ENVIRONM

[EPA-HQ-OPPT-2023-0312; FRL 11015-01-OCSPP]

4,4'-Methylene bis(2-chloroaniline); Request under the Toxic Substances Control Act (TSCA) for Records and Reports of Significant Adverse Reactions to Health or the Environment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Through this notice, the Environmental Protection Agency (EPA) is requiring manufacturers (including importers) and processors of the chemical substance 4,4'-methylene bis(2-chloroaniline) to submit the records and reports of allegations that this chemical substance causes significant adverse reactions to health or the environment that they are required to maintain and submit to EPA when requested under the Toxic Substances Control Act (TSCA). Information submitted to the Agency in response to this notice will help inform future EPA activities regarding this chemical, including aiding EPA activities related to this chemical substance having been identified as a candidate for designation as a High-Priority Substance for TSCA risk evaluation.

DATES: Records must be received by EPA on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA HQ-OPPT-2023-0312, is available online at *https://www.regulations.gov* or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC). Additional instructions on visiting the docket, along with more information about dockets generally, are available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Brian Barone, Data Gathering and Analysis Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency,

1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-0233; email address: *barone.brian@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. *What action is the Agency taking?*

EPA is requiring submission of TSCA section 8(c) records of allegations of significant adverse reactions to health or the environment for the listed chemical. Regulations specifying TSCA section 8(c) recordkeeping and reporting requirements are codified at 40 CFR part 717. Pursuant to TSCA section 8(c) and 40 CFR 717.17(b), each person who is required to maintain records under TSCA section 8(c) and implementing regulations at 40 CFR part 717 shall submit copies of such records to EPA upon request. EPA is issuing this TSCA section 8(c) action so that the health and environmental risks from exposure to this chemical substance can be evaluated. The submitted information is expected to be used to corroborate suspected adverse health or environmental effects of the chemical under review and to help identify trends of adverse effects across the industry that may not be apparent to any one chemical company.

EPA has initiated the prioritization process for this chemical substance as a candidate for designation as a High-Priority Substance for risk evaluation. EPA plans to use data received through this request to support the prioritization process to better understand suspected adverse health or environmental effects of the chemical. Further, should EPA finalize the designation of this chemical as a high-priority substance for risk evaluation, then gathering this type of data before EPA initiates such a risk evaluation could help make the risk evaluation process more efficient and focused. EPA anticipates issuing additional TSCA section 8(c) submission requirements for other chemical substances identified as candidates for prioritization. EPA is using this TSCA section 8(c) submission requirement as a first pilot step in making use of the TSCA section 8(c) data gathering authority as part of the general candidate selection process to be used by EPA for TSCA section 6 prioritization activities.

B. *What is the Agency's authority for taking this action?*

Under TSCA section 8(c), chemical manufacturers (including importers) and processors must maintain records of significant adverse reactions to health or the environment alleged to have been caused by chemical substances or mixtures and, upon request, submit or make the records available to the Agency. Significant adverse reactions are reactions that may indicate a substantial impairment of normal activities or long-lasting or irreversible damage to health or the environment. Regulations implementing TSCA section 8(c) appear in 40 CFR part 717.

C. *Does this action apply to me?*

This action may potentially affect you if you manufacture (defined under TSCA to include import) or process the chemical substance described by this document. The following list of North American Industry Classification System (NAICS) codes is neither intended to be exhaustive nor indicate expected reporting from a given industry sector but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Manufacturing (NAICS codes 31-33), and/or

• Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690).

Other types of entities not included could also be affected. To determine whether your entity is affected by this action, you should carefully examine the applicability criteria found in 40 CFR part 717. If you have questions regarding the applicability of this action to a particular entity or information regarding additional entities that may not be listed in this Notice, please consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

D. *What is 4,4'-methylene bis(2-chloroaniline) (MBOCA)?*

MBOCA is used as a curing agent for liquid polyurethane elastomers. These elastomers have been used to produce shoe soles; rolls for postage stamp machines; cutting bars in plywood manufacturing; rolls and belt drives in cameras, computers, and reproducing equipment; and pulleys for escalators and elevators. Animal studies have reported effects on the lung, liver, and

kidney from chronic oral exposure to MBOCA. Animal studies have reported that MBOCA produces tumors of the liver, lung, urinary bladder, and mammary glands from oral exposure. EPA has classified MBOCA as a Group B2, probable human carcinogen.

II. Request for TSCA Section 8(c) Records

A. *Who must submit records?*

This requirement to submit TSCA section 8(c) allegation records applies to persons who manufacture (defined under TSCA to include import) or process MBOCA, and who are subject to TSCA section 8(c) recordkeeping requirements pursuant to 40 CFR 717.5.

The regulations provide limited exemptions from recordkeeping and reporting requirements for certain manufacturers and sites of manufacture, as described at 40 CFR 717.5(a)(1) and 717.7(a). Persons or site activities are exempt pursuant to 40 CFR 717.7(a)(1) if the means by which they manufacture a chemical substance solely involves mining or other solely extractive functions, e.g., those companies or sites within a company whose sole function is to mine mineral ores, extract petroleum or natural gas, quarry non-metallic minerals (including extraction of salts from seawater or brines), mine or otherwise extract coal, or separate gases from the atmosphere. In addition, the regulations exempt persons whose only manufacturing act is to produce a substance coincidentally under specific circumstances, as described in 40 CFR 717.7(a)(2).

Two types of processors (who are not also manufacturers) are subject to TSCA section 8(c) recordkeeping under the regulations at 40 CFR 717.5(b)(1) and to reporting under this notice: those who produce and market chemical mixtures (including solutions) and those who repackage chemical substances or mixtures.

A person solely engaged in the distribution of chemical substances is exempt from TSCA section 8(c) recordkeeping and reporting pursuant to 40 CFR 717.7(c) unless such person is also a manufacturer or processor subject to the regulations. For example, a “distributor” who repackages chemical substances or mixtures is considered to be a processor and, thus, is not a

sole distributor.

Similarly, pursuant to 40 CFR 717.7(d), a person who is a retailer is exempt from TSCA section 8(c) recordkeeping and reporting unless such person is also a manufacturer or a processor subject to this request.

B. *What types of records must be submitted?*

TSCA section 8(c) requires any manufacturer, processor, or distributor of a chemical substance or mixture to keep records of "significant adverse reactions" to health or the environment, as determined by rule, alleged to have been caused by the chemical substance or mixture. Implementing regulations at 40 CFR part 717 describe the types of records that must be kept and are briefly summarized here.

A "significant adverse reactions" is defined in 40 CFR 717.3(i) as reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment. Allegations subject to the recordkeeping requirement are described at 40 CFR 717.10. "Allegation" is defined at 40 CFR 717.3(a) to mean a statement, made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.

Significant adverse reactions to human health that must be recorded could include, but are not limited to, birth defects, impairment of bodily functions, or impairment of normal activities, as described at 40 CFR 717.12(a). TSCA section 8(c) allegations may focus on serious health effects, but they can also report lesser effects experienced by a group of individuals or repeatedly by an individual. Allegations that do not meet the definition of a "significant adverse reaction" should not be reported to EPA in the TSCA section 8(c) call-in. Additionally, the regulation at 40 CFR 717.12(b) exempts "known human effects" from this recordkeeping requirement. The definition of "known human effects" at 40 CFR 717.3(c) covers commonly recognized human health effects resulting from exposure to a substance as described in publicly available sources such as Safety Data Sheets (SDS), product labeling, or scientific literature,

including, but not limited to, information found at the Agency for Toxic Substances Disease Registry website available at *https://www.atsdr.cdc.gov/index.html* and EPA's Integrated Risk Management System available at *https://www.epa.gov/iris.* However, pursuant to 40 CFR 717.3(c)(2), the exemption does not apply if the reaction was a significantly more severe toxic effect than previously described, or if the reaction resulted from a lower exposure level, a significantly shorter exposure period, or a different exposure route than previously described.

Significant adverse reactions to the environment must also be recorded even if restricted to the environment surrounding a plant or disposal site. Pursuant to 40 CFR 717.12(c), such reactions could include but are not limited to: gradual or sudden changes to composition of animal or plant life, deaths of organisms such as fish kills, reduction of reproductive success of species, changes in behavior or distribution of species, loss of agricultural productivity, and irreversible contamination of the environment.

Pursuant to 40 CFR 717.12(d), a significant adverse reaction to the environment is not required to be recorded if the alleged cause is directly attributable to an incident of environmental contamination that has already been reported to the Federal government under any applicable authority.

EPA is requiring submission of all TSCA section 8(c) records that fall within the record retention period described in TSCA section 8(c) and 40 CFR 717.15(d). Accordingly, this request for records includes:

• Records of significant adverse reactions to the health of employees first reported to or known by the person maintaining such records within the past 30 years, including employee health-related allegations arising from any employment-related exposure, whether or not such allegation was submitted by or on the behalf of that recordkeeper's own employee.

• Any other record of significant adverse reactions first reported to or known by the person maintaining the record within the past five years.

C. *What information must be included with a submission?*

Manufacturers of the chemical substance listed in this notice must submit any records kept pursuant to 40 CFR part 717 of significant adverse reactions alleged to have been caused by the chemical substance. Under the regulations, a manufacturer is responsible for collecting allegations regarding substances it manufactures, as well as allegations regarding certain chemical processing and distribution activities it may carry out. Accordingly, as provided in 40 CFR 717.5(a)(2), manufacturers of the listed chemical substance must submit records of any collected allegations that:

• Identify the listed chemical substance or identify operations used in the manufacture of the chemical substance;

• Identify any of the manufacturer's own processing or distribution in commerce activities with respect to the chemical substance;

• Identify emissions, effluents, or other discharges from activities described in this paragraph; and

• Identify a substance produced coincidentally during processing, use, storage or disposal of a chemical substance it manufactures, where either the coincidentally produced chemical substance or the originally manufactured chemical substance is listed in this notice.

Processors of the chemical substance listed in this notice who are subject to TSCA section 8(c) recordkeeping requirements (i.e., persons who process chemical substances to produce mixtures, or repackage chemical substances or mixtures) must also submit any records kept pursuant to 40 CFR part 717 of significant adverse reactions alleged to have been caused by the chemical substance. As provided by 40 CFR 717.5(b)(2), this includes allegations that:

• Identify any mixture the processor produces and distributes in commerce containing the listed chemical substance, or identify the listed chemical substance or mixture containing the listed chemical substance that the processor repackages and distributes in commerce;

• Identify any of the processor's own further processing or distribution in commerce activities of such products;

• Identify emissions, effluents, or other discharges from activities described in this paragraph;

• Identify a substance produced coincidentally during the processing, use, storage, or disposal of any mixture the processor produces and distributes in commerce or any chemical substance or mixture it repackages and distributes in commerce, where either the coincidentally produced chemical substance or the processed chemical substance is listed in this notice.

As provided by 40 CFR 717.15(b), in addition to the original allegation as received, TSCA section 8(c) reported allegation records must contain the name and address of the site that received the allegation; the date the allegation was received; the implicated chemical substance, mixture, article, company process or operation, or site discharge; a description of the alleger; and a description of the alleged health effect(s) and/or environmental effect(s).

Additionally, the submission must include the results of any self-initiated investigation with respect to an allegation and copies of any further required records or reports relating to the allegation, as described at 40 CFR 717.15(b)(3) and (4)).

EPA encourages respondents to conduct a thorough review of their TSCA 8(c) records, including a search for all known synonyms and trade names associated with the listed chemical. Alternative identifiers can be found through many sources, including PubChem, an open chemistry database operated by the National Institutes of Health (NIH) at *https://pubchem.ncbi.nlm.nih.gov,* EPA's CompTox Chemical Dashboard website at *https://comptox.epa.gov/dashboard* and EPA's Substance Registry Service (SRS) at *https://cdxapps.epa.gov/oms-substance-registry-services/search.*

D. *How does this request for allegation records differ from TSCA section 8(e) reporting?*

TSCA section 8(e) requires manufacturers, processors, and distributors of a chemical substance or mixture to notify EPA immediately of information that reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment, unless that person knows that EPA has already been informed. EPA published a

TSCA section 8(e) Policy Statement and Guidance on June 3, 2003 (68 FR 33129 (FRL-7287-4)), which defines "substantial-risk information" as information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment, and "substantial risk of injury to health or the environment" as a risk of considerable concern because of the seriousness of the effect, and the fact or probability of its occurrence – without consideration for economic or social benefits of use or costs of restricting use. Information related to serious toxic effects should be reported regardless of exposure. Unlike records maintained under TSCA section 8(c), which need only be submitted to EPA upon request, TSCA requires that information required by TSCA section 8(e) be reported "immediately" (i.e., within 30 days of obtaining the information).

The source of the information handled under TSCA sections 8(c) and 8(e) is also different. While allegations recorded pursuant to TSCA section 8(c) are likely to be received directly from workers, consumers, and plant neighbors, TSCA section 8(e) submissions usually result from designed, controlled studies and reports strongly implicating a chemical. TSCA section 8(e) health effects submissions focus on new serious health effects. TSCA section 8(e) reporting requirements are also triggered by information about significant changes in exposure circumstances with a recognized hazardous substance, which may be identified through monitoring studies or other means. TSCA section 8(c) allegations may focus on serious health effects, but they can also report lesser effects experienced by a group of individuals, or repeatedly by an individual.

E. *How to report?*

All submitters must report TSCA section 8(c) data electronically, using the CSPP: Submissions for Chemical Safety and Pesticide Programs software (CSPP Software) accessible via EPA's Central Data Exchange (CDX) system available at *https://cdx.epa.gov/.* The CSPP Software provides a TSCA Communications application that a registered CDX user will access to submit TSCA section 8(c) records. Guidance on how to submit TSCA section 8(c) data is

available in the docket (EPA-HQ-OPPT-2023-0312) and via EPA's TSCA section 8(c) webpage for this action at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-8c-reporting-44-methylene-bis2-chloroaniline-mboca.* You may also obtain help by contacting EPA's TSCA Hotline at *tsca-hotline@epa.gov* or 202-554-1404. For help with accessing your CDX account, please contact the CDX help desk at *https://cdx.epa.gov/contact* or (888) 890-1995 (for international callers: (970) 494-5500).

F. *How to submit confidential business information?*

Any person submitting copies of records may assert a business confidentiality claim covering all or part of the submitted information in accordance with the procedures described in 40 CFR part 703 (88 FR 37155, June 7, 2023 (FRL-8223-02-OCSPP)).

Requirements for asserting and maintaining confidentiality claims are described in 40 CFR 703.5. Such claim must be made concurrent with submission of the information. If no such claim accompanies the submission, EPA will not recognize a confidentiality claim, and the information in that submission may be made available to the public without further notice. Confidentiality claims must be substantiated at the time of submission to EPA pursuant to the requirements of 40 CFR 703.5(b). To assert a claim of confidentiality for information contained in a submitted record, the respondent must submit two copies of the document. One copy must be complete. In that copy, the respondent must indicate what information, if any, is claimed as confidential by marking the specific information on each page with a label such as "confidential", "proprietary", or "CBI." The other copy must be a public version of the submission and attachments, with all information that is claimed as confidential removed. See 40 CFR 703.5(c). Both the copy containing information claimed as CBI and the "sanitized" copy must be submitted electronically, as discussed in Unit II.F. The TSCA Communications Tool incorporates many of the requirements for asserting CBI claims, including substantiation questions, a required certification statement, and prompts to provide a sanitized copy. Further details regarding the requirements for confidentiality claims can be found in 40 CFR part 703.

G. *When is reporting not required?*

As provided by 40 CFR part 717, reporting is not required by certain persons for certain types of activities involving the chemical, including:

• Entities considered manufacturers solely due to mining or other resource extraction activities are not required to report (40 CFR 717.7(a)(1));

• Persons whose sole manufacturing is due to the incidental or coincidental production of chemical substances in certain circumstances are not required to report (40 CFR 717.7(a)(2)(i)-(v));

• Processors are required to report only if they process chemical substances to produce mixtures or repackage chemical substances or mixtures (40 CFR 717.5(b)(1));

• A person solely engaged in the distribution of chemical substances is exempt from 8(c) reporting, unless such person is also a manufacturer or processor subject to 8(c) requirements (40 CFR 717.7(c)); and

• A person who is a retailer is exempt from 8(c) reporting unless such person is also a manufacturer or a processor subject to 8(c) requirements (40 CFR 717.7(d)).

Known human effects (i.e., commonly recognized human health effects in literature or product labels/SDS) need not be reported unless the effect is significantly more severe, occurred after a significantly shorter exposure period or lower exposure level, or occurred due to a different exposure route than previously described (see 40 CFR 717.12(b) and 717.3(c) for details).

Additionally, firms are not required to record a significant adverse reaction to the environment if the alleged cause of that significant adverse reaction can be directly attributable to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to the Federal Government under any applicable authority (40 CFR 717.12(d)).

III. Paperwork Reduction Act (PRA)

According to PRA, 44 U.S.C. 3501 et seq., an agency may not conduct or sponsor, and a

person is not required to respond to a collection of information that requires Office of Management and Budget (OMB) approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements associated with records of allegations of significant adverse reactions to human health or the environment under TSCA section 8(c) are contained in 40 CFR part 717 (OMB Control No. 2070-0224; EPA ICR No. 2703.01) approved by OMB on November 23, 2022. This action does not impose any burden requiring additional OMB approval. The annual paperwork burden per respondent is estimated to be 12.25 hours. This burden estimate includes the time needed to maintain records of allegations of significant adverse reactions, submit copies of these allegation records when required by EPA, and review of the *Federal Register* notice. For additional details, please see the Information Collection Request document that is available in the docket.

Authority: 15 U.S.C. 2607(c).

Dated: December 19, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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