 Report/Study Title** - Provide the title of the entire submission, not the title of any specific study subsection; if insufficient space, check the continuation box and attach a continuation sheet with the complete title.

**5.1 Study/TSCATS Indexing Terms** - Check either Health Effects, Environmental Effects, or Environmental Fate - check only one.

**5.2 Study/TSCATS Indexing Terms** - See the attached Study Indexing Terms Sheet. Find appropriate (checked) Study Type and select relevant, detailed Study Type (for HE, EE, EF), Subject Organism (HE, EE only), Route of Exposure (HE only), and Vehicle (HE only, if applicable); transfer the 4-letter TSCATS code to the cover sheet. If an appropriate indexing term is not available, check other box and clearly print description.

**6.0 Report/Study Information** - If additional space is required for any study information data, check the continuation box and attach a continuation sheet identifying the relevant specific data element and referencing the study/submission. Enter the complete name of the contractor or laboratory which conducted the study. Include the source of data or study sponsor, if different than the submitter. Enter the actual completion date of the study/submission as dd/mm/yy. Check GLP box if existing Good Laboratory Practices were used in the conduct of the study.

**7.0 Submitter Information** - If additional space is required for any submitter information, check the continuation box and attach a continuation sheet identifying this data element and referencing the study/submission (e.g. submitter tracking number). Enter submitter name, title, and phone. Enter company name and address. Enter the address of the submitter if the submitters address is different than the company address. Please provide a key technical contact name and telephone number of an individual who can discuss the content/substance of the study/submission during the EPA scientific review process.

**8.0 Additional Comments** - This space is provided for the submitter to provide any additional study interpretation, comments, etc., which could immediately assist in EPA's screening and review of the study/submission. A continuation sheet may be attached. For TSCA section 8(e) and FYI submissions state rationale for submitting information as 8(e) versus FYI and voluntary actions taken by the submitter in response to the new information.

**Submitter Signature/Date** - TSCA section 8(e) submissions must be signed by the submitter and dated. All submissions should be submitted by certified mail with return receipt to demonstrate submission receipt by the EPA.

**9.0 Continuation Sheet** - If additional space is needed in any of the sections of the cover sheet, please check the "continuation sheet attached" box in the appropriate section and attach a Continuation Sheet, Section 9.0.

**INSTRUCTIONS - continued page 4**

**STUDY INDEXING TERMS**

**FOR HEALTH EFFECT (HE) STUDIES ONLY**

<p><b><u>Study Type</u></b></p> <p><input type="checkbox"/> Acute Toxicity (ATOX)</p> <p><input type="checkbox"/> Subchronic Toxicity (STOX)</p> <p><input type="checkbox"/> Chronic Toxicity (CTOX)</p> <p><input type="checkbox"/> Carcinogenicity (CARC)</p> <p><input type="checkbox"/> Combined Chronic Toxicity/ Carcinogenicity (CTCA)</p> <p><input type="checkbox"/> Cell Transformation (TRFM)</p> <p><input type="checkbox"/> Biochemical Interactions and/or Mechanism of Toxic Effects (BCHM)</p> <p><input type="checkbox"/> Absorption, Distribution, Metabolism Excretion (ADME)</p> <p><input type="checkbox"/> Primary Dermal Sensitization (DSEN)</p> <p><input type="checkbox"/> Primary Dermal irritation (DIRR)</p> <p><input type="checkbox"/> Primary Eye irritation (EIRR)</p> <p><input type="checkbox"/> Reproduction/Fertility Effects (RTOX)</p> <p><input type="checkbox"/> Teratology (TERA)</p> <p><input type="checkbox"/> Combined Teratology/Reproductive Effects (TERE)</p> <p><input type="checkbox"/> Epidemiology Study (EPID)</p> <p><input type="checkbox"/> Case Report (CASE)</p> <p><input type="checkbox"/> Genotoxicity (GTOX)</p> <p><input type="checkbox"/> Gene Mutation (MUTA)</p> <p><input type="checkbox"/> Chromosomal Effects (CHRM)</p> <p><input type="checkbox"/> DNA Effects (DNAF)</p> <p><input type="checkbox"/> Tissue Determination Concentration (TCON)</p> <p><input type="checkbox"/> Industrial Hygiene (HYGN)</p> <p><input type="checkbox"/> Neurotoxicity (NEUR)</p> <p><input type="checkbox"/> Immunotoxicity (ITOX)</p> <p><input type="checkbox"/> Target Organ Toxicity: specify _____</p> <p><input type="checkbox"/> Other: specify _____</p>	<p><b><u>Subject Organism/Test System</u></b></p> <p><input type="checkbox"/> Mammals (MAMM)</p> <p><input type="checkbox"/> Rats (RATS)</p> <p><input type="checkbox"/> Mice (MICE)</p> <p><input type="checkbox"/> Hamsters (HAMS)</p> <p><input type="checkbox"/> Guinea Pigs (GUIN)</p> <p><input type="checkbox"/> Rabbits (RABB)</p> <p><input type="checkbox"/> Dogs (DOGS)</p> <p><input type="checkbox"/> Cats (CATS)</p> <p><input type="checkbox"/> Monkeys (MNKY)</p> <p><input type="checkbox"/> Pigs (PIGS)</p> <p><input type="checkbox"/> Cattle (COWS)</p> <p><input type="checkbox"/> Sheep (SHEP)</p> <p><input type="checkbox"/> Goats (GOAT)</p> <p><input type="checkbox"/> Humans (HUMN)</p> <p><input type="checkbox"/> Other Mammals (OTMA)</p> <p><input type="checkbox"/> Bacteria (BACT)</p> <p><input type="checkbox"/> Algae (ALGA)</p> <p><input type="checkbox"/> Fungi (FUNG)</p> <p><input type="checkbox"/> Yeast (YEST)</p> <p><input type="checkbox"/> Plant (PLNT)</p> <p><input type="checkbox"/> Insect (INSE)</p> <p><input type="checkbox"/> Bird (BIRD)</p>	<p><b><u>Route of Exposure</u></b></p> <p><input type="checkbox"/> Oral (ORAL)</p> <p><input type="checkbox"/> Gavage (GAVG)</p> <p><input type="checkbox"/> Dermal (DERM)</p> <p><input type="checkbox"/> Inhalation (INHL)</p> <p><input type="checkbox"/> Intratracheal Instillation (INTR)</p> <p><input type="checkbox"/> Parenteral (PARN)</p> <p><input type="checkbox"/> Intravenous (INTV)</p> <p><input type="checkbox"/> Intraperitoneal (INTP)</p> <p><input type="checkbox"/> Intramuscular (INTM)</p> <p><input type="checkbox"/> Subcutaneous (SUBC)</p> <p><input type="checkbox"/> Implant (IMPL)</p> <p><input type="checkbox"/> Transplacental (TRPL)</p> <p><input type="checkbox"/> In Vitro (INVR)</p> <p>-----</p> <p><b><u>Vehicle of Exposure</u></b> (check only if applicable)</p> <p><input type="checkbox"/> Water</p> <p><input type="checkbox"/> Corn Oil</p> <p><input type="checkbox"/> Food</p> <p><input type="checkbox"/> Other: specify _____</p>
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**FOR ENVIRONMENTAL EFFECT (EE) STUDIES ONLY**

**FOR ENVIRONMENTAL FATE (EF) STUDIES ONLY**

<p><b><u>Study Type</u></b></p> <p><input type="checkbox"/> Acute Toxicity (ATOX)</p> <p><input type="checkbox"/> Subchronic Toxicity (STOX)</p> <p><input type="checkbox"/> Chronic Toxicity (CTOX)</p> <p><input type="checkbox"/> Critical Life Stage Test (CLIF)</p> <p><input type="checkbox"/> Seed Germination Test (SEED)</p> <p><input type="checkbox"/> Plant Growth or Damage Test (PGRD)</p> <p><input type="checkbox"/> Microbiological Function Test (MICR)</p> <p><input type="checkbox"/> Ecosystem Modeling (ECOS)</p> <p><input type="checkbox"/> Reproduction/Fertilization Test (RTOX)</p> <p><input type="checkbox"/> Absorption, Distribution, Metabolism Excretion (ADME)</p> <p><input type="checkbox"/> Tissue Concentration (TCON)</p> <p><input type="checkbox"/> Other Environmental Effects (OTEE) specify _____</p>	<p><b><u>Subject Organism</u></b></p> <p><input type="checkbox"/> Bacteria (BACT)</p> <p><input type="checkbox"/> Algae (ALGA)</p> <p><input type="checkbox"/> Fungi (FUNG)</p> <p><input type="checkbox"/> Yeast (YEST)</p> <p><input type="checkbox"/> Plant (PLNT)</p> <p><input type="checkbox"/> Amphibians (AMPH)</p> <p><input type="checkbox"/> Mollusks (MOLL)</p> <p><input type="checkbox"/> Fish - Freshwater (FFRE)</p> <p><input type="checkbox"/> Fish - Marine (FMAR)</p> <p><input type="checkbox"/> Reptiles (REPT)</p> <p><input type="checkbox"/> Bird (BIRD)</p> <p><input type="checkbox"/> Insect (INSE)</p> <p><input type="checkbox"/> Invertebrates (INVE)</p> <p><input type="checkbox"/> Other Wildlife (WILD) specify _____</p>	<p><b><u>Study Type</u></b></p> <p><input type="checkbox"/> Physical / Chemical Properties (PCHE)</p> <p><input type="checkbox"/> Water Solubility (WSOL)</p> <p><input type="checkbox"/> Vapor Pressure (VPRE)</p> <p><input type="checkbox"/> Partition Coefficient (PART)</p> <p><input type="checkbox"/> Dissociation Constant (DISS)</p> <p><input type="checkbox"/> Henry's Law Constant (HLAW)</p> <p><input type="checkbox"/> Transport Processes (TSPT)</p> <p><input type="checkbox"/> Biodegradation (BDEG)</p> <p><input type="checkbox"/> Bioconcentration / Bioaccumulation (BIOC)</p> <p><input type="checkbox"/> Photolysis (PHOT)</p> <p><input type="checkbox"/> Hydrolysis (HYDR)</p> <p><input type="checkbox"/> Monitoring Information (MONT)</p> <p><input type="checkbox"/> Production and Process Info (PROD)</p> <p><input type="checkbox"/> Other Studies (OTHR) specify _____</p>
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