Dated: May 15, 1987.

Edwin F. Tinsworth,

Director, Registration Division.

PART 180—[AMENDED]

1. The authority citation for 40 CFR Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. The entry *α*-Butyl-δ-hydroxypoly-(oxypropylene) in 40 CFR 180.1001(e) is revised to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(e) * * *

Inert ingredients	Limits	Uses
* * * * *		
alpha-Butyl-*omega*-hydroxypoly-(oxypropylene) block polymer with poly(oxyethylene); molecular weight 2,400-3,500.	.....	Surfactants, emulsifier, related adjuvants of surfactants.
* * * * *		

[FR Doc. 87-12102 Filed 5-27-87; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 180

[OPP-300083A; FRL 3209-2]

Methyl Poly(Oxyethylene) Alkyl Ammonium Chloride; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule correction.

SUMMARY: This document corrects the entry for methyl poly (oxyethylene) alkyl ammonium chloride in 40 CFR 180.1001(d), from which the word "alkyl" was inadvertently omitted.

EFFECTIVE DATE: May 28, 1987.

FOR FURTHER INFORMATION CONTACT:

Rosalind Gross, Registration Support and Emergency Response Branch, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

Office location and telephone number: Registration Support and Emergency Response Branch, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-7700.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 11, 1984 (49 FR 14343), in FR Doc. 84-9366, EPA added to 40 CFR 180.1001(d) the entry "Methyl poly(oxyethylene) alkyl ammonium chloride." The chemical was correctly stated in the document heading, the preamble, and the amendatory language, but the word "alkyl" was inadvertently omitted from the codified text.

(21 U.S.C. 346a)

Dated: May 15, 1987.

Edwin F. Tinsworth,

Director, Registration Division.

PART 180—[AMENDED]

1. The authority citation for 40 CFR Part 180 continues to read as follows.

Authority: 21 U.S.C. 346a.

2. The entry methyl poly (oxyethylene) alkyl ammonium chloride in 40 CFR 180.1001(d) is revised to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * * * *		
Methyl poly(oxyethylene) alkyl ammonium chloride, where the poly(oxyethylene) content is 3-15 moles and the alkyl group (C_8-C_{18}) is derived from coconut, cottonseed, soya, or tallow acids..	.....	Surfactant.
* * * * *		

[FR Doc. 87-12105 Filed 5-27-87; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 704 and 721

[OPTS-50552A AND OPTS-82026A; FRL-3209-4]

11-Aminoundecanoic Acid; Determination of Significant New Use; Submission of Notice of Manufacture, Import, or Processing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 11-aminoundecanoic acid (11-AA) (CAS Number 2432-99-7). EPA believes that this substance may be hazardous to human health, and that the uses identified in this rule may result in significant human exposure. As a result of this rule, certain persons who intend to manufacture, import, or process this substance for a significant new use are required to notify EPA at least 90 days before commencing that activity. The required notice will furnish EPA with the opportunity to evaluate the intended use and, if necessary prohibit or limit that activity before it occurs.

EPA is also requiring under section 8(a) of TSCA that manufacturers, importers, and processors of 11-AA who are not covered by the SNUR notification requirements notify EPA of prospective manufacture, import, or processing of this chemical substance. This reporting rule will allow EPA to track the manufacture, import, processing, and end uses of this substance and to investigate the health and environmental impacts of such activities. Small businesses that manufacture, import, or process 11-AA are exempt from the section 8(a) reporting rule.

This rule was proposed in the **Federal Register** of July 22, 1986 (51 FR 26273).

DATES: In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on June 11, 1987. This rule becomes effective on July 13, 1987.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St. SW., Washington, DC 20460, Telephone: (202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Authority

The Agency is promulgating this rule pursuant to sections 5(a)(2) and 8(a) of TSCA, 15 U.S.C. 2604(a)(2) and 2607(a).

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a significant new use. This determination is made by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requriements of sections 5(b) and (d)(1), the exemptions authorized by sections 5(h) (1), (2), (3), and (5), and the regulations at 40 CFR Part 720. Once EPA receives a SNUR notice, the Agency may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received the notice. If EPA does not take action, section 5(g) of TSCA requires the Agency to explain in the **Federal**

Register its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR Part 707. Persons who intend to import a chemical substance are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. Persons who import a substance identified in a final SNUR must certify that they are in compliance with the SNUR requirements. The EPA policy in support of the import certification requirements appears at 40 CFR Part 707.

Section 8(a) of TSCA authorizes the Administrator to promulgate rules which require each person (other than a small manufacturer, importer, or processor) who manufactures, imports, or processes or who proposes to manufacture, import, or process a chemical substance to submit such reports as the Administrator may reasonably require.

II. Applicability of General Provisions

In the **Federal Register** of September 5, 1984 (49 FR 35011), EPA promulgated general provisions applicable to SNURs (40 CFR Part 721, Subpart A). On April 22, 1986, EPA proposed revisions to the general provisions (51 FR 15104), some of which would apply to this SNUR. General provisions applicable to section 8(a) rules were published in the **Federal Register** of May 25, 1983 (40 CFR Part 704, Subpart A). These general provisions apply to this rule. The general provisions are discussed in detail in the cited **Federal Register** documents, and interested persons should refer to those documents for further information.

III. Summary of this Rule

A. Significant New Use Rule

EPA is designating any use of 11–AA other than as (1) an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process or (2) a component in photoprocessing solutions as significant new uses of this chemical substance. This rule requires persons who intend to manufacture, import, or process 11–AA for a significant new use to notify EPA at least 90 days before beginning such manufacture, import, or processing.

11–AA has been shown to cause cancer in laboratory animals. The only known uses for 11–AA are either as an intermediate in the manufacture of polymers or as a component in photoprocessing solutions. 11–AA is not subject to any Federal regulation that would notify the government of activities that might result in adverse exposures to this substance or provide a regulatory mechanism that could protect human health from potentially adverse exposures before they occurred.

EPA believes that the significant new uses and associated manufacture, import, or processing of 11–AA have a high potential to increase the magnitude and duration of exposure to this substance and to change the type or form of exposure from that which currently exists. Also, given the toxicity of this chemical substance, the reasonably anticipated situations that could result in exposure, and the lack of sufficient existing regulatory controls, individuals could be exposed to 11–AA at levels which may result in adverse effects.

The consideration of these factors has resulted in EPA's decision to designate any use of 11–AA other than as an intermediate in the manufacture of polymers in an enclosed process, when it is expected that the 11–AA will be fully polymerized during the manufacturing process, or as a component in photoprocessing solutions as a significant new use of this chemical substance. Persons intending to manufacture, import, or process 11–AA for a significant new use would be required to notify EPA 90 days before they begin such manufacture, import, or processing. Advance notification will allow EPA the opportunity to evaluate the risks related to an intended activity and to protect against adverse exposures to 11–AA before they can occur.

B. Section 8(a) Rule

The SNUR described above will ensure EPA is notified in the event that 11–AA is manufactured, imported, or processed for the designated significant new uses. However, persons who manufacture or import 11–AA for use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process or as a component in photoprocessing solutions would not be required to report to EPA if the 11–AA they were manufacturing or importing was to be used for those ongoing uses. Persons could also process 11–AA for these ongoing uses, but certain portions of the processing operation (such as raw material transfer) could result in potentially high human exposures.

EPA is concerned that 11–AA manufacturing, importing, and processing activities associated with these ongoing uses could present the opportunity for human exposure to this chemical substance. Because the SNUR would not provide notification of manufacturing, importing, and processing activities associated with the ongoing uses, and because this substance is a possible human health hazard, EPA believes it is necessary to require reporting under TSCA section 8(a) for those ongoing 11–AA activities which would not be covered by the SNUR.

Therefore, EPA is requiring persons who intend to manufacture, import, or process 11–AA for use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process or for use as a component in photoprocessing solutions to notify EPA within 30 days after making a firm management decision to commit financial resources for such manufacturing, importing, or processing of 11–AA. Persons who initiated manufacturing, importing, or processing of 11–AA for these ongoing uses during the time period between July 22, 1986 and July 13, 1987 are required to notify EPA on or before August 10, 1987.

Persons who manufactured, imported, or processed 11–AA for use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process or for use as a component in photoprocessing solutions at any time during the 3 years ending July 22, 1986 are exempt from reporting. EPA is providing this exemption because the Agency has had the opportunity to evaluate ongoing 11–AA activities, and has found that adequate steps are currently being taken to minimize human exposure.

Small manufacturers (including importers) as described at 40 CFR 704.3 are exempt from reporting. Processors meeting the same size standards as those described for small manufacturers at 40 CFR 704.3 are also exempt from reporting (see § 704.25(a)(7)).

Persons subject to the section 8(a) rule are required to submit a PMN Form (EPA Form 7710–25). A copy of that form can be found at 40 CFR Part 720, Appendix A.

IV. Discussion of Chemical Substance and Comments on Proposed Rule

A. Production and Use Data

11–AA is imported into the U.S. by 1 company at a rate of approximately 9 million lbs. per year. There is no known manufacturer of 11–AA in the U.S. At the time this rule was proposed, the Agency believed that all of the imported 11–AA was used by one company for the manufacture of nylon 11. Two comments received on the proposed rule indicate that 11–AA is processed not only into nylon 11, but also into other polymers, copolymers, and multifunctional copolymers. The commenters, who process the 11–AA into these polymers, stated that the processing operations for the manufacture of nylon 11 as well as the other polymeric materials all take place under enclosed conditions as described in the proposed rule, and the 11–AA is fully polymerized during the process. EPA has therefore modified the significant new use description to provide that significant new use reporting is not required when 11–AA is used to make all polymers rather than just nylon 11. The definition of the term "polymer" used in this regulation is the same as that used for the Premanufacture Notification Exemption regulations codified at 40 CFR Part 723 (see § 723.250(b)).

The Agency has also modified the proposed definition of the term "Enclosed process" that was given in the proposed rule. The proposed definition did not account for possible releases through emergency pressure relief. The definition in the final rule includes such releases.

Another comment received on the proposed rule indicated that in addition to being used to manufacture polymeric materials, one company uses 11–AA as a component in photoprocessing solutions. EPA has modified the significant new use description to provide that significant new use reporting is not required for use of 11–AA as a component in photoprocessing solutions.

B. Health Effects

Results of a National Toxicology Program (NTP) carcinogenesis bioassay on 11–AA published in May 1982 demonstrated limited evidence that 11–AA is carcinogenic in laboratory animals. Under the conditions of the bioassay, 11–AA was carcinogenic for male F344 rats, inducing neoplastic nodules in the liver and transitional cell carcinomas in the urinary bladder at a statistically significant ($p < 0.01$) level. The substance was not carcinogenic for the female F344 rat. No clear evidence was found for the carcinogenicity of 11–AA in $B6C3F_1$ mice of either sex, although an increase in malignant lymphomas in male mice may have been associated with the administration of 11–AA. Other effects of 11–AA included a dose-related decrease in mean body weight gain and survival for male rats and mice of each sex, hyperplasia of transitional epithelium of the kidney and urinary bladder in rats of each sex, and mineralization of the kidney in mice of each sex.

EPA issued Guidelines for Carcinogen Risk Assessment in the **Federal Register** of September 24, 1986 (51 FR 33992). These guidelines define as Group C—Possible Human Carcinogen agents exhibiting: ". . . (a) Definitive malignant tumor response in a single well-conducted experiment, (b) marginal tumor response in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) marginal responses in a tissue known to have a high and variable background rate. . . ."

A limited review of the results of the NTP carcinogenesis bioassay on 11–AA indicates that the substance has been found to induce a definitive malignant tumor response in male rats, and may therefore be a possible human carcinogen according to the Agency's guidelines for carcinogen risk assessment.

Results from the NTP bioassay also demonstrate that 11–AA is capable of causing chronic and subchronic non-oncogenic effects in laboratory animals. For these reasons, EPA has concluded that exposure to the substance may present a risk of injury to human health.

One comment received on the proposed rule disagreed with EPA's interpretation of the available toxicity data as it applies to the SNUR rulemaking process. That commenter believed that the Agency overstated the carcinogenicity case for this substance and that more than a limited review of the data was required. The commenter also suggested that the findings of the NTP could be interpreted in a manner to show little or no carcinogenic hazard.

The results of the NTP carcinogenicity bioassay have recently been independently reviewed by the International Agency for Research on Cancer (IARC). IARC concluded that there is limited evidence for the carcinogenicity of 11–AA in experimental animals. These conclusions were presented in IARC Monographs, Volume 39. A copy of the Monograph on 11–AA is included in the public record for this rulemaking. That Monograph was not available to EPA at the time this rule was proposed.

In addition, section 5(a)(2) of TSCA does not require EPA to make a health (or environmental) hazard finding before promulgating a SNUR. The Agency is instead directed to consider factors related to human (or environmental) exposure. EPA's discussion of the possible carcinogenicity of 11–AA is not intended to demonstrate a health effects "finding" under TSCA. The Agency provided the health effects discussion of 11–AA in the proposed rule, and has included a similar discussion in this final rule, to show that the Agency is concerned about possible human health effects resulting from exposures to this chemical substance, and that monitoring future human exposures to 11–AA is warranted.

EPA is aware that the information available may not be sufficient to make a conclusive statement regarding possible risks to humans which may result from exposure to 11–AA. IARC has suggested that epidemiological data are necessary to evaluate the carcinogenicity of 11–AA to humans. The Agency therefore welcomes the voluntary submission of any information concerning the effects of 11–AA to human health. Of particular importance would be case reports or epidemiological studies. However, other data supporting or disproving the currently available health effects information would also be valuable. Such information should be submitted to EPA at the following address:

TSCA Public Information Section, OTS
Document Processing Center (TS–790),
Attention: FYI Coordinator,
Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Persons are potentially exposed to 11–AA during the manufacture of polymers. Based on information provided by current processors of 11–AA for this purpose, all processing of 11–AA takes place in enclosed operations. Workers engaged in manufacturing various ploymers from 11–AA wear safety glasses, face-shields, safety shoes, longsleeved shirts, rubber or cotton gloves, and dust masks or suitable respirators whenever exposure to 11–AA is possible. Plants are equipped with hooded exhaust areas and local exhaust at points of potential worker exposure to 11–AA.

During the manufacturer of polymers, monomeric 11–AA is expected to be fully polymerized. It is therefore unlikely

that persons will be exposed to 11–AA in products containing these polymers.

One commenter on the proposed rule stated that his company processed small quantities of 11–AA as a component of photoprocessing solutions. The commenter noted that in this processing operation, up to 3 employees are potentially exposed to 11–AA for less than a total of 4 hours per year. Exposures take place under controlled conditions, and steps are taken to minimize employee exposure.

At the time this rule was proposed, the only exposure to 11–AA that EPA was aware of was employee exposure during the manufacturer of nylon 11. The Agency has now had the opportunity to evaluate these previously unknown exposures. Although EPA is concerned about any human exposure to 11–AA, the facilities that process this substance are doing so under conditions which minimize human exposure. The reporting requirements for both the SNUR and section 8(a) portions of this rule have therefore been revised to exempt facilities currently engaged in these activities from further reporting unless they change their uses or operations.

V. Alternatives

In the proposed rule, EPA considered alternative regulatory actions for 11–AA. No comments were received that addressed the regulatory approach chosen. EPA has therefore decided to proceed with the promulgation of a combined SNUR/section 8(a) rule for this substance.

VI. Applicability of Proposal to Uses Occurring Before Promulgation of Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of the SNUR rather than as of the promulgation of the final rule. If uses begun during the proposal period of the SNUR were considered ongoing as of the date of promulgation, it would be difficult for the Agency to establish SNUR notice requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became final; this interpretation of section 5 would make it extremely difficult for the Agency to establish SNUR notice requirements.

Thus, persons who began commercial manufacture, importation, or processing of 11–AA for a significant new use designated in this rule between proposal and promulgation of the SNUR must cease that activity before the effective date of this rule. To resume their activities, these persons must comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

VII. Test Data and Other Information

EPA recognizes that, under TSCA section 5, persons are not required to develop any particular test data before submitting a significant new use notice. Rather, persons are only required to submit test data in their possession or control and to describe any other data know to or reasonably ascertainable by them.

However, in view of the potential risks that may be posed by a significant new use of 11–AA, EPA encourages potential SNUR notice submitters to conduct tests that would permit a reasoned evaluation of risks posed by 11–AA when utilized for an intended use. The Agency believes that the results of epidemiological studies would help to characterize the potential carcinogenic hazard of 11–AA to humans. In addition, the Agency does not have any information available on the effects of 11–AA to the environment. These studies may not be the only means of addressing potential risks. SNUR notices submitted without accompanying test data may increase the likelihood that EPA would take action under section 5(e).

EPA encourages persons to consult with the Agency before selecting a protocol for testing the substance. As part of this optional prenotice consultation, EPA will discuss the test data it believes are necessary to evaluate a significant new use of the substance. Test data should be developed in accordance with TSCA Good Laboratory Practice Standards at 40 CFR Part 792. Failure to do so may lead the Agency to find such data to be insufficient to reasonably evaluate the health of environmental effects of the substance.

EPA urges notice submitters to provide detailed information on human exposure or environmental release that may result from the significant new use of 11–AA. In addition, EPA encourages persons to submit information on potential benefits of this substance and information on risks posed by the substance compared to risks posed by potential substitutes.

VIII. Economic Impact

The Agency has evaluated the potential costs of establishing SNUR and section 8(a) reporting requirements for 11–AA. The estimated cost of reporting for a person subject to either the section 8(a) or SNUR portion of this rule is between $1,400 and $8,000 per notice submitted. This is the same estimated economic impact as discussed in the proposal for this rule. The Agency's complete economic analysis is available in the public record for this rule (OPTS–50552A and OPTS–82026A).

IX. Rulemaking Record

EPA has established a record for this rulemaking (docket control numbers OPTS–50552A and OPTS–82026A). The record includes basic information considered by the Agency in developing this rule. The record now includes the following:

1. Economic analysis of the combined SNUR/section 8(a) rule for 11–AA.
2. A chemical hazard information profile for 11–AA.
3. The NTP carcinogenesis bioassay on 11–AA.
4. *IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans. Volume 39. Some Chemicals Used in Plastics and Elastomers.* 1986. Pages 339–345.
5. Comments received on the proposed rule.

A public version of this record is available in the OTS Public Information Office, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Public Information Office is located in Rm. NE–G004, 401 M St., SW., Washington, DC.

X. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a regulatory impact analysis. The Agency has determined that this rule is not "major" because it will not have an effect of $100 million or more on the economy. EPA also anticipates that this rule will not have a significant effect on competition, costs, or prices.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA certifies that this rule will not have a significant impact on a substantial number of small businesses.

The Agency cannot determine whether persons affected by the SNUR are likely to be small businesses. However, because EPA has no evidence of recent commercial manufacture, import, or processing of 11–AA other than for the manufacture of polymers, or as a component in photoprocessing solutions, EPA believes that few manufacturers, importers, or processors

will submit significant new use notices. Therefore, although the costs of preparing a notice under the SNUR provisions might be significant for some small businesses, the number of such businesses affected is not expected to be substantial.

The section 8(a) rule will exempt "small" manufacturers (as defined in 40 CFR 704.4) and "small" processors from reporting on this chemical substance. Therefore, EPA has determined that the section 8(a) rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and has assigned OMB Control Numbers 2070–0067 and 2070–0038.

List of Subjects in 40 CFR Parts 704 and 721

Chemicals, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, Significant new uses.

Dated: May 15, 1987.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR Chapter I is amended as follows:

PART 704—[AMENDED]

1. In Part 704:

a. The authority citation for Part 704 continues to read as follows:

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

b. By adding a new § 704.25 to read as follows:

§ 704.25 11-Aminoundecanoic acid.

(a) *Definitions.* (1) "11–AA" means the chemical substance 11-aminoundecanoic acid, CAS Number 2432–99–7.

(2) "Enclosed process" means a process that is designed and operated so that there is no intentional release of any substance present in the process. A process with fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to an environmental contamination from the releases.

(3) "Internal subunit" means a subunit that is covalently linked to at least two other subunits. "Internal subunits" of polymer molecules are chemically derived from monomer molecules that have formed covalent links between two or more other molecules.

(4) "Monomer" means a chemical substance that has the capacity to form links between two or more other molecules.

(5) "Polymer" means a chemical substance that consists of at least a simple weight majority of polymer molecules but consists of less than a simple weight majority of molecules with the same molecular weight. Collectively, such polymer molecules must be distributed over a range of molecular weights wherein differences in molecular weight are primarily attributable to differences in the number of internal subunits.

(6) "Polymer molecule" means a molecule which includes at least four covalently linked subunits, at least two of which are internal subunits.

(7) "Small processor" means a processor that meets either the standard in paragraph (a)(7)(i) of this section or the standard in paragraph (a)(7)(ii) of this section.

(i) *First standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company, if any, are less than $40 million. However, if the annual processing volume of a particular chemical substance at any individual site owned or controlled by the processor is greater than 45,400 kilograms (100,000 pounds), the processor shall not qualify as small for purposes of reporting on the processing of that chemical substance at that site, unless the processor qualifies as small under paragraph (a)(7)(ii) of this section.

(ii) *Second standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of the particular chemical substance processed by that company.

(iii) *Inflation index.* EPA will use the Inflation Index described in the definition of "small manufacturer" set forth in § 704.3, for purposes of adjusting the total annual sales values of this small processor definition. EPA will provide notice in the **Federal Register** when changing the total annual sales values of this definition.

(8) "Subunit" means an atom or group of associated atoms chemically derived from corresponding reactants.

(b) *Persons who must report.* Except as provided in paragraph (c) of this section, the following persons are subject to this section:

(1) Persons who manufacture or propose to manufacture 11–AA:

(i) For use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(2) Persons who import or propose to import 11–AA:

(i) For use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(3) Persons who process or propose to process 11–AA:

(i) For use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(c) *Persons not subject to this section.* The following persons are not subject to this section:

(1) Small manufacturers (includes importers) as described in § 704.3.

(2) Small processors.

(3) Persons described in § 704.5.

(4) Persons who, at any time during the 3-year period ending July 22, 1986, manufactured, imported, or processed 11–AA:

(i) For use as a intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process, or

(ii) For use as a component in photoprocessing solutions.

(d) *What information to report.* Persons identified in paragraph (b) of this section must submit a Premanufacture Notice Form (EPA Form 7710–25) as described at 40 CFR Part 720, Appendix A.

(e) *When to report.* (1) Persons who intend to manufacture, import, or process 11–AA for use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process or for use as a component in photoprocessing solutions must notify EPA within 30 days after making a firm management decision to commit financial resources for the manufacturing, importing, or processing of 11–AA.

(2) Persons who initiated manufacturing, importing, or processing of 11–AA for use as an intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11–AA will be fully polymerized during the manufacturing process, or for use as a component in photoprocessing

solutions during the time period between July 22, 1986 and July 13, 1987 must notify EPA by August 10, 1987.

(f) *Recordkeeping.* Persons subject to the reporting requirements of this section must retain documentation of information contained in their reports for a period of 5 years from the date of submission of the report.

(g) *Where to send reports.* Reports must be submitted by certified mail to: Document Control Officer (TS–790), Office of Toxic Substances, United States Environmental Protection Agency, Room 201 East Tower, 401 M Street SW, Washington, DC 20460. ATTN: 11–AA Notification.

PART 721—[AMENDED]

2. In Part 721:

a. The authority citation for Part 721 continues to read as follows:

Authority: 15 U.S.C. 2604 and 2607.

b. By adding a new § 721.109 to read as follows:

§ 721.109 11-Aminoundecanoic acid.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance 11-aminoundecanoic acid, CAS Number 2432–99–7, is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is any use other than as:

(i) An intermediate in the manufacture of polymers in an enclosed process when it is expected that the 11-aminoundecanoic acid will be fully polymerized during the manufacturing process, or

(ii) A component in photoprocessing solutions.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph.

(1) *Definitions.* In addition to the definitions in § 721.3, the following definitions apply to this section:

(i) "Enclosed process" means a process that is designed and operated so that there is no intentional release of any substance present in the process. A process with fugitive, inadvertent, or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases.

(ii) "Internal subunit" means a subunit that is covalently linked to at least two other subunits. "Internal subunits" of polymer molecules are chemically derived from monomer molecules that have formed covalent links between two or more other molecules.

(iii) "Monomer" means a chemical substance that has the capacity to form links between two or more other molecules.

(iv) "Polymer" means a chemical substance that consists of at least a simple weight majority of polymer molecules but consists of less than a simple weight majority of molecules with the same molecular weight. Collectively, such polymer molecules must be distributed over a range of molecular weights wherein differences in molecular weight are primarly attributable to differences in the number of internal subunits.

(v) "Polymer molecule" means a molecule which includes at least four covalently linked subunits, at least two of which are internal subunits.

(vi) "Subunit" means an atom or group of associated atoms chemically derived from corresponding reactants.

(2) [Reserved].

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BILLING CODE 6560–50–M

40 CFR Parts 795 and 799

[OPTS–42048D; FR 3209–5]

Hydroquinone; Final Test Standards and Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On December 30, 1985, EPA issued a final test rule establishing testing requirements under section 4(a) of the Toxic Substances Control Act (TSCA) for manufacturers and processors of hydroquinone (CAS No. 123–31–9). At that time, EPA also proposed that certain TSCA test guidelines and industry-submitted protocols be utilized as the test standards for the required studies and that test data be submitted within specified time frames. EPA has reviewed public comments on the proposal and has decided to promulgate a final rule that specifies certain of these guidelines, protocols, and schedules as the test standards and reporting requirements for the testing of hydroquinone.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ["daylight" or "standard" as appropriate] time on June 11, 1987. This rule shall become effective on July 13, 1987.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Rm. E–543, 401 M St. SW., Washington, DC 20460, (202) 554–1404.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 30, 1985 (50 FR 53145), EPA issued a final Phase I rule under section 4(a) of TSCA to require toxicity testing of hydroquinone to evaluate hydroquinone's toxicokinetics and to determine its potential to produce nervous system, reproductive, and developmental toxicity (teratogenic effects). The Agency is now promulgating a final Phase II rule specifying the test standards and reporting requirements for this testing. This test standards rule for hydroquinone is being promulgated under 40 CFR 799.2200.

I. Background

In the **Federal Register** of December 30, 1985, EPA issued a Phase I final rule pursuant to TSCA section 4 that established testing requirements for manufacturers and processors of hydroquinone. This Phase I rule specified the following testing requirements for hydroquinone: (1) Toxicokinetics; (2) reproductive effects; (3) developmental toxicity; and (4) nervous system effects.

As described in the Hydroquinone Proposed Testing Standards (50 FR 53160) and in a previous notice (50 FR 20652; May 17, 1985) EPA reviewed the method for development of test rules and, to expedite the section 4 rulemaking process, decided to utilize a single-phase approach for most rulemakings. With regard to the section 4 rulemaking for hydroquinone, EPA proposed applicable TSCA test guidelines and EPA-approved industry protocols as test standards. At the same time as the hydroquinone Phase I final test rule was being issued, TSCA test guidelines and EPA-approved industry protocols were available for all the testing requirements included in the Phase I final rule. After publication of the proposed hydroquinone test standards on December 30, 1985, a 45-day comment period was provided to allow the public, including the manufacturers and processors subject to the Phase I rule, to comment on the use of the TSCA guidelines and industry protocols.

Because EPA proposed applicable TSCA test guidelines and industry-submitted protocols as the test standards for the studies required by the hydroquinone Phase I final rule, persons subject to the rule, i.e., manufacturers

and processors of hydroquinone, were not required to submit proposed study plans and schedules for each of the required studies. Persons subject to the rule, however, were still required to submit notices of intent to test or exemption applications in accordance with 40 CFR 790.25. Once the final test standards are promulgated, persons who have notified EPA of their intent to test must submit study plans (which adhere to the promulgated test standards) no later than 45 days before the initiation of each required test. The responsibilities of processors of hydroquinone for testing or exemptions from testing responsibilities were discussed in the hydroquinone Phase I final rule (50 FR 53145).

On June 15, 1983 and prior to the Agency's issuance of the hydroquinone Phase I Proposed Rule, the Eastman Kodak Company notified EPA by letter (Ref. 1) of their intent to conduct voluntary toxicokinetic, mutagenicity, and teratology tests with hydroquinone and submitted the protocols for these studies to the Agency for review. Kodak also submitted protocols for additional confirmatory teratology and reproductive effects studies which they indicated would be conducted under their voluntary plan only after a joint evaluation by Kodak and EPA scientists of any additional EPA health concerns remaining after the initial testing. At the time of the submission of this voluntary testing package, EPA was in the process of concluding its review of the health and environmental effects testing needs for hydroquinone. While the Agency approved several of the Kodak testing protocols, EPA did not accept Kodak's voluntary testing program because the Agency was in the process of issuing a proposed test rule (49 FR 438; January 4, 1984) for hydroquinone that would require more complete health and environmental testing of the chemical.

Kodak, however, initiated its testing program and, sometime later, the manufacturers and importers of hydroquinone formed the Hydroquinone Panel, represented by the Chemical Manufacturers Association. Kodak, in concert with the Panel, is continuing its testing efforts. As part of its comments (Ref. 2) to the proposed Hydroquinone Test Standards (50 FR 53160) the Panel has notified EPA of its intent to sponsor the testing required in the final Phase I test rule for hydroquinone.

After review of the public comments, EPA is now promulgating a final Phase II rule adopting (with appropriate revisions based on public comment) formal test standards under which the manufacturers and processors of hydroquinone must conduct the health effects studies contained in the Phase I test rule for hydroquinone. These standards were proposed in the December 30, 1985 notice (50 FR 53160). These standards and requirements reflect the Agency's evaluation of comments received on the proposed test standards rule.

II. Proposed Phase II Test Rule

A. Proposed Test Standards

The final Phase I rule for hydroquinone required testing for toxicokinetics, developmental toxicity, reproductive effects, and nervous system effects.

The Agency proposed that the toxicokinetic guideline under 40 CFR 798.7650 now 40 CFR 795.235, which was contained in the proposed Phase II test standard rule, be adopted as the test standard for the required toxicokinetic testing.

EPA proposed that the developmental toxicity testing be conducted according to the protocols entitled "Protocol for a Teratology Study of Hydroquinone in Rats" and "Protocol for a Teratology Study of Hydroquinone in Rabbits", submitted to EPA by the Eastman Kodak Company on June 15, 1983 (Ref. 1) and that these industry-submitted protocols be adopted as the test standard for the required developmental toxicity testing.

EPA also proposed that the reproductive effects testing be conducted according to the protocol entitled "Protocol for a Two-Generation Reproduction Study in the Rat" submitted to EPA on June 15, 1983 (Ref. 1) and that this industry-submitted protocol be adopted as the test standard for the required reproductive effects testing.

Finally, the Agency proposed that TSCA test guidelines 40 CFR 798.6050 and 798.6400, describing a functional observational battery and neuropathology, respectively, be adopted as the test standards for the required neurotoxicity testing of hydroquinone.

B. Proposed Reporting Requirements

EPA proposed that all data developed under the Phase II rule be developed in accordance with the final TSCA Good Laboratory Practice (GLP) Standards, which appear at 40 CFR Part 792.

The Agency proposed the following specific reporting requirements:

1. The toxicokinetic tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final Phase II test rule. Interim progress reports shall be provided quarterly.

2. The developmental toxicity tests shall be completed and the final results submitted to the Agency within 18 months of the effective date of the final Phase II test rule. Interim progress reports shall be provided quarterly.

3. The two-generation reproductive effects toxicity test shall be completed and final results submitted to the Agency within 29 months of the effective date of the final Phase II test rule. Interim progress reports shall be provided quarterly.

4. The neurotoxicity tests shall be completed and final results submitted to the Agency within 1 year of the effective date of the final Phase II test rule. Interim progress reports shall be provided quarterly.

III. Response to Public Comments

EPA requested comments on the use of the TSCA test guidelines and Agency-approved industry protocols as the test standards for the required testing of hydroquinone and the proposed schedules for the required testing. The Agency received written comments from the Hydroquinone Panel (Ref. 2); however, a public meeting was not requested.

In keeping with the intent of this Phase II rule, which is to establish the test standards and the scheduling of those tests, the Agency is responding to those industry comments which are relevant to those issues. However, issues in the comments concerning the necessity for testing have been previously discussed in the proposed and final phase I rule and are therefore not discussed here. No comments relating to the test standards for the developmental toxicity and reproductive effects testing were received.

A. Toxicokinetics

The hydroquinone Phase I final rule required skin and oral dosing studies, which will provide data regarding both the rate and extent of absorption of hydroquinone through the skin. In the proposed Phase II test standards rule, the Agency proposed a specific test standard in § 798.7650 recodified as § 795.235 in this rule to be followed when conducting the required oral and dermal testing of hydroquinone in rats.

With regard to the dermal studies, the CMA Hydroquinone Panel has commented that EPA should require an *in vitro* study of the kinetics of hydroquinone penetration through rat skin in place of the proposed *in vivo* rat skin absorption study. They argue that data on dermal penetration in the rat can be obtained in a more reliable, rapid, and cost-effective manner by an

in vitro study and such a study would allow longer exposure periods and direct collection of quantitative data (Ref. 2).

Kodak supports their argument by citing a Kodak study of the percutaneous absorption of [U-^{14}C] hydroquinone in dogs (Refs. 2 and 6). Kodak argues that because the dog study showed very slow skin penetration (about 1.1 ug/cm^2/hr), similar tests in rats would not provide enough penetration to characterize metabolites and would provide only data on the skin penetration rate of hydroquinone through rat skin. The Panel adds that if their suggested *in vitro* study establishes a high rate (higher than the low rate expected by the Panel) they then can conduct an *in vivo* study.

The CMA Hydroquinone Panel requested a meeting with the Agency to discuss these issues, and the meeting was held on September 4, 1986 (Ref. 3). After reviewing (Refs. 4, 5, and 8) the arguments presented by the Hydroquinone Panel (Refs. 1, 6, and 7), the Agency rejects the modification to the test standard as proposed by the Panel. This decision is based on the following reasons: (1) The Agency believes that the dermal penetration study, "Percutaneous Absorption of Hydroquinone in Beagle Dogs," upon which the Panel has based its prediction of limited skin penetration in rats, has serious deficiencies. Deficiencies, such as the failure of the study to account for large amounts of the hydroquinone administered to the test animals, make it impossible for the Agency to reasonably predict the behavior of hydroquinone applied to other test animals such as rats or to the skin of humans exposed to hydroquinone. (2) While the Panel has suggested that they would perform an *in vivo* test if their suggested *in vitro* study shows a "high" skin penetration rate, they have not stated what level of absorption in the *in vitro* study or other factors would dictate that the *in vivo* study should also be conducted.

B. Neurotoxicity

With regard to the neurotoxicity testing required by the hydroquinone Phase I final test rule, the Agency proposed that the functional observational battery and neuropathology be conducted in accordance with 40 CFR 798.6050 and 798.6400, respectively.

In its comments, CMA's Hydroquinone Panel proposed that the functional-observational battery and the neuropathology examinations be conducted sequentially on the same group of rats. They comment that in conducting neurotoxicological evaluations, the best data would be expected from studies which integrate functional observations with microscopical observations. They add that a sequential study would also be the most cost-effective use of testing resources, would reduce the number of test animals, and would provide internal test controls. Critical analysis of any observed functional effects would be used to plan the pathologic examination.

The Panel suggested that the study be conducted by dosing the test animals at three levels and observing all the dosed animals as appropriate for the functional-observational battery. Neuropathology would then be conducted only on the high-dose group. No neuropathology would be conducted on animals receiving the lower doses, unless abnormal effects are observed during the study of the high-dose animals.

EPA believes that the functional-observational battery could indeed be carried out in conjunction with neuropathological assessment, and would spare committing additional animals to the toxicity evaluation. Neuropathological assessment should begin with the highest dose level and work downward until a no-observable-adverse-effects dose level is reached. According to the functional-observational battery testing guideline, the highest dose used should result in clear behavioral effects regardless of whether these are of a neural origin. Smaller doses are selected appropriately so as to provide information on the shape of the dose-response curve. The Agency agrees with the suggestion of a staged neuropathology examination, as described in the TSCA neuropathology test guidelines.

IV. Final Phase II Test Rule

A. Test Standards

The TSCA test guidelines for toxicokinetic studies in 40 CFR 795.235, the neurotoxicity testing in 40 CFR 798.6050 and 798.6400 and the industry-submitted protocols for developmental toxicity and reproductive effects testing shall be the test standards for the testing of hydroquinone required under 40 CFR 799.2200. The Agency believes that the conduct of the required studies in accordance with these test standards is necessary to assure that the results are reliable and adequate.

The revised guidelines for tests included in this Phase II rule, published in the **Federal Register** of May 20, 1987 (52 FR 19056), are adopted in the test standards for the testing of hydroquinone. EPA has responded to comments concerning these guideline revisions and that response to comment document is contained in the record for this rulemaking (Ref. 9).

B. Reporting Requirements

The Agency is requiring that all data developed under this rule be reported in accordance with the TSCA Good Laboratory Practice Standards (40 CFR Part 792).

Test sponsors are required to submit individual study plans at least 45 days prior to the initiation of each study in accordance with 40 CFR 790.50.

The Agency is required by TSCA section 4(b)(l)(C) to specify the time period during which persons subject to a test rule must submit test data. On the basis of its experience with health effects testing, EPA is adopting the proposed schedule for the submission of final test results as the final Phase II rule schedule.

The Agency has revised the reporting requirement for the submission of interim progress reports for testing under section 4 of TSCA. Accordingly, the Agency now requires only 6-month interim progress reports on all studies for hydroquinone, as opposed to the quarterly reporting schedule contained in the proposed test standard rule.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the **Federal Register** as required by section 4(d).

C. Conditional Exemptions Granted

The final rule for test rule development and exemption procedures (40 CFR Part 790) indicates that, when certain conditions are met, exemption applicants will be notified by certified mail or in the final Phase II test rule for a given substance that they have received conditional exemptions from test rule requirements. The exemptions granted are conditional because they will be given based on the assumption that the test sponsors will complete the required testing according to the test standards and reporting requirements established in the final Phase II test rule for the given substance. TSCA section 4(c)(4)(B) provides that if an exemption is granted prospectively (that is, on the basis that one or more persons are developing test data, rather than on the basis of prior test data subnmissions), the Agency must terminate the exemption if the test sponsor has not complied with the test rule.

Because sponsors have indicated to EPA by letter or intent (Ref. 1) their

agreement to sponsor all of the tests required for hydroquinone in the final Phase I test rule for this substance according to the test standards and reporting requirements established in this final Phase II test rule for hydroquinone, the Agency is hereby granting conditional exemptions to all exemption applicants for all of the testing required for hydroquinone in 40 CFR 799.2200.

D. Judicial Review

The promulgation date for the hydroquinone Phase I final rule was established as 1 p.m. eastern standard time on January 13, 1986 (50 FR 53145; December 30, 1985). EPA received no petitions for review of that Phase I final rule. Accordingly, any petition for judicial review of this Phase II final rule will be limited to a review of the test standards and reporting requirements for hydroquinone established in this rule.

E. Other Provisions

Section 4 findings, required testing, test substance specifications, persons required to test, enforcement provisions, and the economic analysis are presented in the final Phase I rule for hydroquinone (50 FR 53145).

V. Rulemaking Record

EPA has established a record for this rulemaking, [docket number (OPTS–42048D]. This record includes basic information considered by the Agency in developing this rule, and appropriate **Federal Register** notices.

This record includes the following information:

A. Supporting Documentation

The supporting documentation for this rulemaking consists of the proposed and final Phase I test rules on hydroquinone and the proposed hydroquinone test standards rule.

B. References

(1) Eastman Kodak Company. Protocols for a Voluntary Test Program on Hydroquinone. Submitted to Steven Newburg-Rinn, Chief, Test Rules Development Branch. (June 15, 1983).

(2) Chemical Manufacturers Association. Comments on Hydroquinone; Proposed Testing Standards 50 FR 53160; December 30, 1985. Submitted by the Hydroquinone Program Panel of the Chemical Manufacturers Association. (February 13, 1986).

(3) Meeting summary. CMA Hydroquinone Panel and EPA's Office of Toxic Substances. (September 4, 1986).

(4) Memorandum USEPA. Charles Abernathy Ph.D., Health and Environmental Review Division, to Gary E. Timm, Existing Chemicals Assessment Division. (June 20, 1986).

(5) Memorandum. USEPA. Charles Abernathy Ph.D., Health and Environmental Review Division, to David Price, Existing Chemicals Assessment Division. (November 17, 1986).

(6) Letter. Geraldine Cox, Chemical Manufacturers Association, to David Price, Existing Chemicals Assessment Division. In attachment, discussion of *in vitro* and *in vivo* testing for skin absorption. (October 2, 1986).

(7) Letter. Kathryn Rosica, Chemical Manufacturers Association, to Document Control Officer, USEPA. Suggested *in vitro* study protocol. (May 28, 1986).

(8) Document review. Review and evaluation of Eastman Kodak Study—"The Percutaneous Absorption of U-^{14}C Hydroquinone in Beagle Dogs" by Research Evaluation Associates. (January 6, 1986).

(9) USEPA. "Response to Public Comments, Proposed Revision of TSCA Test Guidelines as published in 51 FR 1522 (January 14, 1986)". Test Rules Development Branch, Existing Chemicals Assessment Division, Office of Toxic Substances, Environmental Protection Agency, Washington, DC (January 1987).

The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. G–004, Northeast Mall, 401 M Street SW., Washington, DC 20460.

VI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The economic analysis of the testing of hydroquinone is discussed in the Phase I test rule (50 FR 53145; December 30, 1985).

This final Phase II test rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. No comments were received.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, (15 U.S.C. 601 *et seq.*, Pub L. 96–354, September 19, 1980), EPA is certifying that this rule will not have a significant impact on a substantial number of small businesses for the following reasons:

(1) There are not a substantial number of small businesses manufacturing hydroquinone.

(2) Small processors are not expected to perform testing themselves, or to participate in the organization of the testing efforts.

(3) Small processors will experience only very minor costs if any in securing exemption from testing requirements.

(4) Small processors are unlikely to be affected by reimbursement requirements, and any testing costs passed on to small processors through price increases will be small.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070–0033. No public comments on these requirements were submitted to the Office of Information and Regulatory Affairs of OMB.

Lists of Subjects in 40 CFR Parts 795 and 799

Testing, Environmental protection, Hazardous substances, Chemicals, Recordkeeping and reporting requirements.

Dated: May 11, 1987.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, Chapter I of 40 CFR is amended as follows:

PART 795—[AMENDED]

1. In Part 795:

a. The authority citation for Part 795 continues to read as follows:

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

b. Section 795.235 is added, to read as follows:

§ 795.235 Toxicokinetic Test.

(a) *Purpose.* These studies are designed to: (1) Determine the bioavailability of the test substance after dermal or oral treatment.

(2) Ascertain whether the metabolites of the test substance are similar after dermal (assuming significant penetration) and oral administration.

(3) Examine the effects of a multiple dosing regimen on the metabolism of the test substance after *per os* administration.

(b) *Definition of scope of study.* Absorption toxicokinetics refers to the bioavailability, i.e., the rate and extent of absorption of the test substance, and metabolism and excretion rates of the test substance after absorption.

(c) *Test procedures*—(1) *Animal selection*—(i) *Species.* The rat is the animal species of choice since it has been used extensively for absorption, metabolism, and toxicological studies.

(ii) *Rat strain.* Adult male and female Fischer 344 rats shall be used. At 7 to 9 weeks of age, the males should weigh 125 to 175 g and the females 110 to 150 g.

The rats shall be purchased from a reputable dealer and identified with ear tags upon arrival. The animals shall be randomly selected for the testing groups, and no unhealthy animal is to be used for experimentation.

(iii) *Animal care.* (A) Animal care and housing should be in accordance with Department of Health, Education and Welfare Publication No. (NIH)–78–23, 1978. "Guidelines for the Care and Use of Laboratory Animals," or its equivalent.

(B) The animals shall be housed in environmentally controlled rooms with 10 to 15 air changes per hour. The rooms shall be maintained at a temperature of 25±2 °C and humidity of 50±10 percent with a 12-hour light/dark cycle per day. The rats shall be kept in a quarantine facility for at least 7 days prior to use.

(C) During the acclimatization period, the rats shall be housed in polycarbonate cages on hardwood chip bedding. All animals shall be provided with certified feed and tap water *ad libitum.*

(iv) *Number of animals.* There shall be at least four animals of each sex in each experimental group.

(2) *Administration of test substance*—(i) *Test substance.* Test substance of at least 99 percent purity, commercially available, should be used as the test substance. Since both nonradioactive and radioactive (uniformly ^{14}C-labelled) test substances are to be used, they should be chromatographed separately and analyzed together, to ascertain purity and identity. The use of ^{14}C-labelled test substance, diluted with unlabeled test substance, is required for all of the studies under this section, unless otherwise specified, as it will greatly increase the reliability and sensitivity of the quantitative assays and facilitate the identification of metabolites.

(ii) *Dosage and treatment.* (A) Two doses shall be used in studies under this section, a "low" dose and a "high" dose. When administered orally, the "high" dose level should ideally induce some overt toxicity, such as weight loss. The "low" dose level should not induce observable effects attributable to the test substance. If feasible, the same "high" and "low" doses should be administered orally and dermally.

(B) Oral dosing shall be accomplished by gavage after dissolving the test substance in a suitable vehicle. For dermal treatment, the doses shall be administered in a suitable solvent and applied at a volume adequate to deliver the prescribed doses. The backs of the rats should be shaved with an electric clipper one day before treatment. The dose should be applied with a disposable micropipette on a specific area (2 cm^2 for rats) on the shaven skin. The dosed areas shall be occluded with an aluminum foil patch which is secured in place with adhesive tape.

(iii) *Determination of test substance kinetics.* Each experimental group shall contain at least four rats of each sex for a total of eight rats.

(a) *Oral studies.* (*1*) Group A shall be dosed once *per os* with the low dose of the test substance.

(*2*) Group B shall be dosed once *per os* with the high dose of the test substance.

(*3*) For the oral studies, the rats shall be placed in individual metabolic cages to facilitate collection of urine and feces at 8, 24, 48, 72, and 96 hours following administration. The cages shall be cleaned at each time period to collect any metabolites that might adhere to the metabolic cages.

(B) *Dermal Studies.* (*1*) Group C shall be dosed once dermally with the low dose of test substance.

(*2*) Group D shall be dosed once dermally with the high dose of test substance.

(*3*)(*i*) For the dermal studies, the test substance shall be applied for 24 hours. Immediately after application, each animal shall be placed in a separate metabolic cage for excreta collection. At the time of removal of the aluminum foil, the occluded area shall be washed with an appropriate solvent (see below), to remove any test substance that may be on the skin surface and the wash solvent assayed for the amount of test substance recovered. At the termination of the experiments, each animal shall be sacrificed and the exposed skin area removed. The skin (or an appropriate section) shall be solubilized and assayed for the test substance and its metabolites.

(*ii*) Before initiation of the dermal studies, an initial washing efficiency experiment shall be conducted to assess the removal of the applied test substance by washing the exposed skin area with soap and water or organic solvents. Four rats, two of each sex, shall be lightly anesthetized and then test substance applied to a specified area. After application (5 to 10 minutes), the areas should be washed with soap and water (two rats) or ethanol and water (two rats). The amount recovered shall be determined to assess efficacy of test substance removal by washing of the skin.

(C) *Repeated dosing study group E.* Four rats (two of each sex) shall receive a series of single daily oral doses of nonradioactive test substance over a period of at least 14 days, followed at 24 hours after the last dose by a single oral dose of ^{14}C-labelled test substance. Each dose shall be at the low dose level.

(3) *Observation of animals*—(i) *Bioavailability*—(A) *Blood levels.* The levels of ^{14}C shall be determined in whole blood, blood plasma, or blood serum at appropriate intervals from 1 to 96 hours after dosing rats in Groups A through E. Four rats (two of each sex) of each group shall be used for this purpose.

(B) *Urinary and fecal excretion.* The quantities of ^{14}C excreted in the urine and feces by rats in groups A through E shall be determined at 8 hours, 24 hours, 48 hours, 72 hours, and 96 hours after dosing, and if necessary, daily thereafter until at least 90 percent of the applied dose has been excreted or until 7 days after dosing (whichever occurs first). Four animals (two of each sex) shall be used for these analyses.

(ii) *Biotransformation after oral and dermal dosing.* Appropriate qualitative and quantitative methods shall be used to assay the test substance and metabolites in the urine and fecal specimens collected from rat Groups A through D.

(iii) *Changes in Biotransformation.* Appropriate qualitative and quantitative assay methodology shall be used to compare the composition of ^{14}C-labelled compounds in excreta collected at 14 and 48 hours after dosing rat Group A with those in the excreta collected at 24 and 48 hours after the ^{14}C-labelled test substance dose in the repeated dose study (Group E).

(d) *Data and reporting*—(1) *Treatment of results.* Data should be summarized in tabular form.

(2) *Evaluation of results.* All observed results, quantitative or incidental, should be evaluated by an appropriate statistical method.

(3) *Test report.* In addition to the reporting requirements specified in the EPA Good Laboratory Practice Standards (40 CFR Part 792, Subpart J) the following specific information shall be reported:

(i) Specie(s) and strain(s) of laboratory animals.

(ii) Information on the degree (i.e., specific activity for a radiolabel) and site(s) of labeling of the test substance;

(iii) A full description of the sensitivity and precision of all procedures used to produce the data.

(iv) Percent absorption by oral and dermal routes of rats administered ^{14}C-test substance.

(v) Quantity of isotope, together with percent recovery of administered dose in feces, urine, blood, and skin and skin washings (dermal study only for last two portions).

(vi) Quantity and distribution of ^{14}C-labelled test substance in various tissues, including bone, brain, fat, gonads, heart, kidney, liver, lung, muscle, spleen, and residual carcass.

(vii) Counting efficacy data shall be made available to the Agency upon request.

PART 799—[AMENDED]

2. In Part 799:

a. The authority citation for Part 799 continues to read as follows:

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

b. By amending § 799.2200 by adding paragraphs (c)(1) (ii), (iii), (2) (ii), (iii), (3) (ii), (iii), (4) (ii), (iii), and (d) to read as follows:

§ 799.2200 Hydroquinone.

* * * * *

(c) * * *

(1) * * *

(ii) *Test standard.* The toxicokinetic testing shall be conducted in accordance with § 795.235 of this chapter.

(iii) *Reporting requirements.* (A) The toxicokinetic tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the Phase II final test rule.

(B) A progress report shall be provided 6 months from the effective date of the final Phase II rule.

(2) * * *

(ii) *Test standards.* The developmental toxicity testing shall be conducted according to the teratology study plans submitted to the EPA on June 15, 1983 (Eastman Kodak Company, 1983) and reviewed by the Agency as part of the study plan. Copies of the study plan are located in the public record for this test rule (Docket No. OPTS–42048D) and are available for inspection in the OPTS Reading Rm., G–004, Northeast Mall, 401 M. St., SW., Washington, DC 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

(iii) *Reporting requirements.* (A) The Developmental toxicity tests shall be completed and the final results submitted to the Agency within 18 months of the effective date of the final Phase II rule.

(B) Interim progress reports shall be provided at 6-month intervals beginning 6 months from the effective date of the final Phase II rule.

(3) * * *

(ii) *Test standard.* The reproductive effects testing shall be conducted according to the two generation reproduction unit of the study plan, submitted to the EPA on June 15, 1983 (Eastman Kodak Company, 1983) and reviewed by the Agency as a part of the study plan. A copy of this study plan is located in the public record for this test rule (docket no. OPTS–42048D) and is available for inspection in the OPTS Reading Rm., G–004, Northeast Mall, 401 M Street SW., Washington, DC 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

(iii) *Reporting requirements.* (A) The two-generation reproductive effects toxicity test shall be completed and final results submitted to the Agency within 29 months of the effective date of the final Phase II rule.

(B) Interim progress reports shall be provided at 6-month intervals beginning 6 months from the effective date of the final Phase II rule.

(4) * * *

(ii) *Test standards.* The neurotoxicity testing of hydroquinone, consisting of a functional observational battery and neuropathology shall be conducted in accordance with §§ 798.6050 and 798.6400, respectively, of this chapter. The functional-observational battery and the neuropathology assessment may be conducted sequentially on the same group of rats. Neuropathological assessment should begin with the highest dose level and work downward until a no-observable-adverse-effects dose is reached.

(iii) *Reporting requirements.* (A) The neurotoxicity tests shall be completed and final results submitted to the Agency within one year of the effective date of the final Phase II rule.

(B) Interim progress reports shall be provided 6 months from the effective date of the final Phase II rule.

(d) *Effective date.* The effective date of the final Phase II rule for hydroquinone is July 13, 1987.

[FR Doc. 87–12101 Filed 5–27–87; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF DEFENSE

48 CFR Parts 203 and 252

Federal Acquisition Regulation Supplement; Conflicts of Interest in Defense Procurement; Correction

AGENCY: Department of Defense (DoD).

ACTION: Interim rule; correction.

SUMMARY: This document corrects an interim rule issuing changes to the DoD Federal Acquisition Regulation Supplement with respect to Conflicts of Interest in Defense Procurement, published in the **Federal Register** on April 16, 1987 (52 FR 12383). This action is necessary to add coverage which was previously omitted.

FOR FURTHER INFORMATION CONTACT: Mr. Charles W. Lloyd, Executive Secretary, DAR Council, (202) 697–7266.

Charles W. Lloyd,

Executive Secretary, Defense Acquisition Regulatory Council.

Accordingly, the Department of Defense is correcting 48 CFR Parts 203 and 252 as follows:

PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

203.170–2 [Corrected]

Section 203.170–2 is corrected to add in the first sentence after the word "who" the words "left DoD service on or after April 16, 1987, and who".

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.203–7002 [Corrected]

Section 252.203–7002 is corrected to add in the first sentence of paragraph (b)(1) of the clause after the word "official" the words "who left DoD service on or after April 16, 1987, and"; and to add to paragraph (c)(1)(i) of the clause after the word "service" the words "(on or after April 16, 1987),".

[FR Doc. 87–12150 Filed 5–27–87; 8:45 am]

BILLING CODE 3810–01–M

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48 CFR Parts 204, 205, 219, and 252

Federal Acquisition Regulation Supplement; Set-Asides for Small Disadvantaged Business Concerns; Correction

AGENCY: Department of Defense (DoD)

ACTION: Interim rule; correction.

SUMMARY: This document corrects an interim rule issuing changes to the DoD FAR Supplement with respect to Set-Asides for Small Disadvantaged Business Concerns, which were published in the **Federal Register** on May 4, 1987 (52 FR 16263). This action is necessary to correct amendatory language and to make editorial corrections to the rule.

FOR FURTHER INFORMATION CONTACT: Mr. Charles W. Lloyd, Executive Secretary, ODASD(P)/DARS, c/o OUSD(A) Mail Room, Room 3D139, The Pentagon, Washington, DC 20301–3062.

Charles W. Lloyd,

Executive Secretary, Defense Acquisition Regulatory Council.

Accordingly, the Department of Defense is correcting 48 CFR Parts 204, 205, 219, and 252 as follows: