

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 712 and 716**

[OPPTS-82049; FRL-5397-9]

Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The TSCA Interagency Testing Committee (ITC) in its 38th Report to EPA revised the Toxic Substances Control Act (TSCA) Section 4(e) Priority Testing List by recommending for testing 18 chemical substances. The ITC recommendations must be given priority consideration by EPA in promulgating test rules. EPA is adding certain of these chemical substances to two model information-gathering rules: the TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) and the TSCA Section 8(d) Health and Safety Data Reporting Rule. These model rules will require manufacturers and importers of the substances identified herein to report certain production, use, and exposure-related information, and manufacturers, importers, and processors of the listed substances to report unpublished health and safety data to EPA.

DATES: This rule will become effective on November 29, 1996.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, TSCA Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. E-543, Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551, e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This rule adds 18 chemical substances to the PAIR and the section 8(d) Health and Safety Data Reporting Rule. Manufacturers, importers, and processors of these chemicals will be required to report unpublished health and safety data, and manufacturers and importers will be required to report end use, exposure, and production volume data to EPA.

This rule also corrects the previous TSCA section 8(a) final rule published in the Federal Register of February 28, 1996 (61 FR 7421) (FRL-4996-9), by replacing the incorrect CAS number for (1,1,3,3-tetramethylbutyl)phenol (mixed isomers) 2744-41-6 with the correct CAS number for that chemical, 62744-41-6.

I. Background

Section 4(e) of TSCA established the ITC and authorized it to recommend to EPA chemical substances and mixtures (chemicals) to be given priority consideration in proposing test rules under section 4. For some of these chemicals, the ITC may designate that EPA must respond to its recommendations within 12 months. In this time, EPA must either initiate a rulemaking to test the chemical or publish in the Federal Register its reasons for not doing so.

On May 31, 1996, EPA announced the receipt of the 38th Report of the ITC, and it was then published in the Federal Register of July 30, 1996 (61 FR 39832) (FRL-5397-2). The 38th Report revises the Committee's Priority Testing List of chemicals by recommending for testing 18 chemical substances to the section 4(e) Priority Testing List.

This rule adds 18 substances to the PAIR and the section 8(d) Health and Safety Data Reporting Rule. These two rules are model information gathering rules which assist the ITC in making testing recommendations and aid EPA in responding to the ITC recommendations.

EPA issued the PAIR under section 8(a) of TSCA (15 U.S.C. 2607(a)), and it is codified at 40 CFR part 712. This model section 8(a) rule establishes standard reporting requirements for manufacturers and importers of the chemicals listed in the rule at 40 CFR 712.30. These manufacturers and importers are required to submit a one-time report on general volume, end use, and exposure-related information using the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710-35). EPA uses this model section 8(a) rule to gather current information on chemicals for the ITC quickly.

EPA issued the model Health and Safety Data Reporting Rule under section 8(d) of TSCA (15 U.S.C. 2607(d)), and it is codified at 40 CFR part 716. The section 8(d) model rule requires past, current, and prospective manufacturers, importers, and processors of listed chemicals to submit to EPA copies and lists of unpublished health and safety studies on the listed chemicals that they manufacture, import, or process. These studies provide the ITC and EPA with useful information for chemical assessment and have provided significant support for EPA's decisionmaking under TSCA sections 4, 5, 6, 8, and 9.

These model rules provide for the automatic addition of ITC Priority Testing List chemicals. Whenever EPA announces the receipt of an ITC report,

EPA may, at the same time without further notice and comment, amend the two model information-gathering rules by adding the recommended (or designated) chemicals. The amendment adding these chemicals to the PAIR and the Health and Safety Data Reporting Rule becomes effective 30 days after publication in the Federal Register.

II. Chemicals To Be Added

In its 38th Report to EPA, the ITC recommended adding a group of 18 nonylphenol ethoxylates to the section 8(a) PAIR and the section 8(d) Health and Safety Data Reporting Rule. While 18 chemical substances are identified in the regulatory text, 23 CAS numbers are listed. Three chemical substances, nonylphenol polyethylene glycol ether, p-nonylphenol polyethylene glycol ether and nonylphenoxypolyoxyethanol are characterized with multiple CAS numbers. Four chemical substances are not identified by CAS numbers.

For a complete listing of the substances being added to the section 8(d) model rule and the PAIR, see the regulatory text of this document.

III. Reporting Requirements**A. Preliminary Assessment Information Rule**

All persons who manufactured or imported the chemical substances named in this rule during their latest complete corporate fiscal year must submit a Preliminary Assessment Information Manufacturer's Report (EPA Form No. 7710-35) for each manufacturing or importing site at which they manufactured or imported a named substance. A separate form must be completed for each substance and submitted to the Agency no later than January 27, 1997. Persons who have previously and voluntarily submitted a Manufacturer's Report to the ITC or EPA may be able to submit a copy of the original Report to EPA or to notify EPA by letter of their desire to have this voluntary submission accepted in lieu of a current data submission. See § 712.30(a)(3).

Details of the reporting requirements, the basis for exemptions, and a facsimile of the reporting form, are provided in 40 CFR part 712. Copies of the form are available from the TSCA Environmental Assistance Division at the address listed under FOR FURTHER INFORMATION CONTACT.

B. Health and Safety Data Reporting Rule

Listed below are the general reporting requirements of the section 8(d) model rule.

1. Persons who, in the 10 years preceding the date a substance is listed, either have proposed to manufacture, import, or process, or have manufactured, imported, or processed, the listed substance must submit to EPA: A copy of each health and safety study which is in their possession at the time the substance is listed.

2. Persons who, at the time the substance is listed, propose to manufacture, import, or process; or are manufacturing, importing, or processing the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time the substance is listed.

b. A list of health and safety studies known to them but not in their possession at the time the substance is listed.

c. A list of health and safety studies that are ongoing at the time the substance is listed and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the date the substance is listed and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete--regardless of completion date.

3. Persons who, after the time the substance is listed, propose to manufacture, import, or process the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time they propose to manufacture, import, or process the listed substance.

b. A list of health and safety studies known to them but not in their possession at the time they propose to manufacture, import, or process the listed substance.

c. A list of health and safety studies that are ongoing at the time they propose to manufacture, import, or process the listed substance, and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the time they propose to manufacture, import, or process the listed substance, and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete--regardless of the completion date.

The bulk of reporting is required at the time the substance is listed. Persons described in categories 1 and 2 do all or most of their health and safety data reporting at the start of the reporting period. The remaining reporting

requirements, specifically categories 2(d), 2(e), and 3, continue prospectively. Guidance for reporting unpublished health and safety data is provided at 40 CFR part 716.

4. Special exemptions.--Explanations of reporting exemptions are found at 40 CFR 716.20. For this final rule all the chemicals listed have a special exemption referenced at § 716.20(b)(4) which states that studies on mixtures containing the listed substances at levels below one percent of the mixture, except when a purpose of the study includes the investigation of the effects of the listed substance at the levels below one percent, are not subject to the reporting requirements.

C. Submission of PAIR Reports and Section 8(d) Studies

PAIR reports and section 8(d) health and safety studies must be sent to:

TSCA Document Processing Center (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, ATTN: (insert either PAIR or 8(d) Reporting).

D. Removal of Chemical Substances from the Rules

Any person who believes that section 8(a) or 8(d) reporting required by this rule is unwarranted, should promptly submit to EPA in detail the reasons for that belief. EPA, in its discretion, may remove the substance from this rule for good cause (40 CFR 716.105). When withdrawing a substance from the rule, EPA will issue a rule amendment for publication in the Federal Register.

IV. Economic Analysis

A. Preliminary Assessment Information Rule

The economic analysis for the addition of the 18 chemicals to the TSCA Section 4(e) Priority List will be based largely on the methods and data sources developed for the analyses of the original Section 8(a) Preliminary Assessment Information Rule (PAIR). These analyses are:

1. Economic Impact and Small Business Definition Analysis for TSCA Section 8(a) Preliminary Assessment Information Rule. Office of Regulatory Analysis, OTS, U.S. EPA. February 1980.

2. Economic Analysis of the Final Section 8(a) Preliminary Assessment Information Rule. R.A. Horner, Regulatory Impacts Branch, OTS, U.S. EPA. November 12, 1981.

The Chemical Update System (CUS) was searched to determine the manufacturers and importers of the 18

chemicals. However, only 5 of these 18 chemicals were located in CUS. Thus, this report shall estimate burden and costs based upon 5 chemical compounds. This search identified 6 firms manufacturing or importing the 5 chemicals at a total of 6 sites. Manufacturing and/or importing sites were identified for all the chemicals.

Reporting Costs (dollars)

(a) 6 reports estimated at \$1,515 per report = \$9,090

(b) 6 sites at \$476.18 per site = \$2,857.08
Total Cost = \$11,947.08

Mean cost per site = \$11,947.08/6 sites = \$1,991.18

Mean cost per firm = \$11,947.08/6 firms = \$1,991.18

Reporting Burden (hours)

(a) Rule familiarization: 7 hours/site x 6 sites = 42

(b) Reporting: 22.61 hours/report x 6 reports = 135.66

Total burden hours = 177.66

Average burden per site = 177.66 hours/6 sites = 29.61

Average burden per firm = 177.66 hours/6 firms = 29.61

EPA Costs (dollars)

It is estimated that the annual cost to the Federal Government will be 1.315 FTEs (or 2,735 hours annually). At an estimated \$69,370 per FTE, the total of 1,315 FTEs will cost EPA \$91,222.

B. Health and Safety Data Reporting Rule

EPA estimates the total reporting costs for establishing section 8(d) reporting requirements for the five chemicals will be \$15,527. This cost estimate is high because the Agency is uncertain about the likely number of respondents to the rule. Although EPA has used the best available data to make its economic projections, much of the information is based upon the 1994 TSCA Inventory Update. Therefore, EPA tends to overestimate rather than underestimate reporting burden.

The estimated reporting costs are broken down as follows:

Initial corporate review	\$952
Site identification	1,427
File searches at site	3,217
Photocopying existing studies	1,256
Title listing	145
Managerial review for CBI	7,296
Reporting on newly-initiated studies	62

Submissions after initial reporting period	1,116
Additional costs	56
Total	\$15,527

Reporting Burden (hours)

(a) Initial review: 2 hours/firm x 6 firms = 12 hrs

(b) Reporting: 39.33 hours/firm x 6 firms = 236 hrs

Total reporting burden hours = 248 hrs

V. Rulemaking Record

The following documents constitute the record for this rule (docket control number OPPTS-82049). All of these documents are available to the public in the TSCA Nonconfidential Information Center (NCIC), formerly the TSCA Public Docket Office, from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA NCIC is located at EPA Headquarters, Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

1. This final rule.
2. The economic analysis for this rule.
3. The Thirty-eighth Report of the ITC.

VI. Regulatory Assessment Requirements

A. Executive Orders 12866 and 12898

The Office of Management (OMB) has exempted actions under TSCA section 8(a) and 8(d) from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993). In addition, this action does not require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) nor does it involve specified considerations of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

B. Unfunded Mandates Reform Act and Executive Order 12875

This action will not result in the annual expenditure of \$100 million or more, for State, local or tribal governments, in the aggregate or the private sector, and is not a Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4), nor does it uniquely affect small government in any way. As such, the requirements of sections 202, 203, and 205 of Title II of the UMRA do not apply to this action.

C. Regulatory Flexibility Act

EPA has determined that this action does not impose any adverse economic impacts on small entities. Pursuant to 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), this action will not impose a significant economic impact on a substantial number of small entities. Information relating to this determination is included in the docket for rulemaking. Any comments regarding the economic impacts that this action imposes on small entities should be submitted to the Agency at the address listed under FOR FURTHER INFORMATION CONTACT.

D. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid control number assigned by OMB. The OMB control number for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The information collection requirements related to this action have already been approved by OMB, under OMB control number 2070-0054 (EPA ICR No. 586) for PAIR reporting and OMB control number 2070-0004 (EPA ICR No. 575) for TSCA section 8(d) reporting. This action does not impose any burdens requiring additional OMB approval. The public

reporting burden for this collection of information is estimated to be 248 hours. Of that total, an estimated 12 hours are spent performing an initial review of the rule. The remaining 236 hours are associated with the actual reporting activities.

E. Submission to Congress and the General Accounting Office

This action is not a "major rule" as defined by 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted this action to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to its publication in today's Federal Register.

List of Subjects in 40 CFR Parts 712 and 716

Environmental protection, Chemicals, Hazardous substances, Health and safety data, Reporting and recordkeeping requirements.

Dated: October 21, 1996.

Charles M. Auer,

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

Therefore, 40 CFR Chapter I is amended as follows:

PART 712—[AMENDED]

1. In part 712:

a. The authority citation for part 712 continues to read as follows:

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

b. Section 712.30(e) is amended by revising the CAS number entry for "2744-41-6" under the category "Alkylphenols and Alkylphenol Ethoxylates" and alphabetically adding the new category "Nonylphenol ethoxylates" to read as follows:

§ 712.30 Chemical lists and reporting periods.

* * * * *

(e) * * *

CAS No.	Substance	Effective date	Reporting date
Alkylphenols and Alkylphenol Ethoxylates	* * * * *		
62744-41-6	* * *	* * *	* * *
Nonylphenol ethoxylates			
07311-27-5	Ethanol, 2-[2-[2-(p-nonylphenoxy)ethoxy]ethoxy]ethoxy]-	11/29/96	1/27/97
09016-45-9 and 20636-48-0	Nonylphenol polyethylene glycol ether	11/29/96	1/27/97
20427-84-3	Ethanol, 2-[2-(p-nonylphenoxy)ethoxy]-	11/29/96	1/27/97

CAS No.	Substance	Effective date	Reporting date
26027-38-3 and 26064-02-8	p-Nonylphenol polyethylene glycol ether	11/29/96	1/27/97
26571-11-9	Nonylphenol octa(oxyethylene)ethanol	11/29/96	1/27/97
27176-93-8 and 27177-01-1	Nonylphenoxydiglycol	11/29/96	1/27/97
27177-05-5	Nonylphenol hepta(oxyethylene)ethanol	11/29/96	1/27/97
27177-08-8	Nonylphenolnona(oxyethylene) ethanol	11/29/96	1/27/97
27986-36-3	Nonylphenoxy ethanol	11/29/96	1/27/97
37205-87-1	Poly(oxy-1,2-ethanediyl), alpha-(isononylphenyl)-omega-hydroxy	11/29/96	1/27/97
	* * * * *		

PART 716—[AMENDED]

2. In part 716:

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

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

b. Section 716.120(d) is amended by revising the table heading for the second column and alphabetically adding the new category "Nonylphenol ethoxylates" to read as follows:

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

* * * * *

(d) * * *

Category	CAS number	Special exemptions	Effective date	Sunset date
* * *	* * *	* * *		
Nonylphenol ethoxylates				
alpha-(p-Nonylphenol)-omega-hydroxypoly(oxyethylene).	NA	§ 716.20(b)(4) applies	11/29/96	11/29/06
Decaethylene glycol, isononylphenyl ether ...	65455-72-3	§ 716.20(b)(4) applies	11/29/96	11/29/06
Ethanol, 2-[2-(p-nonylphenoxy)ethoxy]-	20427-84-3	§ 716.20(b)(4) applies	11/29/96	11/29/06
Ethanol, 2-[2-[2-(p-nonylphenoxy)ethoxy]ethoxy]ethoxy]-	07311-27-5	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonoxynol-2	NA	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonoxynol-3	NA	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonoxynol-7	NA	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenol hepta(oxyethylene)ethanol	27177-05-5	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenol octa(oxyethylene)ethanol	26571-11-9	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenol polyethylene glycol ether	09016-45-9, 20636-48-0, 26027-38-3, 26064-02-8, 27177-01-1, 37205-87-1, 127087-87-0	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenol polyethylene glycol ether	27177-08-8	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenolnona(oxyethylene) ethanol	27986-36-3	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenoxy ethanol	27176-93-8	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenoxydiglycol	68412-54-4	§ 716.20(b)(4) applies	11/29/96	11/29/06
Nonylphenoxy polyoxyethanol	152143-22-1, 26027-38-3	§ 716.20(b)(4) applies	11/29/96	11/29/06
p-Nonylphenol polyethylene glycol ether	27986-36-3, 37205-87-1, 98113-10-1	§ 716.20(b)(4) applies	11/29/96	11/29/06
Poly(oxy-1,2-ethanediyl), alpha-(isononylphenyl)-omega-hydroxy.	37205-87-1	§ 716.20(b)(4) applies	11/29/96	11/29/06
Poly(oxy-1,2-ethanediyl), alpha-(2-nonylphenyl)-omega-hydroxy.	51938-25-1	§ 716.20(b)(4) applies	11/29/96	11/29/06
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