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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2009-0767; FRL-9915-61]

RIN 2070-AJ52

### Ethylene Glycol Ethers; Significant New Use Rule

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), EPA is promulgating a significant new use rule (SNUR) for seven ethylene glycol ethers (also known as glymes). This rule will require persons who intend to manufacture (including import) or process any of the seven ethylene glycol ethers for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing such manufacture or processing. The required notifications would provide EPA with the opportunity to evaluate the intended use and, if necessary based on the information available at that time, an opportunity to protect against potential unreasonable risks, if any, from that activity before it occurs. EPA is also making a technical amendment to the codified list of control numbers for approved information collection activities so that it includes the control number assigned by the Office of Management and Budget (OMB) to the information collection activities contained in this rule.

**DATES:** This final rule is effective [*insert date 60 days after date of publication in the Federal Register*].

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2009-0767, is available at <http://www.regulations.gov> or at the

Office of Pollution Prevention and Toxics Docket (OPPT Docket), EPA 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:*

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**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture (including import) or process any of the chemical substances covered by this final rule. The North American Industrial Classification System (NAICS) codes identified are 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 of one or more of subject chemical substances (NAICS codes 325 and 324110); e.g., chemical manufacturing and petroleum refineries;

- All other basic organic chemical manufacturing (NAICS code 325199)
- Paint and coating manufacturing (NAICS code 325510);
- Adhesive manufacturing (NAICS code 325520);
- Printing ink manufacturing (NAICS code 325910); and
- Motor vehicle brake system manufacturing (NAICS code 336340).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5 and 40 CFR 721.10299. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*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 those listed in

TSCA section 5(a)(2). 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 (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

*C. What Action is the Agency Taking?*

In the **Federal Register** of July 12, 2011 (76 FR 40850) (FRL-8877-8), EPA proposed a SNUR for 14 ethylene glycol ethers (Ref. 1). EPA's response to public comments received on the proposed rule appears in Unit X. Please consult the July 12, 2011 **Federal Register** document for further background information for this final rule.

This final SNUR applies to seven of the 14 ethylene glycol ethers identified in the proposed rule. EPA is not finalizing the SNUR for the other seven ethylene glycol ethers proposed because the Agency believes that these chemicals are not sufficiently similar to the seven chemicals subject to this SNUR and therefore do not raise the same concern for potential exposure to these chemicals. (See Unit X.A. for more information.) This final SNUR will require persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of:

- Monoethylene glycol dimethyl ether (monoglyme, CASRN 110-71-4) for any use in a consumer product;
- Diethylene glycol dimethyl ether (diglyme, CASRN 111-96-6) for any use in a consumer product;
- Ethylene glycol diethyl ether (ethylglyme, CASRN 629-14-1) for any use in a consumer product;

- Diethylene glycol diethyl ether (ethyldiglyme, CASRN 112-36-7) for any use in a consumer product, except as a component of inks, coatings and adhesives, and as a component of paint/graffiti removers;

- Triethylene glycol dimethyl ether (triglyme, CASRN 112-49-2) for any use in a consumer product, except as a solvent in consumer adhesives, in brake fluid, as a component of consumer paint/graffiti removers, and in consumer paints;

- Diethylene glycol dibutyl ether (butyldiglyme, CASRN 112-73-2) for any use in a consumer product, except as a component of inks, coatings and adhesives, and as a component in soldering compounds; or

- Triethylene glycol dibutyl ether (butyltriglyme, CASRN 63512-36-7) for any use.

#### *D. Why is the Agency Taking this Action?*

This SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of these ethylene glycol ethers for new uses that may produce changes in human and environmental exposures. The rationale and objectives for this SNUR are explained in Unit III.

#### *E. What are the Estimated Incremental Impacts of this Action?*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this final rule. This analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be less than \$8,700 per SNUN submission for large business submitters and \$6,300 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. In addition, for persons exporting a substance that is the subject of

a SNUR, a one-time notice must be provided for the first export or intended export to a particular country, which is estimated to cost less than \$100 on average per notification. Since EPA is unable to predict whether anyone might engage in future activities that would require reporting, potential total costs were not estimated.

## II. Overview of the Chemical Substances Subject to this Rule

The ethylene glycol ethers and the significant new use for each chemical substance subject to this SNUR are identified in Table 1 of this unit.

**Table 1. Chemicals with Significant New Use(s)**

Chemical Name	Chemical Abstracts (CA) Index Name	Chemical Abstracts Service Registry No. (CASRN)	Significant New Use(s) <sup>1</sup>
Monoethylene glycol dimethyl ether or monoglyme	Ethane, 1,2,-dimethoxy-	110-71-4	Any use in a consumer product
Diethylene glycol dimethyl ether or diglyme	Ethane, 1,1'-oxybis[2-methoxy-	111-96-6	Any use in a consumer product
Diethylene glycol diethyl ether or ethyldiglyme	Ethane, 1,1'-oxybis[2-ethoxy-	112-36-7	Any use in a consumer product except as a component of inks, coatings and adhesives, and as a component of paint/graffiti removers
Triethylene glycol dimethyl ether or triglyme	2,5,8,11-Tetraoxadodecane	112-49-2	Any use in a consumer product, except as a solvent in consumer adhesives, in brake fluid, as a component of consumer paint/graffiti removers, and in consumer paints
Diethylene glycol dibutyl ether or butyldiglyme	Butane, 1,1'-[oxybis(2,1-ethanedioxy)]bis-	112-73-2	Any use in a consumer product except as a solvent in consumer inks, coatings and adhesives, and as a component in soldering compounds
Ethylene glycol diethyl ether or	Ethane, 1,2-diethoxy	629-14-1	Any use in a consumer product

ethylglyme			
Triethylene glycol dibutyl ether or butyltriglyme	5,8,11,14-Tetraoxaoctadecane	63512-36-7	Any use

<sup>1</sup> In defining the significant new use for each chemical, the exceptions listed in this table reflect the identified ongoing uses, where they exist, that are excluded from the definition of significant new use.

EPA notes that the seven chemical substances that are the subjects of this SNUR are not the only ethylene glycol ethers that are of concern based on toxicity. EPA has described the ethylene glycol ethers category more broadly under the TSCA New Chemicals Program and under Emergency Planning and Community Right-To-Know Act (EPCRA) section 313. (See the TSCA New Chemicals Program Chemical Categories document (Ref. 2) and the EPCRA section 313 List of Toxic Chemicals “Certain Glycol Ethers” category at 40 CFR 372.65(c) (Ref. 3). Both categories are based on a consideration of structural similarity and hazard.) These categories are broader than the category that is subject to this SNUR. For this rulemaking, EPA considered past and current patterns of use as one factor in determining which ethylene glycol ethers would be included within the scope of this SNUR. EPA believes that the seven ethylene glycol ethers that are the subjects of this SNUR have and/or had similar use patterns and can be anticipated to have at least some similar new uses. Thus, given the potential for similar uses and the potential impact that these will have on type, duration, and magnitude of exposure, EPA believes it is appropriate to focus on these seven ethylene glycol ethers.

### **III. Rationale and Objectives for this Final Rule**

#### *A. Rationale*

EPA is concerned about the potential of the seven ethylene glycol ethers that are the subjects of this SNUR to cause reproductive and/or developmental toxicity, genotoxicity and toxicity to blood and blood forming organs and believes that individuals could suffer adverse effects from their use (Refs. 1-4). This concern is based on a

combination of data and structure-activity relationships. While a specific hazard evaluation is not required by TSCA section 5(a)(2), EPA considered hazard in designating this category of ethylene glycol ethers. In deciding to focus on these chemical substances, EPA considered use patterns as well as toxicity data and structure-activity relationships. EPA considered these factors in conjunction with the statutory factors provided in section 5(a)(2). In designating the significant new uses for these chemical substances, EPA will have the opportunity to evaluate and control, where appropriate, activities associated with those uses, if such manufacturing or processing for the significant new uses were to start or resume. The required notification provided by a SNUN will provide EPA with the opportunity to evaluate activities associated with a significant new use and an opportunity to protect against unreasonable risks, if any, which may occur from exposure to these chemical substances.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to issue a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

#### *B. Objectives*

Based on the considerations in Unit III.A., EPA will achieve the following objectives with regard to the significant new uses that are designated in this rule:

1. EPA will receive notice of any person's intent to manufacture or process any of the chemical substances listed in Table 1 of Unit II. for the described significant new use before that activity begins.

2. EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing the chemical substances listed in Table 1 of Unit II. for the described significant new use.

3. EPA will be able to regulate the prospective manufacture or processing of the chemical substances before the described significant new use of the chemical substance listed in Table 1 of Unit II. occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7.

#### **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 authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of the chemical substances subject to this rule, as discussed herein, EPA considered relevant information

about the potential toxicity of these substances, the range of uses for these chemicals and the four factors listed in section 5(a)(2) of TSCA.

EPA believes that potential new consumer uses could change the type and form of exposure and/or the magnitude and duration of exposure to humans and the environment relative to what currently exists. Use in consumer products could result in different types of exposure, e.g., inhalation exposure through spray applications, dermal exposure if the consumer product is meant to be hand-applied to an object, than currently exist. Use in different consumer products can also change the duration of exposure, which will depend upon the type of consumer product in which the chemical substance is used. Also, new uses of any of these chemical substances would likely result in an increase of the magnitude of exposure relative to current exposures given that these uses would be in addition to ongoing uses. Consumers use a variety of products; thus, their potential exposures to a chemical substance in multiple consumer products would likely be additive.

New uses in consumer products would also result in differences in the processing of the chemical substances that are the subject of this SNUR because these chemical substances may be mixed with other chemicals and may be made part of consumer products with different properties, e.g., different viscosities from existing consumer products. Based on these considerations of the statutory factors, EPA has determined that the uses identified in Table 1 of Unit II. are significant new uses. In addition, because there are no ongoing uses of triethylene glycol dibutyl ether, any new use would result in a change in the volume of manufacturing and processing of this chemical substance, as well as the type, form, magnitude and duration of exposure, and the manner and methods of manufacturing, processing, distribution in commerce, and disposal of this chemical substance.

## V. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) 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 on 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.

Persons who export or intend to export a chemical substance(s) identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

## **VI. Applicability of the Rule to Uses Occurring Before Effective Date of the Final Rule**

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who may have begun commercial manufacture or processing of the chemical substance(s) subject to this rule after the proposal was published on July 12, 2011, must cease such activity before the effective date of this final rule. To resume their activities, these persons will have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses. To the extent that additional ongoing uses were found in the course of rulemaking, EPA has excluded these uses from the final SNUR. EPA promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

## **VII. Test Data and Other Information**

EPA recognizes that TSCA section 5 does not usually require developing any particular test data before submission of a SNUN. There are two exceptions:

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)); and

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 section 4 test rule or a 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 (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture (including import), processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical substance.

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

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

## **VIII. SNUN Submissions**

EPA recommends that entities consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the intended use of the chemical substance. 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 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

## **IX. Economic Analysis**

### *A. SNUNs*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this rule (Ref. 5). In the event that a SNUN is submitted, costs are estimated at approximately \$8,589 per SNUN submission for large business submitters and \$6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). The costs of submission of SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in this SNUR. EPA's complete economic analysis is available in the public docket for this rule (Ref. 5).

### *B. Export Notification*

Under section 12(b) of TSCA and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical substance, depending on the number of required notifications (i.e., the number of countries to which the chemical substance is exported). EPA is unable to make any estimate of the likely number of export notifications for the chemical substances covered in this SNUR.

### **X. Response to Comments**

The Agency reviewed and considered all comments received related to the proposed rule. Copies of all non-CBI comments are available in the docket for this action (EPA-HQ-OPPT-2009-0767). A discussion of the major comments germane to the rulemaking and the Agency's responses follow. Responses to all germane comments received are in the document titled: "Response to Comments on the Proposed Ethylene Glycol Ethers (Glymes) Significant New Use Rule (SNUR)" (Ref. 6), which is also available in the docket.

#### *A. Scope of Ethylene Glycol Ethers Category.*

1. *Comment.* One commenter contends that the term glymes, while technically correct, is a less well-known term for these ethylene glycol ethers. The commenter asserts it may not have been clear to many what chemicals are subject to this rulemaking.

*Response.* EPA disagrees that it was unclear what chemical substances were the subjects of the proposed SNUR. Even if an individual manufacturer or processor were unfamiliar with the term EPA used to designate the category ("glymes"), all of the

chemical substances proposed to be included in the SNUR were also individually identified by their CASRN, CA Index Name, and ethylene glycol ether common name. Notice of the proposal was adequate; there were several ways in which stakeholders could have determined which chemical substances were the subjects of the proposal. However, to increase clarity, EPA will list the “ethylene glycol ether” name instead of the name “glymes” to characterize the chemicals subject to this SNUR.

2. *Comment.* One commenter contends that while the ethylene glycol ethers are structurally similar, they vary in molecular weight, in the number of ethylene glycol groups, and in the length of the terminal alkyl groups. The commenter asserts that the presence of characteristics, such as longer terminal alkyl groups and more ethylene glycol groups act to reduce the developmental and reproductive toxicity of the higher molecular weight ethylene glycol ethers, as compared to the lower molecular weight ethylene glycol ethers. The commenter states that there is a decrease in ethylene glycol ether toxicity with increasing terminal alkyl length and/or increasing ethylene glycol groups, and that the category should be limited to monoglyme, diglyme and ethylglyme. Another commenter contends that the category should be limited based on a consideration of metabolism. The commenter contends that the category should be limited to monoglyme, diglyme, ethyl diglyme and triglyme because only these will be metabolized in the body to chemical substances that have toxicity characteristics of ethylene glycol monomethyl ether and ethylene glycol monoethyl ether. The commenter contends that none of the other ethylene glycol ethers exhibit developmental or reproductive toxicity similar to that of these four chemical substances.

*Response.* A specific evaluation of hazard is not required by TSCA section 5(a)(2) to issue a SNUR. Nonetheless, EPA has based this SNUR in part on considerations of toxicity, so toxicity considerations are relevant in this instance.

EPA believes that based on both toxicity data and structure-activity relationships (Refs. 1-4) ethylene glycol ethers that consist of 1, 2 or 3 glycol ether groups and terminal alkyl groups of 1 to 4 carbons can be anticipated to cause developmental and reproductive toxicity and/or hemolytic toxicity. Based on these same data and structure-activity relationships, EPA agrees with commenters that chemical substances with more than 3 repeating glycol ether units should not be included in the category because the toxicity of such substances is dissimilar from the remaining members of the category. Therefore, EPA removed seven of the proposed category members from the final rule.

While there is evidence that the toxicity is reduced going from methyl to butyl ether and with increasing number of ethylene glycol groups, toxicity is still observed (Refs. 3, 4). Indeed, data provided by one commenter demonstrate the developmental toxicity of six of the seven ethylene glycol ethers (Ref. 7). Among the seven substances listed in Table 1 of Unit II., EPA disagrees that the relevant evidence establishes sufficient variation in degree of toxicity to cull any further substances from the group. Differing doses at which toxicity occurs does not equate with lack of toxicity. Thus, EPA disagrees with the commenter that the category should be further limited to only those chemicals which induce toxicity at the lowest doses. Inclusion in the category is appropriately predicated on *similarity* of toxicity. (EPA notes also that the commenters' individual lists are not in agreement with respect to ethylene glycol ethers that they consider to be the most developmentally toxic, and that there is only partial overlap between these two lists.)

Further, ethylene glycol ethers cause adverse effects in addition to reproductive and developmental toxicity. Data for other toxic effects of ethylene glycol ethers with terminal alkyl groups of one to four carbons do not indicate a trend toward decreasing toxicity with increasing alkyl chain length (Ref. 4). Hemolysis has been reported in

varying degrees for ethylene glycol ethers of one to five carbons in the alkyl chains (Ref. 4). Hemolysis is associated with chain length, and a chain length of four carbons causes this type of toxicity at the lowest dose (Ref. 4).

One commenter contends that “the lower glymes that are generally considered to be toxic following repeated exposure are: monoglyme, diglyme and ethylglyme. The higher glymes that are less toxic following repeated exposure are triglyme, tetraglyme, polyglyme, ethyldiglyme and butyldiglyme” (Ref. 7). EPA disagrees that molecular weight can be appropriately applied, by itself, to establish which substances are sufficiently similar to be included in the SNUR. EPA notes that some level of variation within chemical categories is inevitable when placing similar chemicals into groups, and therefore, variation is expected. The similarity in the toxicity of the chemical substances that are the subject of this SNUR is not primarily based on molecular weight but as discussed above is based on both toxicity data and structure-activity relationships (Refs 1-4). Ethylene glycol ethers that consist of 1, 2 or 3 glycol ether groups and terminal alkyl groups of 1 to 4 carbons can be anticipated to cause developmental and reproductive toxicity and/or hemolytic toxicity. Based on these toxicity considerations, EPA notes that it did, in fact remove some of the higher molecular weight ethylene glycol ethers from the final rule. But EPA disagrees that varying molecular weight, in itself, should be a deciding factor in eliminating a chemical substance from a category of similar chemical substances. While the commenter provides limited data on developmental and reproductive toxicity, they provide no data with respect to other toxicity endpoints of concern (including toxicity to blood and blood forming organs, and potential for gene mutation) and the commenter does not speculate on possible similarities or differences among the chemical substances with respect to these endpoints (Ref. 7).

3. *Comment.* Several commenters contend that the ethylene glycol ether category is too broad. While the chemical substances in the category are similar because they have one or more repeating glycol ether groups and terminal alkyl chains, structural similarity is not sufficient to predict toxicity. One commenter further states that structural similarities alone should not be the basis for toxicity determinations, risk assessment and subsequent regulation.

*Response.* EPA acknowledges the commenters' assertions that the category of ethylene glycol ethers in the proposed SNUR was too broad, and is finalizing this SNUR for only seven of the original 14 chemicals.

The commenters' remaining arguments (about the relevance of structural similarities to risk assessment, and subsequent regulation) are premature. This SNUR is not based on a risk assessment, and it does not establish that subsequent regulation of the ethylene glycol ethers would be necessary in the event EPA receives a significant new use notice after promulgating this rule.

While EPA did consider toxicity in deciding to focus on these chemical substances, under TSCA section 5(a)(2), EPA is neither required to determine that a particular new use of any chemical substance presents, nor even that it may present, an unreasonable risk to human health or the environment. Rather, EPA issues a SNUR for a particular new use of a substance if it has reason to anticipate that the use would raise significant questions related to potential exposure, so that it should have an opportunity to review the use before such use could occur. EPA bases this judgment on a consideration of all relevant factors, including the specific factors identified at section 5(a)(2). EPA considered similarities in toxicity and potential toxicity among these chemical substances, similarities in uses and considered the extent to which the significant new uses that are the subject of this SNUR could result in changes to the processing of these

chemical substances and the type, duration and magnitude of exposures to these chemicals.

*B. Use.*

4. *Comment.* Two commenters request clarification on whether automobiles are considered consumer products. These commenters point to the definition of consumer product at section 3(a)(5) of the Consumer Product Safety Act (CPSA), which excludes motor vehicles. These commenters contend that the EPA definition at 40 CFR 721.3 should be clarified to be consistent with CPSA and exclude motor vehicles.

*Response.* CPSA is a different statute from TSCA. For purposes of significant new use rules issued pursuant to TSCA, consumer product is defined at 40 CFR 721.3 as "...a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation." This is the pertinent regulatory text and it contains no exclusion for automobiles.

However, EPA would not consider ethylene glycol ethers to have been "sold or made available to consumers for their use" merely because they have been sold or made available to automobile manufacturers or commercial auto service establishments (for their use in manufacturing or maintaining customers' motor vehicles). By contrast, ethylene glycol ethers that are sold or made available to a consumer, for the consumer's own use in maintaining his or her own motor vehicle (e.g., as part of an aftermarket brake fluid) would fall within the definition of "consumer product."

5. *Comment.* One commenter asks that EPA clarify the status of brake fluid contained in a new or used motor vehicle at point of sale.

*Response.* EPA would not consider an ethylene glycol ether to have been "sold or made available to consumers for their use," merely because it has been made available to

motor vehicle manufacturers (as part of a brake fluid mixture for their use in manufacturing customers' motor vehicles) or used car dealers. By contrast, ethylene glycol ethers that are sold or made available to a consumer, for the consumer's own use in maintaining his or her own motor vehicle (e.g., as part of an aftermarket brake fluid) would fall within the definition of "consumer product."

6. *Comment.* One commenter requested that EPA clarify how aftermarket components are addressed in this rulemaking.

*Response.* An aftermarket component is any product offered for sale or installation in or on a motor vehicle after such vehicle has left the manufacturer's production line. Use in an aftermarket component would qualify as use in a consumer product if the chemical substances in an aftermarket component are "sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation." 40 CFR 721.3.

7. *Comment.* Two commenters request that EPA modify the listed ongoing use for monoethylene glycol dimethyl ether (monoglyme) listed in the proposed rule - "any use in a consumer product except in electrolyte solution in sealed lithium batteries" to "any use in a consumer product except in electrolyte solutions for primary and secondary sealed lithium batteries" - because this would clarify that the ongoing use of monoglyme is in all primary and secondary batteries.

*Response.* For purposes of defining the scope of the significant new use, EPA has determined that the use of ethylene glycol ethers in sealed lithium batteries (whether primary or secondary) is not use in a consumer product. An ethylene glycol ether is not being "sold or made available to consumers for their use," 40 CFR 721.3, merely because it is contained in the electrolyte of sealed lithium batteries, which are themselves used by

consumers. With this clarification, EPA is finalizing the significant new use for monoethylene glycol dimethyl ether as “any use in a consumer product.”

## **XI. 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 in developing this rule, including the documents referenced within the documents that are in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. US EPA. Glymes; Proposed Significant New Use Rule. 76 FR 40850, July 12, 2011.

2. US EPA. TSCA New Chemicals Program (NCP) Chemical Categories. Last revised August 2010, pages 68 – 69.

*<http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf>*

3. US EPA. Glycol Ethers Category; Toxic Chemical Release Reporting; Community Right-To-Know. 58 FR 36180, July 6, 1993.

4. US EPA. Glycol Ethers Category; Toxic Chemical Release Reporting; Community Right-To-Know. 59 FR 34386, July 5, 1994.

5. US EPA. Economic Analysis of the Significant New Use Rule for Seven Ethylene Glycol Ethers. Prepared by Nishkam Agarwal and Abt Associates Inc. September 30, 2013.

6. US EPA. Response to Comments on the Proposed Ethylene Glycol Ethers (Glymes) Significant New Use Rule (SNUR). October 30, 2013.

7. Novolyte Technologies. Attachment 1: Categorization of Glymes Based on Toxicology and Structural Characteristics. October 12, 2011, pages 1-21.

## **XII. Statutory and Executive Order Reviews**

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This final rule has been designated by OMB as a “significant regulatory action” under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993).

Accordingly, EPA submitted this action to OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

### *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. Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved by OMB under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for an export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system. Additional burden, estimated to be less than 10 hours, could be incurred where additional record keeping requirements are specified under 40 CFR 721.125(a), (b), and (c).

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 the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the

**Federal Register**, are listed in 40 CFR, part 9, and included on the related collection instrument, or form, if applicable. EPA is amending the table in 40 CFR part 9 to list this SNUR. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since the existing OMB approval was previously subject to public notice and comment before OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend the table 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.

*C. Regulatory Flexibility Act (RFA)*

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR will not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a “significant new use.” By definition of the word “new” and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to engage in such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices

per year. During the six year period from 2005-2011, only three submitters self-identified as small in their SNUN submission (Ref. 5). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA believes that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### *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 reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this regulatory action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531-1538.

#### *E. Executive Order 13132: Federalism*

This action does 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 (64 FR 43255, August 10, 1999).

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

This rule does not have Tribal implications because it will not have any effect (i.e., there will be no increase or decrease in authority or jurisdiction) 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. Thus, Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this action.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks for children.

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

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

*I. National Technology Transfer Advancement Act (NTTAA)*

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: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse

human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

### **XIII. Congressional Review Act (CRA)**

Pursuant to the CRA, 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: December 10, 2014.

Wendy C. Hamnett,

*Director, Office of Pollution Prevention and Toxics.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 9--[AMENDED]**

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

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following section in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

\* \* \* \* \*

40 CFR citation	OMB control No.
* * * *	* * *
<b>Significant New Uses of Chemical Substances</b>	
* * * *	* * *
721.10229	2070-0038
* * * *	* * *

\* \* \* \* \*

**PART 721--[AMENDED]**

3. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

4. Add §721.10229 to subpart E to read as follows:

**§721.10229 Ethylene glycol ethers.**

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified in Table 1 of this paragraph are subject to reporting under this section for the significant new uses described in Table 1 of this paragraph.

**Table 1. Ethylene Glycol Ethers and Significant New Uses Subject to Reporting.**

<b>Chemical Name</b>	<b>Chemical Abstracts Index Name</b>	<b>Chemical Abstracts Service Registry No. (CASRN)</b>	<b>Significant New Use(s)</b>
Monoethylene glycol dimethyl ether or monoglyme	Ethane, 1,2,-dimethoxy-	110-71-4	Any use in a consumer product
Diethylene glycol dimethyl ether or diglyme	Ethane, 1,1'-oxybis[2-methoxy-	111-96-6	Any use in a consumer product
Diethylene glycol diethyl ether or ethyldiglyme	Ethane, 1,1'-oxybis[2-ethoxy-	112-36-7	Any use in a consumer product except as a component of inks, coatings and adhesives, and as a component of paint/graffiti removers
Triethylene glycol dimethyl ether or triglyme	2,5,8,11-Tetraoxadodecane	112-49-2	Any use in a consumer product, except as a solvent in consumer adhesives, in brake fluid, as a component of consumer paint/graffiti removers, and in consumer paints
Diethylene glycol dibutyl ether or butyldiglyme	Butane, 1,1'-[oxybis(2,1-ethanedioxy)]bis-	112-73-2	Any use in a consumer product except as a solvent in consumer inks, coatings and adhesives, and as a component in soldering compounds
Ethylene glycol diethyl ether or ethylglyme	Ethane, 1,2-diethoxy	629-14-1	Any use in a consumer product
Triethylene glycol dibutyl ether or butyltriglyme	5,8,11,14-Tetraoxaoctadecane	63512-36-7	Any use

(2) [Reserved]

(b) [Reserved]

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