



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA-HQ-OPPT-2023-0360; FRL-11164-01-OCSPP]

RIN 2070-AL15

Certain Existing Chemicals; Request to Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to require manufacturers (including importers) of 16 chemical substances to submit copies and lists of certain unpublished health and safety studies to EPA. Health and safety studies sought by this action will help inform EPA's responsibilities pursuant to TSCA, including prioritization, risk evaluation, and risk management.

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0360, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Lameka Smith, 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) 564-1629; email address: smith.lameka@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.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import) chemical substances and mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical manufacturing (NAICS code 325);
- Petroleum refineries (NAICS code 324110); and
- Tire manufacturing (NAICS code 32621).

This action may also affect manufacturers of substances for commercial purposes that coincidentally produce the substance during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts and impurities. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

B. What action is the Agency taking?

EPA is proposing to require manufacturers of chemical substances listed in this document to submit copies and lists of certain unpublished health and safety studies to EPA. This proposed rule is intended to provide EPA with useful information for prioritization, risk evaluations, and risk management under TSCA section 6 regarding the chemical substances discussed below.

This action lists the chemical substances and their Chemical Abstracts Service Registry Numbers

(CASRN) that would be added to 40 CFR 716. It also lists proposed specific data reporting requirements.

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

EPA promulgated the Health and Safety Data Reporting Rule that is codified at 40 CFR part 716 under TSCA section 8(d) (15 U.S.C 2607(d)). EPA is proposing this rule under its authority in TSCA section 8(d) to require the submission of health and safety studies, and lists of studies, regarding certain chemical substances.

D. What are the estimated incremental impacts of this action?

EPA prepared an economic analysis of the impacts associated with the proposed addition of the 16 chemical substances to the TSCA section 8(d) Health and Safety Data Reporting rule, titled, "TSCA Section 8(d): Economic Impact Analysis for Adding 16 Chemicals to the Health and Safety Data Reporting Rule" (Ref. 1). This economic analysis is available in the docket and is summarized here.

EPA estimates that the costs of this action will be approximately \$301,956 in the first year of reporting, with 3,388 estimated paperwork burden hours. In addition, EPA has determined that, of the 44 small businesses affected by this action, 1 is estimated to incur a maximum annualized cost impact of more than 1% of revenues. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities as further discussed in Unit IV.C.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so

marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2 and/or 40 CFR part 703, as applicable.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets.html>.

II. Background

A. What chemical substances is EPA proposing to add?

EPA is proposing the addition of 16 chemical substances to amend the list at 40 CFR 716.120. This list contains chemical substances for which the health and safety study data reporting is required. For this proposed rule, the 16 chemical substances will amend the current list and be added at 40 CFR 716.21(a)(11). If any special exemptions are required for a specific chemical substance, it will be identified in the table below under special exemptions. Special exemptions are reporting requirements that are specific to a chemical substance and would include specific language about specific studies and requirements. The chemical substances being added by this proposed rule are listed below:

- 4,4-Methylene bis(2-chloraniline) (CASRN 101-14-4);
- 4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol) (CASRN140-66-9);
- Acetaldehyde (CASRN75-07-0);
- Acrylonitrile (CASRN 107-13-1);
- Benzenamine (CASRN 62-53-3);
- Benzene (CASRN 71-43-2);
- Bisphenol A (CASRN 80-05-7);
- Ethylbenzene (CASRN 100-41-4);
- Naphthalene (CASRN 91-20-3);
- Vinyl Chloride (CASRN 75-01-4);
- Styrene (CASRN 100-42-5);
- Tribromomethane (Bromoform) (CASRN 75-25-2);

- Triglycidyl isocyanurate; (CASRN 2451-62-9);
- Hydrogen fluoride (CARN 7664-39-3);
- N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) (CASRN 793-24-8);

and

- 2-anilino-5-[(4-methylpentan-2-yl) amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (CASRN 2754428-18-5).

B. What are the proposed reporting requirements?

The proposed reporting requirements for the 16 chemical substances listed in Unit II.A. include the following, with the specific types of health and safety studies listed in Unit II.D.:

- Manufacturers who, in the 10 years preceding the date a chemical substance is listed, either have proposed to manufacture or have manufactured any of the listed chemical substances must submit to EPA, during the 60-day reporting period specified in 40 CFR 716.65 and according to the reporting schedule set forth at 40 CFR 716.60, would be required to submit a copy of each specified type of health and safety study which is in their possession at the time the chemical substance is listed in 40 CFR part 716.

- Manufacturers who, either at the time of or after the chemical substance is listed in part 716, propose to manufacture or are manufacturing the listed chemical substance would be required to submit to EPA during the 60-day reporting period specified in 40 CFR 716.65 and according to the reporting schedule set forth at 40 CFR 716.60:

- A copy of each specified type of health and safety study which is in their possession at the time the chemical substance is listed;

- A list of the specified types of health and safety studies known to them but not in their possession at the time the chemical substance is listed;

- A list of the specified types of health and safety studies that are ongoing at the time the chemical substance is listed and are being conducted by or for them;

- A list of the specified types of health and safety studies that are initiated after the date

the chemical substance is listed and will be conducted by or for them; and

- A copy of each specified type of health and safety study that was previously listed as ongoing or subsequently initiated (i.e., listed in accordance with reporting requirements in Unit II.D., respectively) and is now complete regardless of completion date.

The proposed reporting would be required 90 days after date the final rule is issued from those who manufacture or proposes to manufacture the listed chemical substance from [*to be determined 30 days after date of publication of the final rule*] to [*to be determined as 90 days after date of publication of the final rule*] must inform EPA (by submitting a list) of any studies initiated during the period from [*to be determined as 30 days after date of publication of the final rule*] to [*to be determined as 90 days after date of publication of the final rule*] within 30 days of their initiation, but in no case later than [*to be determined as 120 days after date of publication of the final rule*].

The proposed reporting described in Unit II.D. would be required 90 days after the final rule is issued from those who manufactures or proposes to manufacture the listed chemical substance from [*to be determined as 30 days after date of publication of the final rule*] to [*to be determined as 90 days after date of publication of the final rule*] must inform EPA (by submitting a list) of any studies initiated during the period from [*to be determined as 30 days after date of publication of the final rule*] to [*to be determined as 90 days after date of publication of the final rule*] within 30 days of their initiation, but in no case later than [*to be determined as 120 days after date of publication of the final rule*].

In addition, if any such person has submitted lists of studies that were ongoing or initiated during the period from [*to be determined as 30 days after date of publication of the final rule*] to [*to be determined as 90 days after date of publication of the final rule*] to EPA, such person must submit a copy of each study within 30 days after its completion, regardless of the study's completion date. See 40 CFR 716.60 and 716.65.

C. *What are the exemptions under this proposed rule?*

Detailed guidance for reporting unpublished health and safety data is provided at 40 CFR part 716. Also found at 40 CFR 716.20 are explanations of reporting exemptions. EPA is proposing that the exemption listed at 40 CFR 716.20(a)(9), for persons manufacturing a substance only as an impurity, would not be available for the substances subject to this proposed rule. An impurity is defined as a chemical substance that is unintentionally present with another chemical substance. Impurities are not manufactured for distribution in commerce as chemical substances and have no commercial purpose separate from the chemical substance or mixture of which they are a part. Rulemaking proceedings that add chemical substances and mixtures to 40 CFR 716.120 will specify the types of health and safety studies that must be reported and will specify chemical grade/purity that must be met or exceeded in individual studies. Pursuant to the rulemaking procedure that requires EPA to identify the chemical/grade purity, EPA is requiring reporting on any purity level of the chemical.

EPA is proposing to require submissions of health and safety studies from companies manufacturing the identified chemical substances, including when a company is importing the chemical substance as a pure substance, mixture, formulated product, or article contains the subject chemical substance. Reporting would be required where the chemical substance is included as an impurity. EPA considers conditions of use associated with circumstances where a chemical substance subject to a risk evaluation even where the chemical substance is an impurity. To such ends, health and safety information associated with the conditions of use, whether as a pure chemical, part of a mixture or article, or as an impurity helps inform such risk evaluation. Accordingly, the chemicals included in today's action are of particular interest to EPA because they are either in the process of prioritization as candidates for high-priority designation or are expected to be candidates in the upcoming years. For those found to be of high priority, EPA is required to immediately conduct a risk evaluation. Collecting health and safety studies on the chemicals identified by this proposal will assist EPA in selecting chemicals to designate as high-priority chemicals as well as conduct risk evaluation on such designated

chemicals.

D. What types of studies must be submitted?

Pursuant to 40 CFR 716.10 and 716.50, manufacturers are required to submit the following types of information:

- Lists and copies of unpublished health and safety studies for all substances specified in this rule on health effects, such as toxicity studies (e.g., in vivo, in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity and toxicokinetic (absorption, distribution, metabolism, or elimination), including modeling studies, in humans or animals.

- All unpublished studies on environmental effects and physical-chemical properties if performed as described in 40 CFR 716.50.

- All unpublished studies on occupational, general population, consumer, and environmental exposure, such as: unpublished studies on inhalation and dermal exposure, human biomonitoring, environmental monitoring of indoor and outdoor air, soil, water, and household dust, chamber emission rates from products or polymeric matrices, and unpublished modeling studies that estimate environmental concentrations or human exposures.

- Studies showing any measurable content of the tested substance (single substance or mixture). The composition and purity of test substances must be reported if included as part of the study.

- Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4 action are exempt from the submission of lists of health and safety studies required under 40 CFR 716.35 and the submission of studies required under this rule.

- Surveys, tests, and studies of biological, photochemical, and chemical degradation.

Chemical identities are part of the submitted health and safety studies or data and must be submitted to EPA. Information from health and safety studies and/or data is not protected from

disclosure, except to the extent such studies or information reveal information “that discloses processes used in the manufacturing or processing of a chemical substance. Or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture,” 15 U.S.C. 2613(2)(B). Additional information, listed in the rule’s definition of health and safety study, are not part of a health and safety study (e.g., names of laboratory personnel). Submitters asserting a CBI claim for information are required to submit a sanitized copy, removing only the information that is claimed as CBI.

E. *How to report?*

All submitters would be required to report TSCA section 8(d) 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 8(d) Health and Safety Data Reporting application that a registered CDX user will access to submit TSCA section 8(d) records. Information on how to submit TSCA section 8(d) data is available in the docket (EPA-HQ-OPPT-2023-0360) and via EPA's TSCA section 8(d) web page for this action at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/section-8d-health-safety-data-reporting-user-guide-0>. Submitters may also contact 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).

1. *Submitting 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-OCSP)). 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 (40 CFR 703.5(c)). Both the copy containing information claimed as CBI and the “sanitized” copy must be submitted electronically. The TSCA section 8(d) Health and Safety Data Reporting application 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.

2. Submitting harmonized templates. Additionally, EPA finalized the requirement for submitting all existing information concerning health and environmental effects in the format of Organization of Economic Cooperation and Development’s (OECD) harmonized templates, where such templates exist for the type of data (codified at 40 CFR 705.15(f)). OECD templates are accessible to the public online at <https://oecd.org/ehs/templates/harmonised-templates.htm>. This can be accomplished by using the freely available IUCLID6 software by exporting the dossier in the OECD Harmonized Template working context. EPA can accept any dossiers generated using any version of IUCLID6 available at <https://www.epa.gov/tsca-cbi/final-rule-requirements-confidential-business-information-claims-under-tsca#Implementation>. EPA believes that some of the data will already be available as an OECD template if the company had already submitted the studies under the European Union’s Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. In addition to the required template format, those subject to this rulemaking must submit any associated full study reports

or underlying data as support documents. The full study reports and support documents are necessary for EPA to understand the full context and evaluate the quality of the data, which is necessary for the Agency to review to determine whether such data may be used for any future Agency actions. If an OECD-harmonized template is not available for a particular endpoint for which the manufacturer has relevant information, then the manufacturer must still submit the data. Such information may include, but is not limited to, raw monitoring data (regardless of having been aggregated or analyzed) of human or environmental exposure assessments and toxicity tests for either human health effects or ecological other environmental effects.

F. *What is the rationale for adding the 16 chemical substances?*

EPA assessment of chemical substances under TSCA section 6 involves a three-stage process: (1) prioritization, (2) risk evaluation, and, as applicable, (3) risk management.

Prioritization and risk evaluation are carried out in accordance with procedural regulations at 40 CFR part 702, subparts A and B, respectively.

During prioritization, EPA identifies chemical substances that are candidates for prioritization and then uses reasonably available information to screen each candidate chemical substance against certain criteria and considerations specified in TSCA section 6(b)(1)(A):

- The hazard and exposure potential of the chemical substance;
- Persistence and bioaccumulation of the chemical substance;
- Potentially exposed or susceptible subpopulations;
- Storage near significant sources of drinking water;
- The conditions of use or significant changes in the conditions of use of the chemical substance (Conditions of use is defined under TSCA section 3(4) to mean “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.”);
- The volume or significant changes in the volume of the chemical substance

manufactured or processed; and

- Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

EPA identified 15 chemical substances that are the subject of this proposal as potential candidates for prioritization based on a screening process that is based on a combination of hazard, exposure (including uses), and persistence and bioaccumulation characteristics. To support the prioritization process as well as to inform its risk evaluation findings on any of these substances that EPA might designate as a high-priority substance, EPA is seeking unpublished health and safety studies on these chemical substances to ensure that such studies are available to EPA to inform any activities undertaken pursuant to TSCA section 6. EPA is also including the 6PPD transformation product, 2-anilino-5-[(4-methylpentan-2-yl) amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (CASRN: 2754428-18-5) due to a response to a recent citizen's petition filed under TSCA section 21 received on 6PPD and 6PPD-quinone. Cited in the petition are the potential impacts of 6PPD-quinone to aquatic organisms and on population levels for some fish, such as the coho salmon. The Agency is including this chemical in this proposed request for unpublished health and safety studies to address data needs and to better understand and characterize risks associated with this chemical. For details on 6PPD and 6PPD-quinone and EPA's current key actions to address this chemical, please visit, <https://www.epa.gov/chemical-research/6ppd-quinone>.

Information received pursuant to the final rule will help inform other EPA activities involving such chemical substances. Additionally, non-CBI information collected pursuant to the final rule would be made public via ChemView.

Estimated benefits of the final rule include addressing market failure stemming from incomplete or imperfect information regarding the hazards associated with the listed chemicals. This final rule addresses market failure by making information about the health and safety effects of the listed chemicals available to EPA. By making this information available, EPA will be able

to base decisions on actual data rather than relying on assumptions. Additionally, the information provided by this rule can aid in addressing negative externalities that occur when the costs associated with known hazards are external to manufacturers' decision-making and may result in overuse and/or overproduction of certain harmful products.

III. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA. For more information about these references, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**

1. EPA. TSCA Section 8(d): Economic Impact Analysis for the Addition of Sixteen Chemicals to the Health and Reporting Data Rule (March 2024).

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action under Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2070-0224 (EPA ICR No. 2703.01). This action requires the reporting of health and safety data to EPA by manufacturers of certain chemical substances to be added to the Health and Safety Data Reporting Rule. EPA intends to use information collected under the rule to assist in chemical assessments under

TSCA, and to inform any additional work necessary under environmental protection mandates beyond TSCA. Submitters may designate information as confidential, trade secret, or proprietary. EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure. These procedures comply with TSCA section 14 and EPA's confidentiality regulation, 40 CFR part 2, subpart B. This action requires the reporting of health and safety data to EPA by manufacturers of certain chemical substances to be added to the Health and Safety Data Reporting Rule. EPA intends to use information collected under the rule to assist in chemical assessments under TSCA, and to inform any additional work necessary under environmental protection mandates beyond TSCA. Submitters may designate information as confidential, trade secret, or proprietary.

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 OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Consistent with the PRA, EPA is interested in comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden or improving the automated collection techniques for submitting health and safety data to the Agency.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are manufacturers of 16 chemicals to be added to the Health and Safety Data Reporting Rule. The Agency has determined that 44 out of 161 of the firms in the affected universe are small entities. Of those small firms, 13 may experience an impact of above 1% and 3 may have impacts above 3%. Details of this analysis are presented in the Economic Analysis of this rule (Ref. 1), which can be found in the docket.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandates as described in UMRA, 2 U.S.C.

1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Orders 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. It does not have substantial direct effects on tribal government because this action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to regulatory actions considered significant under section 3(f)(1) of Executive Order 12866 and that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of Executive Order 13045.

Since this is not a “covered regulatory action,” EO 13045 does not apply. However, the Policy on Children’s Health does apply. Although this action does not concern an environmental health or safety risk, the information obtained from the reporting required by this rule will be used to inform the Agency’s decision-making process regarding chemical substances to which

children may be exposed. This information will also assist the Agency and others in determining whether the chemical substances included in this proposed rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve any technical standards. As such, NTTAA section 12(d), 15 U.S.C. 272, does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation’s Commitment to Environmental Justice for All

EPA believes that this type of action does not directly impact human health or environmental conditions. Although this action does not directly impact human health or environmental conditions, EPA identifies and addresses environmental justice concerns in accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14096 (88 FR 25251, April 26, 2023) by requiring reporting of unpublished health and safety data. This regulatory action requires the submission of unpublished health and safety data for 16 chemical substances that will result in more information being collected and provided to the public. All consumers of products made from these chemicals could benefit from data regarding the chemicals’ health and environmental effects. By requiring reporting of these unpublished studies, EPA provides communities across the U.S. (including communities with environmental justice concerns) with access to these studies. This information can also be used by government

agencies and others in determining the potential hazards and risks associated with the listed chemicals. Therefore, the informational benefits of the action will have a positive impact on the human health and environmental impacts on communities with environmental justice concerns.

List of Subjects in 40 CFR Part 716

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: March 20, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble, EPA is proposing to amend 40 CFR chapter I as follows:

PART 716 - HEALTH AND SAFETY DATA REPORTING

1. The authority citation for part 716 continues to read as follows:

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

2. Amend § 716.21 by adding paragraph (a)(11) to read as follows:

§ 716.21 Chemical specific reporting requirements.

(a) * * *

(11) For 4,4-Methylene bis(2-chloraniline) (101-14-4); 4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol) (140-66-9); Acetaldehyde (75-07-7); Acrylonitrile (107-13-1); Benzenamine (62-53-3); Benzene (71-43-2); Bisphenol A (80-5-7); Ethylbenzene (100-41-4); Naphthalene (91-20-3); Vinyl Chloride (75-01-4); Styrene (100-42-5); Tribromomethane (Bromoform) (75-25-2); Triglycidyl isocyanurate (2451-62-9); Hydrogen fluoride (7664-39-3); N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD) (793-24-8); and 2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone) (2754428-18-5), all unpublished studies on health effects (including toxicity studies (in vivo and in vitro) on carcinogenicity, reproductive and developmental effects, genotoxicity, neurotoxicity, immunotoxicity, endocrine effects, and other systemic toxicity); toxicokinetics (absorption, distribution, metabolism, or elimination), including modelling studies, in humans or animals; environmental effects; environmental fate; physical-chemical properties if performed as described in 40 CFR 716.50; and occupational (both users and non-users), general population, consumer, bystander, and environmental exposure must be submitted. Studies showing any measurable content of the substance in the tested substance (single substances or mixture) must be reported. The composition and purity of test substances must be reported if included as part of the study. Studies previously submitted to EPA pursuant to a requirement under TSCA or of the submitter's own accord and studies conducted or to be conducted pursuant to a TSCA section 4

action are exempt from the submission of lists of health and safety studies required under 40 CFR 716.35 and the submission of studies required under this rule.

3. Amend § 716.120 by adding alphabetically in the table under paragraph (d) entries for –“4,4-Methylene bis(2-chloraniline);” “4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol);” “Acetaldehyde;” “Acrylonitrile;” “Benzenamine;” “Benzene;” “Bisphenol A;” “Ethylbenzene;” “Naphthalene;” “Vinyl Chloride;” “Styrene;” “Tribromomethane (Bromoform);” “Triglycidyl isocyanurate;” “Hydrogen fluoride;” and “N-(1,3-Dimethylbutyl)-N’-phenyl-p-phenylenediamine (6PPD);” and “ 2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone)” to read as follows:

§ 716.120 Substance and listed mixtures to which this subpart applies.

(d) * * *

Category	CAS Number	Special Exemptions	Effective Date	Sunset Date
4,4-Methylene bis(2-chloraniline)	101-14-4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol)	140-66-9	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Acetaldehyde	75-07-0	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Acrylonitrile	107-13-1	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Benzenamine	62-53-3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Benzene	71-43-2	§ 716.21(a)(11) applies;	[TBD 30 DAYS AFTER DATE	[TBD 90 DAYS AFTER DATE

		§ 716.20(a)(9) does not apply	OF FINAL RULE]	OF FINAL RULE]
Bisphenol A	80-05-7	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Ethylbenzene	100-41-4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Naphthalene	91-20-3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Vinyl Chloride	75-01-4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Styrene	100-42-5	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Tribromomethane (Bromoform)	75-25-2	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Triglycidyl isocyanurate	2451-62-9	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
Hydrogen fluoride	7664-39-3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)	793-24-8	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]
2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone)	2754428-18-5	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply	[TBD 30 DAYS AFTER DATE OF FINAL RULE]	[TBD 90 DAYS AFTER DATE OF FINAL RULE]