

Veolia North America - Industrial Business October, 2023

ENVIRONMENTAL UPDATES

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 Final Rule

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No Health & Safety Updates for October 2023

MISCELLANEOUS UPDATES

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A. Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Final Rule

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 10/11/2023 Effective Date: 11/13/2023

Summary

The Environmental Protection Agency (EPA) has finalized reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (PFAS) under the Toxic Substances Control Act (TSCA). EPA is requiring persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, to submit information to EPA regarding PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects.

EPA is defining "PFAS" using a structural definition. PFAS is defined as including at least one of these three structures:

- R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons;
- R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons; and
- CF3C(CF3)R'R", where R' and R" can either be F or saturated carbons.

EPA is requiring that PFAS manufacturers submit the following information for each PFAS, for each year in which that substance was manufactured since January 1, 2011, to the extent the information is known or reasonably ascertainable.

- Chemical identity,
- Uses,
- Volumes made and processed,
- Byproducts,
- Environmental and health effects,
- Worker exposure, and
- Disposal Information.

The information that is being requested must be reported to EPA within 18 months of the final rule's effective date. Small businesses reporting data only on importing PFAS-containing articles have 24 months to report to the agency. You must use CDX (Central Data Exchange) to complete and submit the reporting form required under this final rule.

Reference/Link

The link below will allow you to view/print the Notice.

https://www.govinfo.gov/content/pkg/FR-2023-10-11/pdf/2023-22094.pdf

B. Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting; Final Rule

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 10/31/2023

Effective Date: November 30, 2023 (Applies for reporting year beginning January 1, 2024 with reports due July 1, 2025.)

Summary

EPA is adding per- and polyfluoroalkyl substances (PFAS) subject to reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA) to the list of Lower Thresholds for Chemicals of Special Concern. These PFAS already have a lower reporting activity threshold of 100 pounds. This final rule eliminates the use of the de minimis exemption, the option to use Form A, and the use of range reporting for PFAS.

EPA maintains a list of PFAS added to the TRI list. For reporting Year 2023 (reporting forms due by July 1, 2024) the list includes 189 PFAS. The list can be accessed at: https://www.epa.gov/toxics-release-inventory-tri-program/list-pfas-added-tri-ndaa

This final rule adds all PFAS included on the Toxics Release Inventory (TRI) to the list of chemicals of special concern and aligns reporting requirements for these PFAS with other chemicals of special concern. As a result, the following will change when completing TRI reporting of PFAS:

- Chemicals of special concern are excluded from the de minimis exemption.
- Chemicals of special concern may not be reported on Form A.
- Range reporting for chemicals of special concern has been eliminated because the
 use of ranges could misrepresent data accuracy for PBT chemicals because the low or
 the high-end range numbers may not really be that close to the estimated value.

As PFAS continue to be added to the list of TRI chemicals, they will also be included in the list of chemicals of special concern as of the date they are added to the TRI.

Additionally, EPA is also eliminating the use of the de minimis exemption under the Supplier Notification Requirements at 40 CFR 372.45(d)(1) for all substances on the list of chemicals of special concern.

The revisions in this final rule have the potential to significantly impact certain facilities. All locations that are required to submit annual TRI reports for chemicals that they manufacture, process, or otherwise use in quantities above the reporting threshold will now be required to review the list of 189 PFAS on the TRI list of reportable chemicals without being subject to the de minimis exemption. This has the potential to require reporting on additional PFAS chemicals as a result.

The link below will allow you to view/print the Final Rule.

https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23413.pdf

C. Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA); Proposed Rule

Agency

Environmental Protection Agency (EPA)

Dates

<u>Published Date:</u> 10/31/2023 <u>Comments Due:</u> 12/15/2023

Summary

The Environmental Protection Agency (EPA) is proposing to regulate trichloroethylene (TCE) under the Toxic Substances Control Act (TSCA). This action is being proposed to address the risk of injury documented in EPA's November 2020 Risk Evaluation for TCE and January 2023 revised risk determination for TCE. TCE is widely used as a solvent in a variety of industrial, commercial and consumer applications.

TSCA requires the EPA to apply requirements, to the extent necessary, when a chemical is found to present an unreasonable risk of injury. EPA determined that TCE presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to TCE, including non-cancer effects (liver toxicity, kidney toxicity, neurotoxicity, immunotoxicity, reproductive toxicity, and developmental toxicity) as well as cancer (liver, kidney, and non-Hodgkin lymphoma) from chronic inhalation and dermal exposures to TCE.

To address the identified unreasonable risk, EPA is proposing to:

- prohibit all manufacture (including import), processing, and distribution in commerce of TCE and industrial and commercial use of TCE for all uses, with longer compliance timeframes and workplace controls for certain processing and industrial and commercial uses (including proposed phaseouts and time-limited exemptions);
- prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, with a time-limited exemption for cleanup projects;
- and establish recordkeeping and downstream notification requirements

Comments on this proposed rule must be received on or before December 15, 2023.

The link below will allow you to view/print the Proposed Rule.

https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23010.pdf

Phasedown of Hydrofluorocarbons: Restrictions on the Use of Certain
 Hydrofluorocarbons Under the American Innovation and Manufacturing Act of 2020;
 Final Rule

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 10/24/2023 Effective Date: 12/26/2023

Summary

The Environmental Protection Agency (EPA) is issuing regulations to implement certain provisions of the American Innovation and Manufacturing (AIM) Act, as enacted on December 27, 2020. This rulemaking restricts the use of hydrofluorocarbons in specific sectors or subsectors in which they are used; establishes a process for submitting technology transition petitions; establishes recordkeeping and reporting requirements; and addresses certain other elements related to the effective implementation of the American Innovation and Manufacturing Act. These restrictions on the use of hydrofluorocarbons address petitions granted on October 7, 2021, and September 19, 2022.

The AIM Act authorizes EPA to address hydrofluorocarbons (HFCs) in three main ways:

- 1. phasing down HFC production and consumption through an allowance allocation program;
- 2. promulgating certain regulations for purposes of maximizing reclamation and minimizing releases of HFCs from equipment;
- 3. and facilitating sector-based transitions to next-generation technologies.

EPA is not finalizing an approach that completely prohibits the use of regulated substances in new products in any sector or subsector in this rulemaking and again maintains that the Agency has the authority to do so in a subsequent rulemaking. EPA is not restricting the use of any specific HFC when used in blends. This rulemaking focuses on the third area—facilitating the transition to next-generation technologies by restricting use of HFCs in the sectors or sub sectors in which they are used.

EPA is establishing recordkeeping and reporting requirements for any entity that domestically manufactures or imports products or specified components that use or are intended to use regulated substances or blends containing a regulated substance. EPA intends to limit to the extent practicable duplicative burden between the AIM Act and the GHGRP and plans to use a mechanism to synchronize these systems similar to the Agency's efforts under the HFC

Allocation program. Where there is overlap in requested data, EPA intends to internally direct data to the appropriate Agency data systems to reduce duplicative burden as much as possible for reporters that fall under this rule and under GHGRP subpart QQ.

The final rule includes "TABLE 3—NAICS CLASSIFICATION OF POTENTIALLY AFFECTED ENTITIES" which lists the NAICS that may be impacted by this Final Rule. Please refer to the posting in the federal register for this list.

Reference/Link

The link below will allow you to view/print the Final Rule.

https://www.govinfo.gov/content/pkg/FR-2023-10-24/pdf/2023-22529.pdf

E. Controlled Substance Destruction Alternatives to Incineration; Advanced Notice of Proposed Rulemaking

Agency

Drug Enforcement Administration (DEA)

Dates

Published Date: 10/31/2023 Comments Due: 11/02/2023

Summary

The Drug Enforcement Administration (DEA) is seeking information about destruction processes which may be used to render controlled substances to a non-retrievable state.

DEA invites comments from stakeholders in the controlled substance disposal industry, as well as registrants engaged in the destruction and disposal of controlled substances in their possession or inventory. For each method or technology identified, the DEA is requesting the following information:

- 1. If known, the potential users of this method or technology.
- 2. A detailed description of the method of destruction or technical process utilized to achieve the non retrievable standard. Does this method or technology involve incineration at any point to attain the non-retrievable standard?
- 3. The controlled substance(s) to which the method of destruction or technology to render the controlled substance(s) non-retrievable may be applicable.
- 4. If known, list any controlled substances that will not be rendered non-retrievable by this method.
- 5. The volume or throughput (per hour) required to render the controlled substance non-retrievable.
- 6. The registrant's anticipated cost to execute, implement, or utilize the method of destruction or technology discussed above.

- 7. The analytical process utilized to evaluate the effectiveness of the method of destruction or technology. Provide the analytical results validating attainment of the non-retrievable standard.
- 8. The characteristics or constituents of any by-products or waste generated through the process used to render the controlled substance non-retrievable. Provide the waste profile sheet or similar documentation showing analytical results of the by-products or waste generated.
- 9. The disposal process of the byproducts or waste generated.
- 10. The Federal, state, or local regulatory requirements associated with the disposal process and/or disposal of the by-products or waste.

The link below will allow you to view/print the Advanced Notice of Proposed Rulemaking.

https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23984.pdf

F. Schedules of Controlled Substances: Placement of Zuranolone in Schedule IV; Final Rule

Agency

Drug Enforcement Administration (DEA)

Dates

Published Date: 10/31/2023 Effective Date: 10/31/2023

Summary

On August 4, 2023, the United States Food and Drug Administration approved a new drug application for ZURZUVAE (zuranolone) capsules for the treatment of post-partum depression.

The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place zuranolone and its salts in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing zuranolone, including its salts, in schedule IV of the CSA. This action facilitates the public availability of zuranolone as a schedule IV controlled substance.

Zuranolone is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distributing, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

- 1. Registration
- 2. Disposal of Stocks
- 3. Security
- 4. Labeling and Packaging
- 5. Inventory
- 6. Records and Reports
- 7. Prescriptions
- 8. Manufacturing and Distributing
- 9. Importation and Exportation
- 10. Liability

Reference/Link

The link below will allow you to view/print the Final Rule.

https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23982.pdf

G. Designation of Halides of 4-Anilinopiperidine as List I Chemicals; Final Rule

Agency

Drug Enforcement Administration (DEA)

Dates

Published Date: 10/31/2023 Effective Date: 11/30/2023

Summary

The Drug Enforcement Administration (DEA) is finalizing the modification of the listing of the list I chemical, N-phenylpiperidin-4-amine (also known as 4-anilinopiperidine; Nphenyl-4-piperidinamine; 4–AP) (hereinafter referred to as 4- anilinopiperidine), to include halides of 4-anilinopiperidine. This rule finalizes the modification of the listing of 4-anilinopiperidine as a list I chemical.

Upon the effective date of this final rule, persons handling halides of 4- anilinopiperidine, including regulated chemical mixtures containing halides of 4-anilinopiperidine, will be required to comply with list I chemical regulations, including the following:

- 1. Registration
- 2. Records and Reports
- 3. Importation and Exportation
- 4. Security
- 5. Administrative Inspection
- 6. Liability

The link below will allow you to view/print the Final Rule.

https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23927.pdf