ENVIRONMENTAL PROTECTION AGENCY
40 CFR Parts 9 and 721
RIN 2070–AB27

Significant New Use Rule on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 29 chemical substances that were the subject of premanufacture notices (PMNs). This action requires persons who intend to manufacture (including import) or process any of the chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit the activity before it occurs.

DATES: This final rule is effective February 2, 2016.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0390, is available at http://www.regulations.gov or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket). Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: moss.kenneth@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. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. 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:

- Manufacturers (including importers) or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refiners.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 12(b) (15 U.S.C. 2611(b)) requirement to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit the activity before it occurs.

The Clinton Railroad Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that the drawbridge shall open on signal. There are no alternate routes for vessels transiting this section of the Upper Mississippi River. The bridge cannot open in case of emergency.

The Clinton Railroad Drawbridge provides a vertical clearance of 18.7 feet above normal pool in the closed-to-navigation position. Navigation on the waterway consists primarily of commercial tows and recreational watercraft and will not be significantly impacted. This temporary deviation has been coordinated with waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 25, 2015.

Eric A. Washburn,
Bridge Administrator, Western Rivers.

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BILLING CODE 9110–04–P
exposed. This test guideline is designed as a tiered approach which is shown and explained in the guideline. Each tier is triggered by the results of the previous tier.

As stated in the proposed rule, EPA determined that the results of a ready biodegradability test with product-specific chemical analytics to validate the degradation products (including intermediate products) and the rates of degradation (including intermediate degradation rates) and a hydrolysis as a function of pH and temperature test would help characterize the environmental effects of the PMN substance P–14–72. Without additional data identifying the hydrolysis products EPA continues to have concerns for toxicity at surface water concentrations as low as 3 ppb. As a result, EPA is finalizing the SNUR as proposed and has determined that additional information is still necessary in order to determine whether or to what extent hydrolysis products may be of concern to aquatic organisms, which was the basis for the original direct final SNUR of October 27, 2014. Tier 3 of OECD Test Guideline 111, the identification of hydrolysis products, could be conducted to better understand those products. The results of this full hydrolysis study on PMN substance P–14–72 would then inform the need for further recommended testing, including aquatic toxicity or ready biodegradability testing.

EPA received comments from the PMN submitter of the remaining 28 chemicals to the proposed rule. These chemicals were submitted as three consolidated PMNs: P–14–89 through P–14–92, P–14–158, P–14–159, P–14–161, P–14–162, P–14–163, P–14–173, P–14–175 through P–14–188, and P–14–190 through P–14–193. The commenter stated that the Agency had changed its regulatory decision on these PMN substances in an arbitrary and capricious manner, from a SNUR with the significant new use defined as uses other than as described in the PMNs to one with the significant new use defined as any release of the PMN substances to surface waters resulting in the quotient from the equation provided in 40 CFR 721.90 exceeding a certain surface water concentration listed in the SNUR. Further, the commenter claimed that a SNUR for water releases (or a limit on water concentration) presents an analytical and record-keeping burden on customers for the intended PMN end uses of mineral flotation products and surfactants in asphalt emulsions that will cause these customers to instead select other less-environmentally beneficial products. The PMN submitter cited its practice of environmentally-beneficial reuse and recycling in the manufacture of these PMN substances starting with byproducts and other waste streams from industrial processes. The commenter also noted that there is no incentive to conduct any testing to address the Agency’s aquatic toxicity concerns, because the PMN substances are expected to exhibit some aquatic toxicity and such results may only result in an adjustment of the water concentration levels while the analytical and record-keeping burden remains.

EPA examined the comments on these 28 chemicals and has decided to modify the proposed SNURs. EPA has determined that any manufacturing, processing or use of the substances excluding uses as described in the PMNs may result in surface water concentrations exceeding the listed concentrations of concern, which may result in significant adverse environmental effects. Because (1) the potential benefits from use of low-value byproduct waste streams to produce the PMN substances and (2) the Agency has determined that the uses described in the PMNs are not expected to result in significant releases exceeding the listed concentrations of concern, EPA is finalizing the SNURs on these 28 chemicals to limit the significant new use to use other than as described in the PMNs where the use is as a surfactant in asphalt emulsions (for P–14–89 through P–14–92); additives in mineral flotation products and as chemical intermediates (for P–14–158, P–14–159, P–14–161, P–14–162, P–14–163); or flotation additives in mineral processing (for P–14–173, P–14–175 through P–14–188, and P–14–190 through P–14–193).

In addition, this final rule retains the significant new use of where the surface water concentrations described under the significant new uses in a new paragraph (a)(3)(i) are exceeded, but these water release concentrations only apply for uses other than as described in the PMNs and mentioned in the previous sentence.

EPA also received comments on the proposed SNUR for the chemical substance that is the subject of PMN P–13–793. EPA is deferring action on that substance to a later date, and intends to respond to those comments and issue a final SNUR at that time.

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors, listed in Unit IV. of this rule. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the final rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 720. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(h) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the Federal Register its reasons for not taking action.

III. Rationale and Objectives of the Final Rule

A. Rationale


B. Objectives

EPA is issuing final SNURs for 29 chemical substances described above to achieve the following objectives with
regard to the significant new uses designated in this final rule:

- EPA will receive notice of any person’s intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA’s determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the chemical substances listed in this final rule, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

V. Applicability of the Significant New Use Designation

If uses begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the final rule was issued. Therefore EPA has designated the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing. Consult the Federal Register Notice of April 24, 1990 (55 FR 17376, FRL 3658–5) for a more detailed discussion of the cutoff date for ongoing uses.

Any person who began commercial manufacture or processing of the chemical substances identified in this rule for any of the significant new uses designated in the proposed SNUR after the date of publication of the proposed SNUR, must stop that activity before the effective date of the final rule. Persons who ceased those activities will have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires, before engaging in any activities designated as significant new uses. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

VI. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require the development of any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing.

Recommended testing that would address the criteria of concern of § 721.170 can be found in Unit IV. of the proposed rule. Descriptions of tests are provided only for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E–PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

VIII. Economic Analysis

EPA evaluated the potential costs of SNUN requirements for potential manufacturers and processors of the chemical substances in the rule. The Agency’s complete Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2014–0390.

IX. Statutory and Executive Order Reviews

A. Executive Order 12866

This final rule establishes SNURs for chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993).

B. 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 OMB approval under 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. EPA is amending the table in 40 CFR part 9 to list the OMB approval.
number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB’s implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is “good cause” under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 et seq.), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUR submitted by any small entity would not cost significantly more than $8,300.

A copy of that certification is available in the docket for this final rule.

This final rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit VIII, and EPA’s experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

• A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
• Submission of the SNUN would not cost any small entity significantly more than $8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA’s experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this final rule. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 et seq.).

E. Executive Order 13132

This action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This final rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 62249, November 9, 2000), do not apply to this final rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

X. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

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

Dated: November 24, 2015.

Maria J. Doa,
Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

§ 721.10780 Propaneperoxic acid, 2,2-dimethyl-1,1,3,3-tetramethylbutyl ester.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as propaneperoxic acid, 2,2-dimethyl-1,1,3,3-tetramethylbutyl ester (PMN P–14–72; CAS No. 22288–41–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:
(i) Release to water. Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) [where N=110 for PMNs P–14–89 and P–14–90; N=240 for PMN P–14–90; N=53 for PMN P–14–91].
(ii) [Reserved].

(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
(i) Release to water. Requirements as specified in §721.125(a), (b), (c), (i) and (k) are applicable to manufacturers and processors of these substances.

§ 721.10781 Fatty acid amide hydrochlorides (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as fatty acid amide hydrochlorides (PMNs P–14–89, P–14–90, P–14–91 and P–14–92) are subject to reporting under this section for the significant new uses described in paragraphs (a)(2) and (3) of this section.

(2) The significant new uses are:
(i) Industrial, commercial, and consumer activities. Requirements as specified in §721.80. The significant new use is any use other than as a surfactant in asphalt emulsions where the surface water concentrations described under the significant new uses in paragraph (a)(3)(i) of this section are exceeded.
(ii) [Reserved].

(3) The significant new uses for any use other than as a surfactant in asphalt emulsions:
(ii) [Reserved]

(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
(1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a), (b), (c), (i) and (k) are applicable to manufacturers and processors of these substances.

§ 721.10782 Fatty acid amides (generic).


(2) The significant new uses are:
(i) Industrial, commercial, and consumer activities. Requirements as specified in §721.80. The significant new use is any use other than as additives in mineral flotation products and as chemical intermediates where the surface water concentrations described under the significant new uses in paragraph (a)(3)(i) of this section are exceeded.
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA--HQ--OAR--2013--0290 and EPA--HQ--OAR--2013--0291; FRL--9939--35--OAR]

RIN 2060--AP69

NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing: Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) published a final rule in the Federal Register on October 26, 2015, titled NESHAP for Brick and Structural Clay Products Manufacturing; and NESHAP for Clay Ceramics Manufacturing. These amendments make two technical corrections to the published regulation.

DATES: This action is effective December 28, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Sharon Nizich, Sector Policies and Programs Division (D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541–2825; facsimile number: (919) 541–5450; email address: nizich.sharon@epa.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 95

Centers for Medicare & Medicaid Services

42 CFR Part 433

[CMS--2392--F]

RIN 0938--AS53

Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems (90/10)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will extend enhanced funding for Medicaid eligibility systems as part of a state’s mechanized claims processing system, and will update conditions and standards for such systems, including adding to and updating current Medicaid Management Information Systems (MMIS) conditions and standards. These changes will allow states to improve customer service and support the dynamic nature of Medicaid eligibility, enrollment, and delivery systems.

DATES: Effective Date: These regulations are effective on January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Victoria Guarisco (410) 786–0265, for issues related to administrative questions.

Carrie Feher (410) 786–8905, for issues related to the regulatory impact analysis.

Christine Gerhardt (410) 786–0693 or Martin Rice (410) 786–2417, for general questions.

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