UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Order Under Section 4(a)(2) of the Toxic Substances Control Act

Chemical Subject to this Order:

Chemical Name: *trans*-1,2-Dichloroethylene

Chemical Abstract Service Registry Number (CASRN): 156-60-5

Docket Identification (ID) Number: EPA-HQ-OPPT-2018-0465[1]

Recipients of this Order:

Company Name: 3M

Company Name: BASF Corporation

Company Name: Chemical Compounding CO

Company Name: Huntsman International

Company Name: Microcare Corp

Company Name: Occidental Chemical Holding Corp

Company Name: Olin Corp

Company Name: The Boeing Company

Company Name: Unistar Chemical

Company Name: Versum Materials Inc

Company Name: Westlake Chemical Corp

Dear Sir or Madam:

This Order requires you and the other named manufacturer(s) and/or processor(s) of *trans*-1,2-Dichloroethylene (CASRN 156-60-5) to develop and submit certain information for *trans*-1,2-dichloroethylene, or otherwise respond to the U.S. Environmental Protection Agency (referred to herein as "EPA" or "the Agency"). Failure to respond to this Order, or failure to otherwise comply with its requirements, is a violation of section 15 of the Toxic Substances Control Act (TSCA), 15 U.S.C. §

[1] To access the docket, go to https://www.regulations.gov.

2614. Any person who violates TSCA shall be liable to the United States for penalties in accordance with section 16 of TSCA, 15 U.S.C. § 2615.

This Order is **effective 5 calendar days after its date of signature.** The timeframes and options for responding are described in **Unit IV. of this Order** (Responding to the Order). Please note that the initial response deadline as defined in **Unit IV.C. of this Order** (Schedule for Responding to the Order) is calculated for you and included in the email that transmitted this Order to you. A subsequent email will provide a company specific Order number for you to use in responses and communications about this Order.

This Order is organized as follows:

I. PURPOSE AND AUTHORITY

This Order is being issued under the authority of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 *et seq*. Under TSCA, EPA has the authority to issue regulatory actions designed to gather or develop health and safety information and exposure information on chemical substances and mixtures, and to control unreasonable risks associated with new and existing chemical substances. TSCA section 4 authorizes EPA to require the development of information related to chemicals and the use of prescribed "protocols and methodologies" in order to inform EPA and other federal agencies about chemical risks, which in turn will inform TSCA decisionmakers for purposes of prioritization for risk evaluation, risk evaluation and risk management of those chemicals as necessary

This Order requires manufacturers and processors to develop and submit new information on *trans*-1,2-dichloroethylene that is necessary for EPA to perform a risk evaluation under TSCA section 6(b).

II. STATEMENT OF NEED

The basis for requiring the development of new information by this Order is described in this unit. This statement of need, as required by TSCA section 4(a)(2), includes: A) The need for the new information;

B) How information reasonably available to the Administrator was used to inform the decision to require the new information; C) Why issuance of this Order is warranted instead of promulgating a rule or entering into a consent agreement; and D) Why the Agency is not requiring the testing of vertebrate animals in this Order. **Unit III.A. of this Order** (Required Tests) indicates which tests apply specifically to manufacturers and/or processors subject to this Order.

A. THE NEED FOR THE NEW INFORMATION

This section serves to delineate what new information is being required in this Order and why such information is needed for the risk evaluation of *trans*-1,2-dichloroethylene under TSCA section 6(b).

The *Final Scope of the Risk Evaluation for trans-1,2-Dichloroethylene* [2] includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expects to consider in the TSCA section 6(b) risk evaluation for *trans*-1,2-dichloroethylene. EPA has used the scope document and the conceptual models therein for workers and occupational non-users (ONUs), consumers and bystanders, and environmental releases as a starting point for identifying information needs under this Order. The conceptual models[3] visually represent the exposures (pathways and routes), receptors and hazards associated with the conditions of use of *trans*-1,2-dichloroethylene to humans and the environment. For each exposure (pathway and route), receptor and hazard that is visually represented, the EPA has identified the information needed to conduct a quantitative risk evaluation for this chemical.

EPA received public comments on the draft scope documents for the 20 High Priority Substances designated under TSCA in December 2019, including *trans*-1,2-dichloroethylene, that emphasized the importance of conducting risk evaluations to a high degree of accuracy and developing conclusions of high confidence to develop effective risk mitigation strategies that are specifically tailored to a condition of use. With this goal in mind, EPA must seek additional information where there are data needs that are not addressed by the available information necessary to conduct the risk evaluation of *trans*-1,2-dichloroethylene.

EPA has identified the following information as necessary to conduct the risk evaluation of *trans*-1,2-dichloroethylene. The list below identifies the information needs and provides context for the role that each set of information plays in conducting robust chemical risk evaluations.

1. Environmental Hazard:

Identifying hazards to aquatic and terrestrial organisms is needed to conduct a risk evaluation. EPA used the conceptual model in the *Final Scope of the Risk Evaluation for trans-1,2-Dichloroethylene* to identify the specific releases of the chemical, resulting exposure pathways, and relevant species as they pertain to the testing scenarios in this Order. There are no relevant environmental hazard data needs for *trans*-1,2-dichloroethylene.

2. Occupational Exposure:

Information about occupational exposure pathways is necessary to evaluating risk to potentially exposed subpopulations to this substance. The conceptual model in the *Final Scope of the Risk Evaluation for trans-1,2-Dichloroethylene* identifies worker and ONU inhalation exposure, as

[2] *https://www.epa.gov/sites/production/files/2020-09/documents/casrn_156-60-5_trans-12-dichloroethylene_final_scope.pdf*.
[3] During Scoping, EPA used the conceptual models to identify pathways and routes of exposure associated with environmental releases which are under the jurisdiction of TSCA and no other EPA-administered statutes and associated regulatory programs and then made determinations on which exposure pathways should be included in the TSCA risk evaluation.

well as worker dermal exposure, as exposure pathways in the life cycle of *trans*-1,2-dichloroethylene. More importantly, as identified in the scope document, EPA needs occupational exposure data tied to the specific conditions of use the EPA expects to assess for the risk evaluation. The relevant occupational exposure data needs for *trans*-1,2-dichloroethylene are as follows:

a. *Worker and ONU (as defined in the scope document) Inhalation Exposure:*
    i. Air/vapor concentrations of *trans*-1,2-dichloroethylene in the worker and ONU personal breathing zone and/or work area, and;
    ii. Occupational exposure information, such as the facility process description, process parameters, job or activity description and corresponding title of worker or group of workers performing each job or activity, the number of workers performing each job or activity, daily duration of exposure to releases of *trans*-1,2-dichloroethylene from each job or activity, and the rest of the monitoring parameters on occupational inhalation exposure found in Enclosure E and in NIOSH Method 1003 (2003).

b. *Worker Dermal Exposure:*
    i. Absorption of *trans*-1,2-dichloroethylene on the skins of humans and animals.
    ii. Concentration on worker hands from vapor, mist, and spillage.
    iii. Account for evaporation and trans-epidermal water loss (skin surface vapor loss is an indicator of the integrity of the skin barrier) of *trans*-1,2-dichloroethylene resulting from dermal exposure as volatility and integrity of skin impact the load of the permeant. Full details can be found in Enclosure F.
    iv. Occupational exposure information, including facility process description, process parameters, job or activity description and corresponding title of worker or group of workers performing a specific job or activity, the number of workers performing each job or activity, daily duration of exposure to releases of *trans*-1,2-dichloroethylene, and the rest of the monitoring parameters on worker dermal exposure found in Enclosures E and F.

B. HOW INFORMATION REASONABLY AVAILABLE TO THE ADMINISTRATOR WAS USED TO INFORM THE DECISION TO REQUIRE NEW INFORMATION

This section details the systematic review processes used by EPA to identify information that is not currently available in existing literature. This section describes the systematic review process in three parts: 1) Scoping and Conceptual Models; 2) The Systematic Review of Reasonably Available Existing Information; and 3) Discipline-Specific Approach for Identifying Data Needs.

1. Scoping and Conceptual Models

EPA's assessment of data needs for risk evaluation began with the conceptual models in the *Final Scope of the Risk Evaluation for trans-1,2-Dichloroethylene*. The conceptual models[4] describe the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of *trans*-1,2-dichloroethylene to humans and the environment. The Agency performed a review of reasonably available information on the exposures (pathways and routes),

[4] During Scoping, EPA used the conceptual models to identify pathways and routes of exposure associated with environmental releases which are under the jurisdiction of TSCA and no other EPA-administered statutes and associated regulatory programs and then made determinations on which exposure pathways should be included in the TSCA risk evaluation.

receptors and hazards identified in the conceptual models and identified potential data needs related to environmental hazard and occupational exposure (specifically, worker and ONU inhalation exposure and worker dermal exposure scenarios).

2. Systematic Review of Reasonably Available Existing Information

Reasonably available information on the physical and chemical properties, environmental hazard, and information on worker and ONU inhalation exposure scenarios and worker dermal exposure scenarios during manufacturing, processing, distribution, use, and disposal have been incorporated into EPA's systematic review for this chemical. As appropriate, analogous chemicals were identified and reasonably available information regarding analogous chemicals (*e.g.,* environmental hazard data) was also integrated into the systematic review.

The systematic review process began with searching peer-reviewed literature databases (*e.g.*, Agricola, PubMed, Science Direct, ECOTOX Knowledgebase) for studies using *trans*-1,2-dichloroethylene, synonyms and trade names. EPA also conducted a search for gray literature (e.g., technical reports, reference books, dissertations, and other information not found in standard, peer-reviewed literature databases), as well as public comments and information submitted to the Agency under TSCA sections 4, 5, 8(e), 8(d), and For Your Information (FYI) submissions.

The collected compilation of information was then screened for relevance. This process applied title/abstract screening and/or full-text screening based on screening criteria developed *a priori* for environmental hazard (Population, Exposure, Comparator and Outcomes (PECO)); physical and chemical properties (Pathways and Processes, Exposure, Setting or Scenario, and Outcomes (PESO)) or occupational exposure literature (Receptors, Exposure, Setting or Scenario, and Outcomes (RESO)). See the *Application of Systematic Review in TSCA Risk Evaluations*[5] (May 2018) for more details on this process.

As a result of the data searching and screening, EPA determined that reasonably available information on physical and chemical properties of *trans*-1,2-dichloroethylene is adequate for conducting a risk evaluation and, therefore, no further testing of physical and chemical properties is needed. Due to the limited nature of the information that was identified for environmental hazard and occupational exposures, EPA has determined that additional information needs to be developed in order to complete the risk evaluation of *trans*-1,2-dichloroethylene.

3. Discipline-Specific Approach for Identifying Data Needs

a. Environmental Hazard

As determined in the *Final Scope of the Risk Evaluation for trans-1,2-Dichloroethylene*, the manufacturing, processing, distribution, use and disposal of *trans*-1,2-dichloroethylene can result in releases to the environment and exposure to aquatic organisms. EPA expects to assess environmental risks to aquatic vegetation, invertebrates and vertebrates and therefore requires hazard data for each of these assessment endpoints. EPA also expects to assess organisms for both aquatic and terrestrial hazard when those organisms transition between aquatic and terrestrial ecosystems depending on the life stage evaluated (*e.g.*, midges inhabit sediment as larvae but mature into adults that inhabit terrestrial and aquatic ecosystems). Furthermore,

[5] *https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf*.

multiple exposure routes and media will be considered, if relevant to the environmental conceptual models.

Evaluation of reasonably available information for *trans*-1,2-dichloroethylene included consideration of existing data for *trans*-1,2-dichloroethylene and analogous chemicals for all pathways identified in the environmental conceptual model in the *Final Scope of the Risk Evaluation for trans-1,2-Dichloroethylene*. EPA identified nine analogues to *trans*-1,2-dichloroethylene using EPA's Analog Identification Methodology (AIM) software (see Table 1.0). EPA identified existing measured environmental hazard data for aquatic and terrestrial species for *trans*-1,2-dichloroethylene and the identified analogues from the EPA's ECOTOX Knowledgebase (ECOTOX) and information submitted under TSCA (*e.g.*, under TSCA sections 4, 8e, and FYI). To evaluate the fitness of a chemical analogue for assessing hazards of *trans*-1,2-dichloroethylene, EPA used Ecological Structure Activity Relationships (ECOSAR) to estimate aquatic hazards resulting from acute and chronic exposures to *trans*-1,2-dichloroethylene and the identified analogues. ECOSAR estimates of environmental hazard to aquatic organisms were considered as relevant information if estimates for toxicity resulting from acute or chronic exposure were within a ten-fold difference of measured values from available and relevant data.

As shown below in Table 1.0. environmental hazard data were identified for *trans*-1,2-dichloroethylene and four of the nine identified analogues to assess all relevant pathways in the environmental conceptual model in regards to exposed aquatic organisms, except for benthic invertebrate toxicity data due to acute and chronic exposure via sediment. However, the *Final Risk Evaluation for Trichloroethylene* has sufficient environmental hazard information for use as analogue data for *trans*-1,2-dichloroethylene on benthic invertebrate toxicity data due to acute and chronic exposure via sediment.

Table 1.0. - Measured *aquatic* environmental hazard data identified for *trans*-1,2-dichloroethylene and identified analogues

Chemical Name	CASRN	Environmental Hazard Data Availability for *trans*-1,2-dichloroethylene						
		Acute Exposure			Chronic Exposure			Algae
		Fish	Pelagic Invertebrate	Benthic Invertebrate via Sediment	Fish	Pelagic Invertebrate	Benthic Invertebrate via Sediment	
***trans*-1,2-Dichloroethylene**	156-60-5	X	X	N/A	N/A	N/A	N/A	X
Analogues for *trans*-1,2-Dichloroethylene								
Ethene, 1,1,2-trichloro-	79-01-6	X	X	N/A	X	X	N/A	X
1,2-Dichloroethene(cis)	156-59-2	X	N/A	N/A	N/A	N/A	N/A	X
Tetrachloroethene	127-18-4	X	X	N/A	X	X	N/A	X
Hexachlorobutadiene	87-68-3	X	X	N/A	X	N/A	N/A	X
Trichloroethylene*	79-01-6	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Tetrachloro-1,3-butadiene	58334-79-5	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1,1,4-Trichlorobutadiene	83682-46-6	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pentachlorobutadiene	55880-77-8	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1,1,4,4-Tetrachlorobuta-1,3-diene	36038-53-6	N/A	N/A	N/A	N/A	N/A	N/A	N/A

An "X" or "N/A" denotes when environmental hazard data was or was not identified, respectively, for the specified chemical for specific taxa and exposure durations.

*The *Final Risk Evaluation for Trichloroethylene* has sufficient environmental hazard information for use as analogue data for *trans*-1,2-dichloroethylene.

b. Occupational Exposure

i. Worker and ONU Inhalation Exposure.

Data sources on ONU inhalation exposure to *trans*-1,2-dichloroethylene were not located. For worker exposure to *trans*-1,2-dichloroethylene, data sources identified during the systematic review process detailed under **Unit II.B.2. of this Order** contain insufficiencies which introduce uncertainty and potential bias into the risk evaluation.

Examples of insufficiencies include:

- A lack of specific or range of values of interest for inhalation exposure parameters that represent exposure patterns and variability associated with the specific and various conditions of use that EPA expects to assess;
- Use of unreliable protocols that lack clarity and completeness with respect to the collected data (*e.g.*, missing quality assurance information on background sampling, reproducibility, and representativeness);
- Lack of data qualifier narratives, description of sampling and analytical methods used (*e.g.*, whether the results are representing area samples, personal breathing zone samples, and usage of individual and/or in tandem sampling devices/ analytical instruments with higher method detection limits than the required reported limit that are unreasonable for the intended use of the information); and
- Omissions of detection limits and/or deficiencies in defining reported detection limits.

Additionally, in TSCA risk evaluations, the source areas/exposure zones are determined by professional judgment and dependent on the specific facility and could be judged by several factors such as the chemical inventory, ventilation of the facility, vapor pressure and emission potential of the chemical, process temperature, size of the room, job tasks, and modes of chemical dispersal from activities. The lack of information on the near-field and far-field values and exposure analysis reflecting the job responsibilities and exposure scenarios specific to different types of workers and *trans*-1,2-dichloroethylene prevent identification and verification of the worker exposures under various conditions of use.

ii. Worker Dermal Exposure

The data sources identified during the systematic review process detailed under **Unit II.B.2. of this Order** on worker dermal exposure to *trans*-1,2-dichloroethylene contain one or more insufficiencies. Limited dermal data reported in the literature used non-standard protocols without the description of methods, thereby preventing robust evaluation of whether the data can be used to assess the specific and various conditions of use that EPA expects to assess. Information on dermal exposure to *trans*-1,2-dichloroethylene in the workplace should provide details on test conditions and protocols followed for intended purpose (*e.g.*, condition of use). For example, a worker's exposure is generally not uniform over time due to routine and non-routine tasks performed throughout the day. In workplaces, tasks, activities, work processes, and locations change over time, resulting in occupational exposures that could vary both within a worker over time and between workers in the same job. Both facility-specific data and job-specific data are needed to identify exposure patterns

and variability associated with the specific and various conditions of use that EPA expects to assess. These insufficiencies in the existing information support the Agency's decision to require the development of new information on worker dermal exposure for *trans*-1,2-dichloroethylene.

C. WHY ISSUANCE OF THIS ORDER IS WARRANTED INSTEAD OF PROMULGATING A RULE OR ENTERING INTO A CONSENT AGREEMENT

EPA is using its order authority under TSCA section 4(a)(2) to inform the risk evaluations under TSCA section 6(b) in accordance with the requirements and timeframes for conducting those risk evaluations. Use of this TSCA section 4(a)(2) authority will allow EPA to target known manufacturer and processor recipients to obtain the needed information more quickly than if EPA were to issue a TSCA section 4 rulemaking or consent agreement.

D. EPA DETERMINED THAT VERTEBRATE TESTING WAS NOT NEEDED IN THIS ORDER

EPA considered each of the reasonably available existing information types articulated in 4(h)(A), and has determined that vertebrate testing is not needed for assessing the particular exposure pathways and receptors discussed in this Order because reasonably available data, computational toxicology, or high-throughput screening methods and the prediction models of those methods are available and can be used. The analysis for determining data needs in the environmental hazard assessment described in **Unit II.B.3. of this Order** included use of acceptable NAMs, specifically EPA computational toxicology and informatics tools, AIM and ECOSAR to identify analogues with existing toxicity information that could fill ecological hazard data needs. For testing dermal absorption, EPA's *List of Alternative Test Methods and Strategies*[6] includes new approach methods (NAMs), *i.e.*, *in vitro* studies as alternatives to *in vivo* vertebrate testing, that can be used to determine dermal absorption. Consistent with TSCA section 4(h), EPA is requiring testing be conducted using the *in vitro* test method for determining dermal absorption, in order to replace testing on vertebrates for this endpoint.

III. INFORMATION REQUIRED BY THIS ORDER

This unit applies to Option 1: Develop the Information and Option 2: Submit Existing Information (**Units IV.A.1.** and **IV.A.2. of this Order**).

A. REQUIRED TESTS

This Order requires the testing of *trans*-1,2-dichloroethylene. The tests required by this Order are listed in Table 1.1, as they pertain to manufacturers and/or processors (as identified in Enclosure D) and as specified in the version of the test protocol/methodology current on the day this order is signed. The Company individually, or as a member of the Consortium, must submit the testing below within the timeframes specified in Tables 1.1 and 1.2.

The EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-605-6000) and on the EPA's Chemical Safety and Pollution Prevention website[7]. The Organization for Economic Co-operation and Development (OECD) guidelines are available on the web at *https://www.oecd-ilibrary.org*. The

[6] *https://www.epa.gov/sites/production/files/2019-12/documents/alternative_testing_nams_list_first_update_final.pdf.*
[7] *http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances*.

National Institute for Occupational Safety and Health (NIOSH) test method is available at *https://www.cdc.gov/niosh/docs/2003-154/method-2000.html.*

Once EPA has completed its initial review and accepted data identified in this Order, EPA will notify the designated contact for the company or consortium subject to the Order to inform them that this Order has been satisfied, which in turn will close out the Orders for the companies and participants in the consortium subject to the Order.

EPA reserves the right to revise this Order to extinguish specific testing obligations where existing information subsequently comes to the Agency's attention that in EPA's scientific judgment obviates the need for specific test data required under the Order.

Table 1.1: Required Tests, Protocols/Methodologies

Test Name	Protocol/ Methodology	Manufacturers† Subject? **X** if yes.	Processors† Subject? **X** if yes.
Exposure			
Occupational Inhalation Exposure at each facility under your company's control where there is potential for exposure to *Trans*-1,2-dichloroethylene	NIOSH Method 1003 (2003)	**X**	**X**
Dermal Hand Wipe Sampling-Solvents at each facility under your company's control where there is potential for exposure to *Trans*-1,2-dichloroethylene	Enclosure F	**X**	**X**
Dermal Absorption: In Vitro Method using human and animal skins*	OECD 428 (2004)	**X**	

†Details of how companies were identified as manufacturers and processors of *trans*-1,2-dichloroethylene for this Order are available in Enclosure D.

*The origin of the human and animal skin (gender, animal species, sites [*e.g.*, abdomen, chest or upper leg], and hydration of skin), thickness, and temperature to be specified by the test submitter as these factors influence the integrity of results.

References to Other Considerations for Conducting the Listed Test Guidelines*	
Reference to Other Considerations	Applicable Test Guideline
Background and Special Considerations – Tests with Aquatic and Sediment-Dwelling Fauna and Aquatic Microcosms	OCSPP 850.1000 (2016)
Background and Special Considerations – Tests with Terrestrial and Aquatic Plants, Cyanobacteria, and Terrestrial Soil-Core Microcosms	OCSPP 850.4000 (2012)
Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures	OECD 23 (2019)
Guidance Document for the Conduct of Skin Absorption Studies	OECD 28 (2004)
Guidance Notes on Dermal Absorption	OECD 156 (2011)
Occupational Exposure Data Reporting resource	Enclosure E

*References, guidance, and information from additional sources could be considered, with EPA approval, during the development of study plans when no standard operating procedure (SOP) is available to meet test objectives.

B. STUDY PLANS

If you choose to develop the required information to comply with this Order, you must obtain and review the required protocols/methodologies. You may not modify the required protocols/methodologies unless you first consult with the Agency and obtain Agency approval of any planned modification prior to submitting your initial study plan. The initial study plan is due to the Agency 75 days after the

effective date of the Order. A final study plan is due 60 days after the initial study is submitted. During this time the Agency will review the initial study plan and provide input to ensure adequacy of the final study plan.

Prior to initiating any test, the Company/Consortium must first address EPA's input on the initial study plan and receive EPA's acceptance of the final study plan. EPA's acceptance of a final study plan does not constitute pre-acceptance of any future test results.

All testing must follow the EPA accepted final study plan. If problems occur during testing, the Company/Consortium must request EPA's approval before modifying the accepted final study plan.

You must also secure EPA's approval prior to submitting the initial study plan, if you wish to use a protocol/methodology not listed in this Order. Within your initial study plan, you must submit a detailed description of the protocol/methodology you are requesting to use or your requested modifications of the required protocol/methodology and your reason(s) for using a different or modified protocol/methodology. Indicate whether and how the requested protocol/methodology is appropriate and whether its deviations from the protocol/methodology required by this Order are such that they could alter the validity of the study. If EPA has concerns about the requested protocol/methodology or your requested modifications of the required protocol/methodology, the Agency will inform you of concerns that must be addressed before EPA will approve your request. If testing conducted according to a requested protocol/methodology or requested modifications of the required protocol/methodology is initiated prior to EPA approval, that testing will not satisfy the requirements of the Company under this order. Development of information required by this Order which does not fully comply with the terms of this Order may result in a violation of TSCA section 15.

EPA has identified the protocols/methodologies that must be followed to perform each required test. They are listed in Table 1.1 and may include protocols/methodologies (also known as test guidelines) from OECD or OCSPP/OPPTS. These protocols/methodologies are available via the Internet. It is highly recommended that your final test report be submitted along with the data in the associated OECD harmonized template format which can be located at *https://www.oecd.org/ehs/templates/harmonised-templates.htm*[8]. If questions and /or issues arise during Study Plan development, EPA encourages consultation with the Agency prior to submitting the Study Plan.

The Study Plans must contain the following information:

1. The Order number, excluding the unique 6-digit company number so as to protect each company's private access to the reporting module via CDX. This should look similar to the following example with X's used in place of the unique company number: TO-2020-0000-XXXXXX-00-0. The remainder of the Order number should be identical to the number received with this Order.

2. Name of test to be covered by the test protocol/methodology.

3. The name/number of the protocol/methodology identified by Table 1.1 in the Order which you intend to follow, or a copy of the identified protocol/methodology with your modifications that the EPA has approved, or a copy of the protocol/methodology you requested to use which EPA has approved. If approval for the identified protocol/methodology with your modifications or the use of a protocol/methodology you requested to use is not granted by EPA in time to be included

[8] *https://www.oecd.org/ehs/templates/harmonised-templates.htm*.

in the study plan, they must be referenced as "submitted and pending approval" and the final protocol/methodology submitted later, once approved, in final form in an amended study plan.

4. The rationale for any modification, or pending modification, of the identified protocol/methodology. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant protocols/methodologies.

5. The identity and supporting data on the chemical substance to be tested including physical constants, spectral and chromatographic data, chemical analysis, and stability under test and storage, and test conditions required by the protocol. Per the respective protocol, the purity and Certificate of Analysis of the test substance should be included.

6. The sampling and analytical method that will be used, including whether the sampling method was validated by an approved organization (*e.g.*, NIOSH, OSHA, the American Society for Testing and Materials (ASTM), the International Standards Organization (ISO)) or an industrial hygiene/analytical laboratory.

7. For dermal exposure monitoring, the procedures used to optimize collection efficiency and extraction of the test chemical to ensure that 60% to 125% of the test chemical will be analyzed using the analytical method identified.

8. A description of the preparation and processing of samples that will be done before sampling and during sampling, including equilibration, weighing, calibration, test conditions (temperature, humidity), number and type of samples, and identification of equipment and accessories used (make, model, size/capacity, and operating conditions), including the specific sampling media and sampling instruments that will be used.

9. The sampling strategy that will be used for sample collection, including sample location, flow rates, sampling time, field blanks and sample replication; the sample handling, storage and transport procedures and whether they will be followed; the sample pumps and other instruments and whether they will be properly calibrated with primary standard equipment.

10. For exposure-related testing, the number of samples to be taken for each similar exposure group, and how the workers or others will be selected for sampling (*e.g.*, random sampling, select workers with highest likelihood of exposure or some other statistically valid sampling strategy, and other relevant information suggested by the American Industrial Hygiene Association (AIHA)[9]). Also include the number of samples and length of sampling periods that will be taken to ensure the results are statistically significant for worker and ONU exposure groups, and indicate the statistical method used to demonstrate that the number of samples and length are statistically significant. A list must be included to contain all job descriptions/titles and work activities where workers and ONUs may be exposed and the total number of workers and ONUs per shift and number of shifts per day, length of shifts, length of shifts if not full, number of

[9] The strategy for assessing occupational exposures recommended by the AIHA for successful evaluation include the following: a) collecting information and data to characterize the project site (or facility), process, operations, work force, and environment; b) defining similar exposure groups by process, task, environment, and engineering controls; c) developing exposure profile (*e.g.*, by assigning qualitative ratings on exposure, health effects, and uncertainty to each similar exposure groups); d) determine the acceptability of exposure and need for additional exposure monitoring; and e) re-assess the exposure profiles and data collection, as needed (AIHA, 2015).

operating days/year for job description/title or work activities, and information on industrial hygiene (IH) programs (*e.g.,* respirator testing program).

11. The specific number of quality assurance field samples (including sample volume for limits of detection and quantification) and analytical QA/QC protocols to be followed (*e.g.*, specific number of field blanks, replicates of field samples, and replicate samples). NIOSH 95-117 (Kennedy et al., 1995) provides guideline for sampling and analytical method development and evaluation.

12. The rationale for any combination of protocols/methodologies; the rationale for species/strain selection, dose selection (and supporting data), and route or method of exposure; description of diet to be used and its source (including nutrients and contaminants and their concentration); for in-vitro and/or ex-vivo test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

13. The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.

14. The names, mailing addresses, phone numbers, and e-mail addresses of the appropriate individual(s) for EPA to contact concerning the planned test.

15. The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol follows appropriate quality assurance and quality control procedures.

16. Description of data and results that contain data supporting information that facilitate quality review of the results, *e.g.*, facility process descriptions, operation and process parameters, sampling and monitoring parameters, sample populations, job description/title and the number of workers for each job description or activity and the total daily duration of exposure, engineering controls (*e.g.* local exhaust ventilation), room volume, air exchange rates, air changes per hour of work area, ventilation rates, air speeds, work practices, and personal protective equipment used.

See Enclosure C for more information on monitoring data requirements.

If, after the study plan has been submitted or after testing is underway, you need to make a modification to an identified protocol/methodology or need to use a different protocol/methodology, you must submit a request to EPA to make these changes in your study and you must still meet the deadlines set out in Table 1.2 and Table 1.3 for the relevant test or request an extension (see also **Unit III.C. of this Order**), if needed.

For purposes of satisfying the requirements of this Order, you are required to follow the Good Laboratory Practice (GLP) standards described in 40 CFR part 792, as specified in the CFR on the day this Order is signed. You are also required to provide a statement of compliance with these GLP standards when submitting information to EPA pursuant to this Order.

C. EXTENSION OF DEADLINES

If you believe you cannot submit the required initial response, initial study plan, final study plan, or final study information to the Agency by the deadlines specified in this Order and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency through EPA's CDX portal as

soon as you know you may need an extension. Your request must include: (1) a detailed description of the expected difficulty, including technical and laboratory difficulties, and (2) a proposed schedule including alternative dates for meeting such requirement(s) on a step-by-step basis. Generally, extensions will be granted only in cases of extraordinary testing problems beyond the expectation or control of the manufacturer(s) or processor(s). Extensions will not be considered if the request for the extension is not made in a timely manner, *i.e.* as soon as it is suspected that the deadline cannot be met.

D. FEES FOR SUBMITTING INFORMATION

See 40 CFR § 700.45 for information concerning, when applicable, the requirement to pay a fee when subject to an Order under TSCA section 4. An applicable fee as specific by 40 CFR § 700.45 shall be paid in full no later than 120 days after the effective date of this Order by manufacturers that conduct testing under this Order.

IV. RESPONDING TO THE ORDER

Within 45 calendar days of the effective date of this Order, you, the Order recipient, are required to respond to the Order through EPA's CDX portal informing the Agency which of the five options you have chosen to comply with the Order. **Follow the instructions in Enclosure C for submission to EPA.**

You must comply with this Order by the deadlines applicable to you in **Unit IV.C.** of this Order.

A. FIVE OPTIONS FOR RESPONDING TO THE ORDER

You have five options from which to choose to comply with the Order. You will receive an e-mail from EPA that provides two CDX Order numbers to submit your initial response using one of the five options below. A company that is a manufacturer or both a manufacturer *and* processor of *trans*-1,2-dichloroethylene will utilize the first CDX Order number, while a company who is *only* a processor of *trans*-1,2-dichloroethylene will utilize the second CDX Order number to access the initial response screen for this Order. Details of how companies were identified as manufacturers and processors of *trans*-1,2-dichloroethylene for this Order are available in Enclosure D.

1. Option 1: Develop the Information

If you choose to develop information in response to this Order, you must select this option in the CDX portal form. For more information on the Order's required tests, required protocols/methodologies, and deadlines for submission of test reports see **Unit III.A. and B.** and **Unit IV.C. of this Order.**

Once EPA has completed its review of the submitted test reports and accepts the information as fully complying with your testing obligations under the Order, EPA will confirm this through CDX correspondence.

In considering whether to choose this option to comply with the Order, you should be aware that if other companies, subject to the same Order for the same chemical(s), requested exemptions from testing and those requests were granted due to your intention to test, those companies are responsible for reimbursing you for their share of the final testing costs. See **Unit IV.A.3. of this Order** and **Enclosure B**.

2. Option 2: Submit Existing Information

If you choose to respond to this Order by submitting an existing study and/or other relevant information that you believe EPA has not considered, your Initial Response in EPA's CDX portal must include the

study and/or other relevant information, along with supporting rationale that explains how the study and/or other relevant information meets part or all of the information described as necessary in **Unit II. of this Order**.

EPA's determination regarding whether the study and/or other relevant information satisfies part or all of the Statement of Need will be based on the weight of the scientific evidence from all relevant information reasonably available to the Agency. The Agency will notify you of its determination through CDX. If the Agency determines that the study and/or relevant information is acceptable, EPA will repeal all obligations of this Order that apply to the testing for which the existing information is a substitute, with respect to all recipients of this Order. If the study was your only testing obligation under the Order, all your obligations under the Order will be extinguished upon notification by the Agency.

If EPA determines that the study and/or relevant information is not acceptable, you must modify your Initial Response in EPA's CDX portal to choose one of the other response options in **Unit IV.A. of this Order** within 10 calendar days of being notified by EPA. All remaining deadlines specified in this Order will be extended by the number of days between submission of the existing information and EPA's rejection of the information.

3. Option 3: Request an Exemption

Any person required by this Order to conduct tests and submit information on a chemical may apply for an exemption from such requirement (TSCA section 4(c)(1)).

EPA will grant a request for exemption from the requirement to conduct tests and submit information on a chemical substance if:

1. Information on an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order, or consent agreement, and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order, or consent agreement.

See Enclosure A for what EPA considers satisfactory equivalence data.

As explained in Enclosure B on Cost Sharing, persons who receive exemptions from testing have an obligation to reimburse the person(s) who perform the required testing and submit the required information for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Normally, this is worked out by the parties involved, without the involvement of EPA. However, if agreement cannot be reached on the amount or method of reimbursement, and the company who is entitled to reimbursement requests in accordance with the procedures in Enclosure B that EPA order reimbursement, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement. See TSCA section 4(c).

An exemption request must be submitted through the CDX portal and contain the following:

1. The Order number, the chemical identity, and the CAS No. of the test substance subject to this Order on which the application is based.

2. The specific testing requirement(s) from which an exemption is sought.

3. The basis for the exemption request when another company(ies) has/have submitted the information or is developing information for an equivalent chemical pursuant to a TSCA section 4(a) rule, order, or consent agreement. Your request must identify the company(ies) that submitted or is/are developing the information.

4. The chemical identity of the equivalent chemical (the test substance in the information submitted or being developed) on which the application is based.

5. The equivalence data specified in Enclosure A.

6. The name, mailing address, telephone number, and e-mail address of applicant.

7. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.

8. A Statement of Financial Responsibility: The following sworn statement (*i.e.*, signed and notarized) must accompany each request for an exemption:

9. "I understand that if this application is granted, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit information and upon whose information the granting of my application was based."

EPA's grant of an exemption is conditional upon the completion of the required tests according to the specifications of this order (or other applicable rule, order or consent agreement), including any modifications approved by EPA. If the Agency subsequently determines that none of the companies identified in the exemption request has complied with that rule, order, or consent agreement, the Agency will provide notice through CDX of its intent to terminate the exemption. Within 30 days after receipt of such notice, the exemption holder may submit information in the CDX portal either to rebut EPA's preliminary decision to terminate the exemption or notify EPA of its intent to develop the required information pursuant to the specifications established in the Order and any modifications approved by EPA. If the exemption holder submits information to rebut EPA's preliminary decision to terminate the exemption, then EPA will notify the exemption holder of its decision whether to terminate the exemption and provide the exemption holder an opportunity to request a hearing prior to issuing a final decision to terminate the exemption.

If you receive the Agency's decision to terminate the exemption, you must resubmit the initial response in accordance with one of the options described in **Unit IV.A. of this Order** within 30 calendar days of receipt of the Agency's decision to terminate the exemption, including as applicable the information required under **Unit IV.B. of this Order**, unless before that date EPA has received your request for a hearing in accordance with the procedures provided in the notification. Failure to timely resubmit the initial response or a hearing request will constitute a violation of this Order and of TSCA section 15(1). If you submit a request for a hearing, you will not be required to resubmit the initial response until and unless subsequent to the hearing EPA rules that the exemption is terminated, or you withdraw the hearing request.

If EPA repeals a testing obligation pursuant to **Unit IV.A.3. of this Order**, the corresponding exemption will be extinguished, as the exemption will no longer be necessary. In such a situation, companies who

requested an exemption from that specific testing obligation are not required to reimburse the company that submitted existing data.

4. Option 4: Claim that You Are Not Subject to the Order

You may claim that you are not subject to this Order if you do not manufacture or process the chemical(s) identified on page 1 of this Order or you believe the Order was otherwise sent to you in error. An explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim, must accompany your Initial Response in the CDX portal so that EPA can evaluate the claim. If EPA cannot verify your claim, the original requirements and deadlines in this Order remain. If your claim is approved, EPA will notify you that you are not subject to this Order through CDX correspondence. EPA expects to provide such notification within 50 days of the effective date of the Order.

5. Option 5: Cease the Manufacture or Processing of the Chemical

If, within 90 days of the effective date of the Order, you intend to cease the manufacture of the chemical(s) for which you are required by this Order to submit information, you may satisfy the requirements of this Order by informing the Agency in your Initial Response in the CDX portal that you intend to cease manufacture (including import) or process within 90 days of the effective date of this Order. You must also attach a letter in CDX which includes the following certifying statement: "I certify that the statements made in this letter are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law." The letter must be signed by an authorized representative of the company and include the representative's name and title/position in the company. Failure to cease manufacture or process within 90 days of the effective date of this Order will constitute a violation of this Order and of TSCA section 15(1) and may result in liability under 18 U.S.C. §1001.

If you choose to respond to the Order by ceasing manufacture and/or processing, and then resume manufacture and/or processing of the chemical, you must submit a new response to this Order upon resumption. In the event that EPA ceases work on a risk evaluation for *trans*-1,2-dichloroethylene, the Agency may withdraw this Order.

B. Instructions If you Choose to Participate in a Consortium

If you choose to form or join a consortium to share in the cost of developing the required information, you (as well as the other participants of the consortium) must individually in CDX, state your intention to participate in a testing consortium for each specific chemical and specific test.

For your obligations under this order to be satisfied, the designated lead for the consortium must submit a consortium response to EPA through CDX for the consortium. The response must confirm the formation of the consortium, identify its member companies, and list the testing obligations that the consortium plans to fulfill on behalf of each company by indicating each specific test. The letter must also include contact information for the designated lead of the consortium, who must be domiciled in the U.S. The designated lead for the consortium must submit the Initial Response and required information on behalf of the consortium and its member companies by the deadlines listed in **Unit IV.C. of this Order** Submissions made on behalf of the consortium must be in accordance with instructions in Enclosure C. After the results of the last required test of the Order is submitted and EPA accepts the information as complying with the Order, or EPA accepts existing information submitted by the Consortium, EPA will then provide notification of compliance with the Order to the Order Recipients and the designated lead of the consortium.

Even if you agree to jointly submit the information as part of a consortium, each Order Recipient is still required to comply with the Order and is individually liable in the event of any failure to comply with the Order. If the consortium fails to submit the information or meet any of the requirements of the Order on your behalf, you will be in violation of the Order unless you submit the required information or meet the requirement individually.

The Agency has provided a list of the manufacturers and processors that have received this Order at the top of this Order in the Summary Information section. This list of manufacturers and processors can be used to help Order Recipients form a consortium to jointly develop information, consolidate testing and share the cost of testing. Information on cost sharing is provided in Enclosure B.

C. SCHEDULE FOR RESPONDING TO THE ORDER

Tables 1.2 and 1.3 present the deadlines in chronological order for completing the required actions under this Order if you chose Option 1: to develop the information or Option 2: to submit existing information.

Table 1.2: Deadlines for responding to the order if you chose Options 1 or 2

Deadline	Option 1: Develop the Information by Testing	Option 2: Submit Existing Information
45 days after effective date of order	Submit Initial Response and indicate if joining a testing consortium	Submit Initial Response and submit existing information and indicate if joining a consortium
75 days after effective date order	Submit initial study plan(s) for tests to be conducted	N/A
135 days after effective date of order	Submit final study plan(s) for tests to be conducted	N/A

Table 1.3: Deadlines for submitting final test reports for each required test if you chose Option 1

Test Names	Protocols/ Methodologies	Deadlines to Submit Final Reports to EPA
Exposure		
Occupational Inhalation Exposure at each facility under your company's control where there is potential for exposure	NIOSH Method 1003	8 months after effective date of order
Dermal Hand Wipe Sampling-Solvents at each facility under your company's control where there is potential for exposure to 1,1,2-trichloroethane	Enclosure F	9 months after effective date of order
Dermal Absorption in vitro method using human and animal skins*	OECD 428	12 months after effective date of order

*The origin of the human and animal skin (gender, animal species, sites [*e.g.*, abdomen, chest or upper leg], and hydration of skin), thickness, and temperature to be specified by the test submitter as these factors influence the integrity of results.

Pursuant to TSCA section 4(b)(1)(C), the Agency considers these deadlines to be reasonable because they are based on estimates EPA obtained from up to nine testing laboratories for the time needed by the laboratories to complete tests according to the required test protocols and to analyze results. Companies are encouraged to submit study reports as soon as possible, they need not wait for the final deadline date to submit.

D. CONFIDENTIALITY

Under TSCA section 14(b)(2), health and safety studies submitted under TSCA and data reported to or otherwise obtained by the Administrator from health and safety studies are not protected from disclosure if the studies and data concern a chemical that is offered for commercial distribution, or for which testing is required under TSCA section 4 or notification is required under TSCA section 5. However, TSCA section 14(b)(2) does not apply to information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised of the chemical subject to the Order. Therefore, some or all of the information in the studies required to be submitted under this Order might not be eligible for TSCA confidential business information (CBI) protections.

Information submitted under TSCA that you wish to have EPA protect as CBI must be clearly identified as such when submitted. For sections of the report that are claimed to be CBI, the report must be accompanied by a sanitized version of the report only removing the specific CBI content. When claiming and certifying information to be CBI, you must state the following:

> "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."

In addition, information claimed as CBI must be substantiated upon submission, with the exception of information described in TSCA section 14(c)(2). Guidance for substantiating CBI claims may be found at *https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations*[10].

Failure to follow the statutory requirements for asserting and substantiating a CBI claim may result in the information being made available to the public without further notice to the submitter.

When a claim of CBI under TSCA section 14 is approved by EPA, the Administrator will generally protect that information from disclosure for 10 years (unless the protection from disclosure is withdrawn by the person that asserted the claim), whereupon the claim must be reasserted and re-substantiated if

[10] *https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations*.

the submitter wishes to maintain the CBI claim. In certain cases, EPA may review claims prior to the expiration of the 10-year period.

Under circumstances stated in TSCA section 14(d), EPA may disclose information approved as CBI to appropriate persons including Federal and State authorities, health and environmental professionals, poison control centers, emergency responders, and other appropriate persons.

V. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS ORDER

Failure to comply with any of the requirements in this Order is a violation of TSCA and could subject you to civil and/or criminal penalties under TSCA section 16, 15 U.S.C. § 2615 as modified by the Inflationary Adjustment Act. Each day that failure to meet the requirements continues constitutes a separate violation.

VI. REFERENCES

The following is a listing of the documents that are specifically referenced in this Order. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. van Wendel de Joode, B., Tielemans, E., Vermeulen, R., Wegh, H., & Kromhout, H. Dermal exposure assessment to benzene and toluene using charcoal cloth pads. Journal of Exposure Analysis and Environmental Epidemiology (2005), 47–50r 2005 Nature Publishing Group

2. Kennedy, E.R., Fischbach, T.J., Song, R., Eller, P.M. and S.A. Shulman. 1995. Guidelines for Air Sampling and Analytical Method Development and Evaluation. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Physical Sciences and Engineering DHHS (NIOSH), Publication No. 95-117, Cincinnati, Ohio.

3. National Institute of Occupational Safety and Health. Method 1501, Hydrocarbons, Aromatic. NIOSH Manual of Analytic Methods Fifth Edition, 2020.

VII. PAPERWORK REDUCTION ACT NOTICE

This collection of information is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq*. (**OMB Control No. 2070-0033**). Responses to this collection of information are mandatory under the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 *et seq*. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 137 hours for the average response on a per-chemical basis. Under the PRA, burden is defined at *5 CFR 1320.3(b)*. 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 to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

VIII. FOR FURTHER INFORMATION CONTACT

For technical information contact: Sarah Clark, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3977; email address: *clark.sarahe@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

IX. SIGNATURE

Under the authority in TSCA section 4(a)(2), the United States Environmental Protection Agency hereby issues this Order to take effect on the date of my digital signature.

Dated: January 14, 2021

ALEXANDRA DAPOLITO DUNN

Digitally signed by ALEXANDRA DAPOLITO DUNN
Date: 2021.01.14 18:13:07 -05'00'

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Enclosures

ENCLOSURE A - EQUIVALENCE DATA

For purposes of this Order, "equivalence data" means "chemical data or biological test data intended to show that two substances or mixtures are equivalent." Also, when a chemical substance is "equivalent," it means "that a chemical substance is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance," as defined in 40 CFR § 790.3.

If testing under TSCA section 4(a) is required of an equivalent chemical substance, EPA may grant an exemption from testing to the manufacturer or processor of one substance if the information required under TSCA section 4(a) is submitted or is being developed on the other, and the manufacturer or processor submits the following information to support equivalence with its exemption application:

1. The chemical identity of each chemical substance or mixture manufactured or processed by the applicant for which the exemption is sought. The exact type of identifying data required may be specified in this Order and may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining whether the applicant's substance or mixture is equivalent to the specific test substance.

2. The basis for the applicant's belief that the substance or mixture for which the exemption is sought is equivalent to the test substance or mixture.

3. Any other data which exemption applicants are directed to submit in this Order which may have bearing on a determination of equivalence. This may include a description of the process by which each chemical substance or mixture for which an exemption is sought is manufactured or processed prior to use or distribution in commerce by the applicant.

ENCLOSURE B - COST SHARING

EPA encourages Order recipients that are responsible for developing the same information on the same chemical(s) to avoid duplicative testing and share the cost of information development. If a test is conducted according to a final, approved protocol, it is sufficient that the test is conducted once. Two ways to avoid duplicative testing are discussed in the Order. They are forming or joining a consortium, discussed in **Unit IV.B. of the Order**, or requesting an exemption, discussed in **Unit IV.A.3. of the Order**.

Consortia

Persons that form or join a consortium typically execute an agreement with the other members of the consortium concerning how costs will be shared and how the consortium will operate.

Exemptions

Persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the testing and submit the required information that is the basis for the exemption for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Apportionment of costs between persons receiving exemptions and the person who actually conducts the test(s) is ideally negotiated between the companies involved, without EPA participation. EPA has promulgated regulations that explain how EPA views fair and equitable reimbursement in the context of TSCA section 4(a) test rules. In general, those regulations (40 CFR § 791.40 through § 791.52) make a presumption that a person's fair share of the test costs is in proportion to their share of the total production volume of the test chemical over a specified period of time that begins one calendar year before the effective date of the rule and continues up to the latest data available upon resolution of a dispute. While those regulations do not apply to TSCA section 4 Orders, you may wish to consider them as you decide how to share the costs.

If persons subject to an Order include a person that has been granted an exemption and agreement cannot be reached on the amount and method of sharing the cost of developing the information, the person whose information is the basis for the exemption may request that the Administrator order the person(s) granted the exemption to provide fair and equitable reimbursement after considering all relevant factors, including the share of the market and the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed. See TSCA section 4(c)(3)(A). Upon receipt of such a request, EPA will determine fair and equitable reimbursement and issue an order accordingly. The Agency may, at its discretion, make use of procedures and standards applicable to data reimbursement regarding TSCA section 4 rules, contained in 40 CFR § 791.

ENCLOSURE C - INFORMATION COLLECTED BY THE AGENCY AND RECORDKEEPING

Requirements for Submission of Test Reports

Each test report submitted to EPA must include the following, as applicable:

1. A title page including the following information:

    - The title of the study, including identification of the substance(s) tested and the required test addressed by the study.
    - The author(s) of the study.
    - The date the study was completed.
    - If the study was performed in a laboratory, the name and address of the laboratory, project numbers or other identifying codes.
    - If the report is a commentary on or supplement to another previously submitted report, full identification of the other report with which it should be associated in review.

2. For NIOSH Method 1003 and Enclosure F the final test report and underlying and contextual data must include the following (for further considerations, please refer to Enclosure E):

- Facility and Process Parameters:
    - Description of process (*e.g.*, equipment/machinery/instruments/handling accessories, reaction, activities) and relevant associated layout, process, and instrumentation diagrams.
    - Physical state(s) (solid/liquid/emulsion/particulate/gas) and flow rate of unit operation and/or process train (*e.g.*, kg/hour or m^3/hour).
    - Weight fraction(s) of *trans*-1,2-dichloroethylene in the process(es).
    - Frequency of operation of individual processes (*e.g.*, days/year; days/month and months per year; or days/week and weeks/year).
    - Individual process duration (*e.g.*, hour/day).
- Sampling and Monitoring:
    - Purpose of sampling (*e.g.*, compliance, worst-case, ceiling, short-term, peak).
    - Sample type: (*e.g.*, area/personal/dermal/ field blank, replicates, fortified sample).
    - Sampling and monitoring methods used (*e.g.*, EPA/ASTM/NIOSH/equivalent method and number).
    - Sampling device(s) used to collect samples.
    - Sample ID#.
    - Dates of sampling (mm/dd/year).
    - Duration and frequency of sample(s) collected or sampling start and end times.
    - Locations of sampling devices (*e.g.*, distance from the process/release source and height).

- Analytical method(s) used (*e.g.*, EPA/ASTM/NIOSH/equivalent method and number).
- A description of the data validation and data quality procedures performed to ensure sample integrity during transportation, reproducibility of sample results, and quality assurance/quality control measures implemented (*e.g.*, field blanks, replicates, duplicates, spiked samples), sampling and analytical reproducibility, extraction efficiency, accuracy, precision, and reliable quantitation limit of measurements.
- Method detection limit, limit of quantification and limit of detection of *trans*-1,2-dichloroethylene (*e.g.*, ug/L, ug/m^3 or ug/kg).
- Data acceptance criteria (for each field sampling and analytical operations).
- Results, including units.
- Chain of custody procedures used.
- Observer notes (*e.g.*, deviations from sampling and analytical plan, anomaly and other field observations).

- Information Regarding the Representative Sample Population:
  - Worker (which includes ONU) demographics (age, sex, and length of service) submitted as data points with no personal identifying information.
    - For age, place each worker within one of the following age ranges: 16-20 years old, 21-30 years old, 31-40 years old, 41-50 years old, 51-60 years old, 61-70 years old, 70+ years old.
  - Worker job title (*e.g.*, material handler, loader; however, do not include names of individual workers) and description of that employee's activities.
  - Duration of Work/Activity (*e.g.*, hour/shift of worker).
  - Shift duration (*e.g.*, hour/day); note, samples should generally be collected to cover the entire work shift; if partial shift, indicate length of time.
  - Concentration (µg/L; µg/m^3; or µg/kg) of *trans*-1,2-dichloroethylene at the source of the worker activity and Area/Worker Location.

- Ventilation, Engineering Controls, and Personal Protective Equipment:
  - Are existing administrative and engineering controls in place? (yes/no).
  - If so, describe for each engineering control(s) the type of control used (*e.g.*, annular exhaust for capturing vapors during drum filling).
  - Describe the room/ work area volume (m^3).
  - Describe the type of room/work area ventilation (positive/ negative pressure, indoor, outdoor).
  - Describe the air changes per hour in the Work Area.
  - Describe the ventilation rate (*e.g.*, m^3/hour or cm^3/second).
  - Type of Personal Protective Equipment (PPE), including material of construction of gloves for dermal; types of cartridges for respirators and other specification as applicable, and duration of PPE use during normal operations.
  - Type and duration of PPE usage during emergency (*e.g.*, accidental release, spillage).

3. If sections of the report are claimed to be CBI, the report must be accompanied by a signed and dated document containing the appropriate statement(s) regarding confidentiality in **Unit IV.B. of the Order** and a sanitized version of the report only removing the specific CBI content must be submitted.

4. A statement of compliance with respect to GLP standards as set forth in 40 CFR § 792 and applicable to this Order.

Submission Instructions

The Initial Response, proposed and final study plans, final test reports with underlying data, existing studies, any testing related requests, and all related correspondence must be submitted electronically to EPA as follows:

1. Submit to EPA's Central Data Exchange (CDX) system. CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for submissions to the Agency.

2. The URL for the CDX website is https://cdx.epa.gov/ which takes you to the CDX homepage.

3. On the homepage you may select "Log in" or, if you haven't already registered, select "Register with CDX."

4. Once you have logged on to CDX, follow the instructions for submitting TSCA section 4 Order information. To access the instructions, select "Report electronically" on EPA Internet homepage at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data.

5. The CDX Help Desk is available for data submission technical support between the hours of 8:00 am and 6:00 pm (EST) at 1-888-890-1995 or helpdesk@epacdx.net. The CDX Help Desk can also be reached at 970-494-5500 for international callers.

Recordkeeping

Retain copies of all information documenting your compliance with this Order for ten years. This includes your Initial Response and other documents and correspondence submitted to comply with this Order, such as test protocols, testing related requests, final test reports with their underlying data, and any penalties remitted.

ENCLOSURE D - ORDER RECIPIENT SELECTION RATIONALE

The manufacturers and processors of the chemical subject to this Order were determined in the following manner:

1. **Manufacturers**: All companies included in the *final list* of manufacturers subject to fee payments for *trans*-1,2-dichloroethylene developed under the "Fees for Administration of Toxic Substances Control Act" rule in 2020 are subject to this order. This final list was developed using the following methodology to capture manufacturers of the subject chemical:

   EPA used a diverse pool of data sources to compile a preliminary list of all manufacturers (including importers) of the High Priority Substances based on information submitted or available to the Agency within the past 5 years. These data sources included information submitted to EPA (*e.g.*, information submitted under TSCA sections 5(a), 8(a) (including Chemical Data Reporting (CDR)), 8(b), and to the Toxics Release Inventory (TRI)) along with publicly available information (*e.g.,* Panjiva (a provider of data on trade that can be used to help identify customers of certain products)) or information submitted to other agencies to which EPA has access (*e.g.,* U.S. Customs and Border Patrol data). Once compiled, this preliminary list was published to the Federal Register for a public comment period of no less than 30 days. This public comment period allowed stakeholders the opportunity to make corrections to the list and provided the platform for a legally required and enforceable self-identification and certification process for manufacturers on the preliminary list (or absent from the preliminary list despite being manufacturers of the chemical in question). After closure of the comment period and further EPA review, the Agency published the final list of manufactures of the subject chemical at *https://www.epa.gov/tsca-fees/final-list-fee-payers-next-20-risk-evaluations*. For more detail on the methods used under "Fees for Administration of Toxic Substances Control Act," see the complete rule text in docket EPA-HQ-OPPT-2016-0401-0072.

2. **Processors**: All companies who reported as "Processors" for this chemical to the 2019 Toxics Release Inventory before 09/01/2020 are subject to this Order *unless* they reported that their *only* processing activity occurs under the "As an Impurity" category. A snapshot of TRI, which is a continuously changing database that does not have a cutoff date for reporting, was taken on 09/01/2020 to determine the Order recipients for the subject chemical. Because process impurities are not included in the scope of the TSCA section 6 risk evaluation for the subject chemical, EPA does not need data on these activities and will not be collecting information from processing companies whose only handling of the subject chemical is as an impurity. Although EPA recognizes that there are processors who do not report to TRI, this database was used to identify processors for the purposes of this order because it is the Agency's most comprehensive source to establish a well-verified list of processing companies.

ENCLOSURE E - RESOURCE FOR REPORTING OCCUPATIONAL EXPOSURE DATA

In Enclosure E, EPA is providing a sample matrix of monitoring parameters to collect monitoring data and reporting the results. The table could be modified as needed for a given chemical, industry sector and condition of use. Additional information may be required for case-specific conditions.

Table. Monitoring Parameters[1] for Occupational Exposures Data Template

	Facility and Process Parameters						Sampling and Monitoring								Representative[3]
Parameter / Information	Identity of Workplace/Facility	Description of Process (e.g., equipment/ machinary/ handling accessories, reaction, activities, etc.)	Physical State(s) (solid/liquid/ imulsion/ particulate/gas) and Flow Rate of Unit Operation and/or Process Train (e.g., kg/hr or m^3/hr)	Weight fraction(s) of Chemical in the Process	Frequency of Operation of Individual Processes (e.g., days/year; days/month and months per year; or days/week and weeks/year)	Individual Process Duration (e.g., hr/day)	Purpose of Sampling (e.g., compliance, worst-case, ceiling, short-term, peak)	Sample Type: (area/personal)	Sampling and Monitoring Methods Used (e.g., EPA/ASTM method and number)	Sampling Devise(s) Used to Collect Samples	Sample ID#	Dates of Sampling (mm/dd/yr)	Duration of Sample(s) Collected or Sampling Start and End Times	Locations of Sampling Devices (e.g., distance from the process/release source and height)	Analytical Method(s) Used (e.g., EPA/ASTM method and number)
Name and City/State:															
Chemical Name (CAS Registry Number)/ Categories of Chemicals Used*:															
Annual Throughput/Mass Flow Rate of Chemical Produced/Imported/ Handled (kg/yr):															
• Total Number of Employees: • Number of employees Handling Chemical(s) (e.g. occupational users): • Number of employees Not Handling Chemical(s) (e.g. occupational non-users):															
Type of Facilty Operation (batch-manual; semi-automatic; automatic, closed-system)[5]:															
Hours of Operation (24 hr x 7 d x 52 wks):															

Notes:

*: If more than single priority chemicals (HPS) are manufactured/produced/imported at the facility, this table could be modified/adapted for presentating data.

**: Include material of construction of gloves for dermal; types of cartridges for respirators and other specification as applicable.

1: This table could be considered as an **example** to collect monitoring data and reporting the results. The table could be modified as needed for a given chemical, industry sector and condition of use. Additional information may be required for case-specific conditions.
Unless otherwise mentioned, it will be assumed that no CBI information included above. The U.S. EPA's Data Quality Objectives could determine additional type, quantity, an quality of the data needs.

2: Identify the processes involved for a specific chemical (five representative cells are included). Additional rows to be included if more than single chemicals manufactured/imported/processed/handled. Chemical specific process issues that involve complexities (e.g., high temperature, vacuum or high pressure) may require additional information.

3: Data verification and data validation are important to support ultimate goal of defensible products and decisions. Data validation is the systematic review of data deliverables and can help identify laboratory and site/workplace sample analytical uncertainty. Data usability assessment also encompasses sampling uncertainty including the overall sampling plan, sampling processes and conditions during sampling. For example, after samples have been collected after an event, analyzed, and the results reported, the data set is submitted for data verification. The data verification process documents that the analyte recoveries for spiked samples fell below control limits. The data validation process traces the cause for the non-conformance to an elevated pre-spike sample concentration. The data validator notes that the control samples have recoveries within criteria, that other spiked samples have recoveries within criteria, and that the duplicate results have significant variability. The data validation process determines that the low analyte recovery is a result not of analytical bias, but of the heterogeneity of the matrix. The data quality assessment process considers the fact that all samples had appropriate analyte concentrations so that the data quality is adequate for the purpose of the monitoring. EPA's Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9), is a five-step process: a) Review the Data Quality Objectives and Sampling Design; b) Conduct a Preliminary Data Review; c) Select the Statistical Test; d) Verify the Assumptions of the Statistical Test; e) Draw Conclusions from the Data.

4: Additional examples may be available in various literature including NIOSH [2015]. Best practices: engineering controls, work practices and exposure monitoring for occupational exposures to diacetyl and 2,3-pentanedione. By Dunn KH, McKernan LT, Garcia A. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication 2015-197.

5. A facility may have variety of operations at different workplaces. Add additional rows or pages as appropriate.

Table. Monitoring Parameters [1] for Occupational Exposures Data Template

Facility and Process Parameters		Representative Sample Population								Infrastructure and Personal Protective Equipment								
Parameter / Information	Identity of Workplace/Facility	Data Validation [3] Performed (yes/no)	Method Detection Limit (µg/L; µg/m^3; or µg/kg)	Worker Demographics (age, sex, length of service, etc.)	Employee Job Title (e.g., material handler, loader)	Description of Employee Activity	Duration of Work/Activity (e.g., hr/shift of Employee)	Shift Duration (e.g., hr/day)	Concentration of Analyte (specify analyte) at Source and Area/Employee Location (µg/L; µg/m^3; or µg/kg)	Existing Engineering Control (yes/no)	Engineering Control(s) [4] (e.g., annular exhaust for capturing vapors during drum filling)	Room/ Work Area Volume (m^3)	Type of Room/Work Area (positive/ negative pressure, indoor, outdoor)	Air Changes per Hour of Work Area	Air Speed (e.g., cm/second or m/hour)	Ventialtion Rate (e.g., m^3/hour or cm^3/second)	Type and Duration of PPE** Use During Normal Operation	Type and Duration of PPE Usage During Emergency (e.g., accidental release, spillage)
Name and City/State:																		
Chemical Name (CAS Registry Number)/ Categories of Chemicals Used*:																		
Annual Throughput/Mass Flow Rate of Chemical Produced/imported/ Handled (kg/yr):																		
• Total Number of Employees: • Number of employees Handling Chemical(s) (e.g. occupational users): • Number of employees Not Handling Chemical(s) (e.g. occupational non-users):																		
Type of Facilty Operation (batch-manual; semi-automatic; automatic, closed-system) [5]:																		
Hours of Operation (24 hr x 7 d x 52 wks):																		

Limitations and Disclaimer

The above matrix does not provide an in-depth analysis of standards and regulations and cannot address all occupational exposures and releases. It does not increase or diminish any OSHA and/or other agency requirement or employer obligation under those requirements. It is intended as an example to guide and quick reference for general data needs. This table does not alter or determine compliance responsibilities in applicable standards, or the equivalent State Plan standards and requirements.

ENCLOSURE F - DERMAL HAND WIPE SAMPLING – SOLVENTS

1.0. Purpose and Scope

1.1. This general protocol describes procedures for collecting dermal exposure samples from the hand surfaces of workers and occupational non-users (ONU)s. The protocol is intended to measure exposure to workers as they perform their normal work functions.

1.2. The monitoring procedures shall minimize cross-contamination between samples to the extent practicable.

2.0. EQUIPMENT REQUIRED

The following materials are required for collecting dermal hand samples:

a. Two 3-inch x 3-inch or appropriate size activated charcoal cloth pads

b. Disposable gloves

c. 120 mL amber glass jar with teflon-coated or other tightly sealed lids

d. Parafilm or equivalent to seal the glass jar

e. Cooler with dry ice or a freezer

f. Paper for hand tracing (or use the back of the sample collection form)

g. Large Ziplock® bags or equivalent quality sealable plastic bags

3.0. ABSORPTIVE CAPACITY AND SAMPLE STABILITY DETERMINATION

3.1. Determine the absorptive capacity of the selected activated charcoal cloths in the lab by placing the activated charcoal cloth pads in a beaker placed in a tightly closed jar containing 99.99 percent of the test chemical at room temperature. Remove three pads from the jar at 24, 48, 72 and 96 h and analyze them using gas chromatograph coupled with a flame ionization detector (GC-FID) for the test chemical. Determine the maximum absorptive capacity of the samples taken at all sampling intervals in comparison with anticipated dermal exposure in the field.

3.2. Determine the sample stability by placing two fortified (spiked) activated charcoal cloth pads in a 120mL amber glass jar tightly sealed with parafilm in a freezer.

3.3. Perform laboratory analysis to determine the amount retained on the activated charcoal cloth pads for 7 or more consecutive days to determine the length of time for which the concentration of the test chemical is stable on the activated charcoal cloth pads.

4.0. SAMPLING PROCEDURE

4.1. The field personnel collecting samples will wear clean, disposable gloves while collecting the dermal wipe samples.

4.2. Collect dermal hand wipe samples pre-, mid-, and post-shift from the hands of workers and ONUs to be monitored.

4.3. Place two sterile activated charcoal cloth pads (of predetermined size, based on absorptive capacity testing) in 120 mL amber glass jars. The jars are tightly sealed and stored at approximately 5° C for up to 7 days (or as determined based on the sample stability determination), until they were used for collection. Do not use jars that are older than a week (or as determined in the sample stability determination) for sample collection.

4.4. If the worker is wearing additional Personal Protective Equipment (PPE), such as gloves, goggles or a respirator, the worker will remove all PPE before having the hand wipes collected and before washing hands.

4.5. Samples shall be collected in an area outside of the work area (*e.g.*, at company headquarters, in a construction trailer, etc.). During sample collection and immediately after glove removal, if applicable, participants are instructed to grab one of the activated charcoal cloth pads and wipe both sides of their bare hands (the area from the bend of the wrist to the fingertips) for 30 s. Then they are instructed to grab the other wipe and repeat the process. Both activated charcoal cloth pads are placed into the same jar, sealed, and stored at refrigerated temperatures until analyzed. Once both activated charcoal pads are placed back into the jar, it is sealed with parafilm or equivalent, and stored at refrigerated temperatures until analyzed. At the mid- and post-shift hand wipe collection, the process is repeated. Workers are asked how many times they washed their hands since pre-shift; the information is recorded on the sample collection form. Note, workers are not to wash their hands prior to dermal wipe sampling. Trace the participant's right hand on the back of the sample collection form.

4.6. The following information shall be obtained and recorded on the sample collection sheet for each participant:

a. How many times did the participant wash their hands?

b. What types of gloves were worn?

c. If gloves were worn for what duration and for which tasks?

4.7. Field fortification (spiked) and field blank samples are collected to provide a "recovery" value which will quantify stability of the test chemical during sample collection, storage in the field, shipment to the laboratory, and storage in the laboratory freezer. At least one field blank is collected for each hand wipe samples collected. Field blank samples are taken by soaking a gauze pad in isopropanol and placing it directly into a glass jar. Replicate samples are collected in the field to detect variation between samples.

4.8. Similar quality control procedures are followed in the laboratory, including control and fortification samples which are designed to detect background residues, monitor the performance of the method, and detect matrix or reagent interferences which may be present.

5.0. FIELD STORAGE

Place samples collected during the study in the field in a cooler with dry ice or portable freezer until processed and placed into frozen storage for shipping at the end of the monitoring day (or as soon as practical).

6.0. SAMPLE EXTRACTION AND PREPARATION

6.1. Left and right hands are sampled separately but extracted and analyzed together, providing one measurement per participant.

6.2. Samples are extracted[11] with spectrographic grade carbon disulfide (CS_2) by desorbing the sorbed analytes directly into a glass container following the NIOSH method 1501. The extract is filtered on cellulose based filter to remove carbon residues and injected for the GC-FID analysis. The blank is prepared by using activated charcoal without any treatment.

6.3. Limits of detection and quantification are determined according to NIOSH guidance 95-117 (Kennedy et al., 1995). One procedural blank and at least one field blank are run with each batch of samples (ten samples). One blank spike and at least two blanks are run with each batch of ten samples. The blank spike and blank spike duplicate must be extracted and analyzed within holding time. Each spiked replicate may be adjusted for background chemical contamination in consideration with the matrix blank.

7.0. INTERFERENCES

A potential interference in the applicability of this method could be that the pads could absorb organic vapors through passive diffusion in addition to dermal exposure to droplets and aerosols. Appropriate corrections for ambient levels of the organic compounds may be required. The wipe pads have been found to contain high background concentrations of potential interferents (EPA, 2007). In such instances where there is an interference, the wipes must be pre-cleaned, removing the potential interferent, before any sampling can occur (EPA, 2007).

[11] Alternatively, thermal desorption, using a heat source to increase the volatility of the analytes, could be used to recover solvents from activated charcoal pad. This technique requires no solvent thus the adsorbed chemicals are not diluted, but thermal desorption could have wide variations and depends on the volatility of the solvent chemicals, with decreasing recovery as boiling-point of chemical of interest increases.