

**Kentucky**

(a) Kentucky Natural Resources and Environmental Protection Cabinet: submitted on December 27, 1993, and supplemented on November 15, 1994, April 14, 1995, May 3, 1995 and May 22, 1995; interim approval effective on December 14, 1995; interim approval expires on December 14, 1997.

(b) Air Pollution Control District of Jefferson County, Kentucky: submitted on February 1, 1994, and supplemented on November 15, 1994, May 3, 1995, July 14, 1995 and February 16, 1996; full approval effective on April 22, 1996.

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**40 CFR Part 799**

[OPPTS-42185; FRL-5356-7]

RIN 2070-0033

**Testing Consent Order For Alkyl Glycidyl Ethers**

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

**ACTION:** Final consent agreement and order; final rule.

**SUMMARY:** Pursuant to the Toxic Substances Control Act (TSCA), EPA has issued a testing consent order (Order) that incorporates an enforceable consent agreement (ECA) with Air Products and Chemicals, Inc., Callaway Chemical Company, Ciba-Geigy Corporation, CVC Specialty Chemicals, and Shell Chemical Company (the Companies). The Companies have agreed to perform certain health effects tests on alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether (CAS No. 120547-52-6), as a representative of the alkyl glycidyl ethers subcategory of EPA's proposed test rule for glycidol and its derivatives. This notice summarizes the ECA, adds alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether to the list of chemical substances and mixtures subject to testing consent orders, and announces that export notification requirements apply to alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether.

**EFFECTIVE DATE:** March 22, 1996.

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

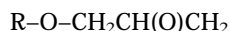
**SUPPLEMENTARY INFORMATION:** This notice amends 40 CFR 799.5000 by adding alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether to the list of chemical substances and

mixtures subject to testing consent orders and export notification requirements.

**I. Background**

Alkyl glycidyl ethers (AGEs) are epoxy resin additives derived from glycidol and are used as modifiers for other epoxides in flooring and adhesives. Their annual production volume is approximately 7 million pounds. Approximately 37,000-69,000 workers may be exposed to AGEs.

In its Third Report to the EPA Administrator, published in the Federal Register on October 30, 1978 (43 FR 50630), the TSCA section 4 Interagency Testing Committee (ITC) designated the category glycidol and its derivatives (collectively referred to as "glycidyls") for priority consideration for health effects testing with regard to the following endpoints: Carcinogenicity, mutagenicity, teratogenicity, and other adverse health effects, with particular emphasis on the reproductive system. Epidemiological studies were also recommended. The rationale for the original designation is discussed in the same Federal Register notice. This chemical category was defined by the ITC as all substances with the general formula:



where R is a hydrogen atom or any alkyl, aryl, or acyl group. R is unrestricted as to the number and type of substituents it may carry.

On December 30, 1983, EPA published an advanced notice of proposed rulemaking (ANPRM) (FRL-2480-7) in the Federal Register (48 FR 57562) to require testing glycidyls under section 4(a) of TSCA.

In the November 7, 1991 issue of the Federal Register (56 FR 57144), EPA published a notice of proposed rulemaking (FRL-3736-2) for testing the category glycidol and its derivatives. Unit I.D. of the notice described EPA's evaluation of the testing needs for glycidyls. The proposal contained testing requirements for, among others, the following chemical substances: lauryl glycidyl ether (CAS No. 2461-18-9); hexadecyl glycidyl ether (CAS No. 15965-99-8); n-octadecyl glycidyl ether (CAS No. 16245-97-9); tetradecyl glycidyl ether (CAS No. 38954-75-5); alkyl (C<sub>10</sub>-C<sub>16</sub>) glycidyl ether (CAS No. 68081-84-5); and alkyl (C<sub>12</sub>-C<sub>14</sub>) glycidyl ether (CAS No. 68609-97-2). The proposal designated these chemical substances as subcategory II-A.

The November 7, 1991, notice proposed that manufacturers of subcategory II-A chemical substances conduct tests on a representative

member of the subcategory for the following endpoints: Subchronic toxicity, developmental toxicity, subchronic neurotoxicity (functional observational battery, motor activity, and neuropathology), and genetic toxicology (immediately required testing—the *salmonella typhimurium* reverse mutation assay; *in vitro* mammalian bone marrow cytogenetics; and *in vivo* mammalian bone marrow cytogenetics tests: chromosomal analysis or micronucleus assay).

**II. Enforceable Consent Agreement Negotiations**

On July 17, 1992, EPA published a Federal Register notice (57 FR 31714) (FRL-4078-9) announcing an "open season". The open season was a time during which industry and other interested parties could submit to EPA proposals for enforceable consent agreements (ECAs) to test chemical substances for which the Agency had not issued final test rules. In that notice, EPA indicated that it would review the submissions and select candidates for negotiation of ECAs pursuant to 40 CFR 790.22. EPA also indicated that it would, at a future date, publish a Federal Register notice soliciting persons interested in participating in or monitoring negotiations for the development of ECAs on the chemical substances selected.

On September 15, 1992, the Companies submitted a proposal (Ref. 1) for a categorization scheme and a testing program that would be an alternative to that described in the proposed test rule for the category glycidol and its derivatives. The Companies proposed a testing program for, among others, a representative of the subcategory II-A chemical substances. On April 26, 1993, the Companies made another proposal (Ref. 2) that expanded the scope of the testing program.

On August 18, 1993, EPA published a Federal Register notice (58 FR 43893) (FRL-4639-5) that solicited interested parties to participate in or monitor ECA negotiations on subcategory II-A chemical substances.

On November 30, 1994, the Companies submitted a draft proposed ECA (Ref. 3) that revised the material that they had previously submitted in this matter. The Companies proposed as the test substance alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether (CAS No. 120547-52-6) which is subsumed within the six subcategory II-A substances (60 FR 31154, June 13, 1995) (FRL-4960-3). These seven chemicals are referred to as alkyl glycidyl ethers (AGEs). The Companies proposed the following tests—subchronic toxicity (with an

assessment of testicular toxicity), developmental toxicity, subchronic neurotoxicity (functional observational battery, motor activity, neuropathology, and electrophysiology), and genetic toxicity (*in vivo* mammalian bone marrow cytogenetics test: micronucleus assay). In addition, the Companies offered to undertake voluntarily a product stewardship program to address the potential health and environmental hazards associated with AGEs in the workplace.

On June 13, 1995, EPA published a Federal Register notice (60 FR 31154) (FRL-4960-3) that resolicited interested parties to negotiate an ECA for AGEs, and announced a public meeting for this negotiation. EPA held the public meeting, which was attended by representatives of the Companies and

other interested parties, on July 26, 1995. During the public meeting and following the meeting (Refs. 4, 5, 6, and 7), consensus was reached on the ECA, with alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether to be tested as a representative of AGEs, and on the tests to be included in the ECA (see table 1 in Unit IV of this preamble). On January 22, 1996, EPA received the ECA and a memorandum of understanding (MOU) for a product stewardship program, both signed by the Companies.

On March 15, 1996, EPA signed the ECA and accompanying Order, and the MOU.

### III. Proposed Test Rule

EPA has decided not to finalize the proposed test rule for AGEs contained in the proposed test rule for the category glycidol and its derivatives (56 FR

57144, November 7, 1991) (FRL-3736-2). EPA has instead reached agreement with the Companies that the testing requirements for AGEs in the proposed rule will be met by implementing the ECA and Order, and that the issuance of the ECA and Order constitutes final EPA action for purposes of 5 U.S.C. 704. Should EPA decide in the future that it requires additional data on AGEs, the Agency will initiate a separate action.

### IV. Testing Program

Table 1 describes the required testing, test standards, and reporting requirements under the ECA for alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether as a representative of AGEs. This testing program will allow EPA to characterize further the potential health hazards resulting from exposure to AGEs.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS FOR ALKYL (C<sub>12</sub>-C<sub>13</sub>) GLYCIDYL ETHER AS A REPRESENTATIVE OF AGEs

Description of test	Test standard (40 CFR citation)	Deadline for final report <sup>1</sup> (months)	Interim reports <sup>2</sup> required (number)
Subchronic Toxicity: 1. 90-day dermal subchronic toxicity study in rats with assessment of testicular toxicity.	(Appendix I)	21	3
Developmental Toxicity: 1. Dermal developmental toxicity screen in rats.	(Appendix II)	21	3
Neurotoxicity: 1. Dermal subchronic functional observational battery in rats. 2. Dermal subchronic motor activity test in rats. 3. Dermal subchronic neuropathology in rats. 4. Dermal subchronic electrophysiology in rats.	(Appendix III)	21	3
Genetic Toxicity: 1. <i>In vivo</i> mammalian bone marrow cytogenetics test: Micronucleus assay in mice.	798.5395	12	1
2. The salmonella typhimurium reverse mutation assay.	798.5265	12	1
3. Detection of gene mutations in somatic cells in culture.	798.5300	12	1

<sup>1</sup> Number of months after the effective date of the testing consent order.

<sup>2</sup> Interim reports are required every 6 months from the effective date until the final report is submitted. This column shows the number of interim reports required for each test.

### V. Export Notification

The issuance of the ECA and Order subjects any persons who export or intend to export alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether, of any purity, to the export notification requirements of section 12(b) of TSCA. The listing of a chemical substance or mixture at 40 CFR 799.5000 serves as notification to persons who export or intend to export such chemical substance or mixture that the substance or mixture is the subject

of an ECA and Order and that 40 CFR part 707 applies.

### VI. Public Record

EPA has established a record for this ECA and Order under docket number OPPTS-42185 (FRL-5356-7), which is available for inspection Monday through Friday, excluding legal holidays, in Rm. NE B607, 401 M St., SW., Washington, DC 20460, from 12 noon to 4 p.m. Information claimed as Confidential Business Information (CBI),

while part of the record, is not available for public review. This record contains the basic information considered in developing this ECA and Order and includes the following information.

#### A. Supporting Documentation

(1) Testing Consent Order for Alkyl Glycidyl Ethers, with incorporated Enforceable Consent Agreement and associated testing protocols attached as appendices.

(2) Federal Register notices pertaining to this notice, the testing consent order and the enforceable consent agreement, consisting of:

(a) "Third Report of the Interagency Testing Committee; receipt of the report and request for comments" (43 FR 50630, October 30, 1978).

(b) Advance notice of proposed rulemaking for glycidol and its derivatives (48 FR 57562, December 30, 1983) (FRL-2480-7).

(c) Notice of proposed rulemaking for glycidol and its derivatives (56 FR 57144, November 7, 1991) (FRL-3736-2).

(d) Notice of Opportunity to Initiate Negotiations for TSCA Section 4 Testing Consent Agreements (57 FR 31714, July 17, 1992) (FRL-4078-9).

(e) Notice of Testing Consent Agreement Development for Listed Chemical Substances; Solicitation for Interested Parties (58 FR 43893, August 18, 1993) (FRL-4639-5).

(h) Testing Consent Agreement Development for Alkyl Glycidyl Ethers; Solicitation of Interested Parties and Notice of Public Meeting (60 FR 31154, June 13, 1995) (FRL-4960-3).

(3) Communications consisting of:

(a) Written letters.

(b) Meeting summaries.

(4) Reports - published and unpublished factual materials.

**B. References**

1. The Epoxy Resin Systems Task Group of The Society of the Plastics Industry, Inc. Letter from Lynne R. Harris to Gary E. Timm. Proposed Testing Program for the Chemical Category Glycidol and Its Derivatives. Washington, DC (September 15, 1992).

2. The Epoxy Resin Systems Task Group of The Society of the Plastics Industry, Inc. Letter from Lynne R. Harris to TSCA Public Docket Office. Testing Consent Agreement Development. Washington, DC (April 26, 1993).

3. The Epoxy Resin Systems Task Group of The Society of the Plastics Industry, Inc. Letter from Lynne R. Harris to Charles M. Auer. Draft

Enforceable Consent Agreement Proposed for Alkyl Glycidyl Ethers and Product Stewardship Program. Washington, DC (November 30, 1994).

4. EPA. Letter from Frank D. Kover to Lynne R. Harris. Dermal Absorption Study—ECA for Alkyl Glycidyl Ethers. Washington, DC (August 16, 1995).

5. EPA. Letter from Charles M. Auer to Lynne R. Harris. Enforceable Consent Agreement for Alkyl Glycidyl Ethers; Final Draft for Test Sponsors Signatures. Washington, DC (September 21, 1995).

6. The Epoxy Resin Systems Task Group of The Society of the Plastics Industry, Inc. Letter from Lynne R. Harris to Keith Cronin. Draft Protocols for Studies Required Under Enforceable Consent Agreement. Washington, DC (December 21, 1995).

7. The Epoxy Resin Systems Task Group of the Plastics Industry, Inc. Letter from Lynne R. Harris to Keith Cronin. Revisions to Draft Protocols for Studies Required Under Enforceable Consent Agreement. Washington, DC (February 9, 1996).

**VII. Regulatory Requirements**

**A. Regulatory Assessments**

This notice announces a testing consent order incorporating a negotiated enforceable consent agreement between EPA and the Companies. Since the action announced is not a "regulation", "rule" or "regulatory action" as these terms are defined by sections 3(d) and (e) of Executive Order 12866 (58 FR 51735, October 4, 1993), the Executive Order is not applicable. The current action is not a "rule" as defined by section 601(2) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*; therefore, this statute does not apply. Similarly, because the action is not a "regulation" or a "rule" within the meaning of section 101(a) of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), the act is not applicable.

**B. Paperwork Reduction Act**

An agency may not conduct or sponsor, and a person is not required to

respond to a collection of information, unless it displays a currently valid control number assigned by the Office of Management and Budget (OMB). The information collection requirements related to the action announced in this notice have already been approved by OMB pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, under OMB control number 2070-0033 (EPA ICR No. 1139). This action does not impose any burdens requiring additional OMB approval.

The public reporting burden for this collection of information is estimated to average 586 hours per response. The estimate includes time for reviewing the test protocols attached to the ECA and gathering and analyzing the data generated by the tests.

**List of Subjects in 40 CFR Part 799**

Environmental protection, Chemicals, Chemical export, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, and Testing.

Dated: March 15, 1996.

Lynn R. Goldman,  
*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

Therefore, title 40 of the Code of Federal Regulations, chapter I, subchapter R, part 799 is amended as follows:

**PART 799—[AMENDED]**

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by adding alkyl (C<sub>12</sub>-C<sub>13</sub>) glycidyl ether to the table in CAS number order, to read as follows:

**§ 799.5000 Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.**

\* \* \* \* \*

CAS Number	Substance or mixture name	Testing	FR publication date
* * * * *	* * * * *	* * * * *	* * * * *
120547-52-6	Alkyl (C <sub>12</sub> -C <sub>13</sub> ) Glycidyl Ether .....	Health Effects .....	March 22, 1996
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[FR Doc. 96-7040 Filed 3-21-96; 8:45 am]

BILLING CODE 6560-50-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****45 CFR Part 74**

RIN 0991-AA56

**Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements With States, Local Governments and Indian Tribal Governments****AGENCY:** Department of Health and Human Services (HHS).**ACTION:** Final Rule including an Interim Final Rule for State-Administered Entitlement Programs.

**SUMMARY:** This final rule amends the HHS grants administration regulations to incorporate changes resulting from comments received in response to the publication of an interim rule implementing Office of Management and Budget (OMB) Circular A-110 on August 25, 1994. The revision of Section 74.1(a)(3), which applies this rule to the entitlement programs, remains an interim final rule until permanent policies are developed for these programs.

**EFFECTIVE DATES:** This final rule is effective April 22, 1996. The interim final rule revising § 74.1(a)(3) is effective April 22, 1996.

**FOR FURTHER INFORMATION CONTACT:** Charles Gale, Director, Division of Grants Policy and Oversight, HHS, Room 517-D, 200 Independence Ave. SW, Washington, DC 20201; telephone (202) 690-6377; fax (202) 690-8772; for the hearing impaired only: TDD (202) 690-6415.

**SUPPLEMENTARY INFORMATION:** The interim rule published by the Department on August 25, 1994 (59 FR 43754) provided recipients with substantial flexibility regarding OMB Circular A-110. This flexibility included, for example, declining to exercise the authority to require prior approval for percentage budget transfers (Circular A-110, Section \_\_\_\_\_.25(f)), declining to exercise the authority to require prior approval for fund transfers between direct and indirect costs (Circular A-110, Section \_\_\_\_\_.25(c)(5)), and declining to exercise the authority to require a notice of Federal interest in equipment

(Circular A-110, Section \_\_\_\_\_.37). This final rule continues that flexibility.

The Department received comments on the interim rule from several organizations representing the grantee community and from within HHS. Organizations commenting included community action agencies, community health centers, universities, State governments, law firms, and firms of certified public accountants. Many comments were supportive of HHS' implementation of OMB Circular A-110. All comments were considered in developing these final amendments.

The following section presents a summary of the comments, grouped by subject, and a response to each. Whenever possible we have cited the specific provision under consideration.

**General**

*Comment:* HHS should control the use of policy options by HHS awarding agencies. (For example, the choice of how program income shall be used under particular grants may be determined by HHS awarding agencies pursuant to Section 74.24(b).)

*Response:* We believe the regulation strikes an appropriate balance between providing overall HHS uniformity, and giving flexibility to HHS awarding agencies, particularly in that HHS awarding agencies must operate within the requirements of the new rule in exercising their options.

*Comment:* The definition of "Federal share" includes property improved with Federal funds. Do not apply the Federal share requirement to property improved with Federal funds.

*Response:* We do not agree. Improvement of property with Federal funds creates a Federal interest in the same way as methods of financing property with Federal funds creates a Federal interest. (Section 74.2)

*Comment:* The definition of "Federal share" includes "improvement expenditures." Define "improvement."

*Response:* "Improvement" needs no special definition because this is not a specialized use of the term. Only the ordinary, common sense meaning is intended. (Section 74.2)

*Comment:* The definition of "Federal share" discusses property acquired on an amortized basis. Give examples of the Federal share on an amortized basis.

*Response:* We have dropped that addition to the definition in order to avoid any implication of a change in the basic definition. It was not intended to alter the definition. The Federal share of property acquired on an amortized basis is determined in the same way as the Federal share of any other property. (Section 74.2)

*Comment:* The external policy issuances of HHS awarding agencies should be rescinded.

*Response:* There is no need to rescind HHS agencies' policy issuances. In many cases those issuances provide helpful explanations of HHS policy as it applies to special situations. Provisions of those issuances which conflict with this regulation, if any, are superseded. (Section 74.3)

*Comment:* Deviations from the Part 74 rules, in individual cases, should be approved at the HHS level, rather than by the HHS awarding agencies.

*Response:* We do not agree. HHS agencies make thousands of awards each year. It is not administratively feasible to route all individual cases to a central office. It would entail unacceptable delays for recipients. (Section 74.4)

*Comment:* We would hope that the new rule continues to exempt block grants and other grants and subgrants covered by 45 CFR Part 92.

*Response:* Part 74 applies to subawards made by State and local governments under 45 CFR Part 92 when those subawards are made to organizations covered by Part 74. Part 74 does not apply to subawards under block grants covered by 45 CFR Part 96. We have amended the text to make it clear that it does not apply to block grants. (Section 74.5(a)(1))

*Comment:* May a recipient impose special conditions on a subrecipient as it deems necessary or appropriate? For example, may a recipient insist on obtaining title when a subrecipient purchases equipment?

*Response:* A recipient may impose special conditions on a subrecipient provided the special conditions are consistent with the provisions of this regulation. Rules which apply to recipients flow down also to subrecipients, as provided in Section 74.5. When a subrecipient purchases equipment, the subrecipient retains title subject to the recipient's right to require transfer under Section 74.34(h).

**Pre-Award Requirements**

*Comment:* Why was the previous subpart E, Waiver of Single State Agency Requirements, dropped from the regulation?

*Response:* Subpart E was dropped from the interim final because it was decided that it would be better placed in the individual program regulations. However, in recognition of its placement in Part 74 for many years, we have now concluded it should be retained in this regulation as a matter of general information. Accordingly, we