

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 63**

[AD-FRL-7933-2]

RIN 2060-AM72

National Emission Standards for Hazardous Air Pollutants: Miscellaneous Coating Manufacturing**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Withdrawal of direct final rule.

SUMMARY: On May 13, 2005, the EPA issued direct final amendments to the national emission standards for hazardous air pollutants (NESHAP) for Miscellaneous Coating Manufacturing. The amendments were issued as a direct final rule, along with a parallel proposal to be used as the basis for final action in the event EPA received any adverse comments on the direct final amendments. Because an adverse comment was received on one provision, EPA is withdrawing the corresponding parts of the direct final rule. We stated in that direct final rule that if we received adverse comment by June 13, 2005, we would publish a timely withdrawal in the **Federal Register**. We will address the adverse comment in a subsequent final action based on the parallel proposal published on May 13, 2005 (70 FR 25684). As stated in the parallel proposal, we will not institute a second comment period on this action.

DATES: As of July 6, 2005, EPA withdraws the direct final rule revision for 40 CFR 63.8055(b)(4), published on May 13, 2005 (70 FR 25676). The remaining provisions published on May 13, 2005, will be effective on July 12, 2005.

ADDRESSES: EPA has established a docket for this action under Docket ID No. OAR-2003-0178. All documents in the docket are listed in the index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at: Air and Radiation Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Mr. Randy McDonald, Organic Chemicals Group, Emission Standards Division (Mail Code C504-04), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5402, electronic mail address mcdonald.randy@epa.gov.

SUPPLEMENTARY INFORMATION: On May 13, 2005, we published a direct final rule (70 FR 25676) and a parallel proposal (70 FR 25684) amending the NESHAP for Miscellaneous Coating Manufacturing (40 CFR part 63, subpart HHHHH). The direct final rule amended the NESHAP by providing additional compliance options and clarifications. Specifically, the direct final rule amendments specified that compliance with a percent reduction emission limit may be demonstrated by measuring total organic compounds (TOC), compliance with the weight percent hazardous air pollutant (HAP) limit in coatings products may be demonstrated based on formulation data, and the cover or lid on a process vessel may be opened for material additions and sampling. The direct final rule amendments also clarified the requirements for cleaning operations, the compliance date for equipment that is added to an existing source, the conditions under which you must determine whether an emission stream is a halogenated vent stream, and the terminology used to describe the emission limits for process vessels. The direct final rule amendments also revised the definition of Group 2 transfer operations to clarify that all product loading operations are part of the miscellaneous coating manufacturing. We stated in the preamble to the direct final rule and parallel proposal that if we received adverse comments by June 13, 2005, (or if a public hearing was requested by May 23, 2005) on one or more distinct provisions of the direct final rule, we would publish a timely notice in the **Federal Register** specifying which provisions will become effective and which provisions will be withdrawn due to adverse comment. We subsequently received adverse comment from one commenter on the amendment to allow compliance with the weight percent HAP limit in coating products may be demonstrated based on formulation data. The commenter's claim is that if EPA does not allow the mass cutoffs of 0.1 percent for OSHA-defined carcinogens or 1 percent for other HAP used in Material Safety Data

Sheets (MSDS), then the option is very limited.

Accordingly, we are withdrawing the amendment, 40 CFR 63.8055(b)(4). The amendment is withdrawn as of July 6, 2005. We will take final action on the proposed rule after considering the comment received. We also received a comment regarding chemical processes involving reactions that produce materials that may have a coating-application end use. However, the commenter referred to preamble language merely clarifying existing rule language in overlapping standards, and not new language provided by the direct final rule. We have not changed any of the rule language discussed in the clarification of overlapping standards section of the preamble. Thus, this comment is not an adverse comment on the amendments themselves, but rather an adverse comment on the definition of coating manufacturing in the original rule.

We will not institute a second comment period on this action. The provisions for which we did not receive adverse comment will become effective on July 12, 2005, as provided in the preamble to the direct final rule.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 29, 2005.

Jeffrey R. Holmstead,
Assistant Administrator, Air and Radiation.
[FR Doc. 05-13275 Filed 7-5-05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-2002-0294; FRL-7720-9]

Alpha-cyclodextrin, Beta-cyclodextrin, and Gamma-cyclodextrin; Exemption from the Requirement of a Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance under 40 CFR 180.950 for residues of alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin when used in or on various food commodities. Wacker Specialties submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act

(FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin.

DATES: This regulation is effective July 6, 2005. Objections and requests for hearings must be received on or before September 6, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP-2002-0294. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Rame Cromwell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9068; e-mail address: cromwell.rame@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide

for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of November 14, 2002 (67 FR 220) (FRL-7279-3), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (2E6514) by Wacker Specialties, 3301 Sutton Road, Adrian, MI, 49221-9397. The petition requested that residues of a certain pesticide chemical in or on various food commodities be exempted from the requirement of a tolerance. This notice included a summary of the petition prepared by the petitioner Wacker Specialties. No comment was submitted.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical

residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risk from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of the pesticide chemical. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Inert ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Description of Alpha-cyclodextrin, Beta-cyclodextrin, and Gamma-cyclodextrin

Alpha-cyclodextrin is a non-reducing cyclic saccharide comprised of six glucose units linked by alpha-1,4 bonds. It is produced by the action of cyclodextrin glucosyltransferase (CGTase) on hydrolyzed starch syrups at neutral pH and moderate temperatures. Beta-cyclodextrin is a cyclic heptamer composed of seven glucose units joined "head-to-tail" by alpha-1,4 links. Gamma-cyclodextrin is a ring-shaped molecule made up of eight glucose units linked by alpha-1,4 bonds. Alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin are naturally occurring compounds derived from the degradation of starch by the glucosyltransferase enzyme (CGTase). They are formed naturally from bacteria and synthetically. The annular (or doughnut-shaped) structure provides a hydrophobic cavity that allows formulation of inclusion complexes with a variety of non-polar organic molecules of appropriate size. The hydrophobic nature of the outer surface of the cyclic structure makes the compounds water soluble. The hydrophobic cavity and the hydrophilic outer surface form the basis for its use in the food industry.

V. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The Joint Expert Food Committee Additives (JEFCA) is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). In the Food Additive Series 32, 42, and 48, JEFCA reviewed alpha-, beta-, and gamma-cyclodextrins and assigned an acceptable daily intake (ADI) of "not specified" to alpha-cyclodextrin. As to beta-cyclodextrin, a temporary ADI of 0–6 milligrams/kilogram (mg/kg) was allocated, based on a no adverse observed effect level (NAOEL) of 2.5% in the diet (equal to 1,230 mg/kg/bwt day) in the study of dogs using a safety factor of 200. As to gamma-cyclodextrin, there were sufficient data to allocate a

temporary ADI of "not specified." A "not specified" designation is used to refer to a food substance of very low toxicity, with, on the basis of the available data (chemical, biochemical, and other) and the total dietary intake of the substance, does not, in the opinion of the Committee, represent a hazard to health. These compounds are natural occurring cyclic non-reducing torus-shaped maltooligosaccharides. They originate from the decomposition of starch by a bacterial enzyme called cyclodextrin glucosyltransferase. Alpha-, beta-, and gamma-cyclodextrins are comprised of D-glucose molecules.

In its May 20, 2003, response to a Generally Recognized as Safe (GRAS) notification, the Food and Drug Administration (FDA) had no questions regarding a conclusion by qualified experts that alpha-, beta-, and gamma-cyclodextrins meet appropriate food grade specifications and if manufactured in accordance with good manufacturing practices are generally recognized as safe.

Alpha-cyclodextrin was examined by JEFCA for its ability to induce ocular irritation in albino rabbits in two separate studies. In the first study, a dose of 0.062 g instilled in the conjunctival cul-de-sac of the right eye of three rabbits was irritating but not corrosive. In the second study, two groups of three rabbits were given alpha-cyclodextrin as a 14.5% or a 50% dilution in demineralized water. No or minimal irritation was found in the eyes and there was no corrosion.

A sample of 0.5 of alpha-cyclodextrin moistened with tap water was applied to the shaven backs and flanks of three albino rabbits for 4 hours under a semi-occlusive dressing. No skin irritation was observed for up to 72 hours. Similarly, in guinea-pigs, a 10% or 30% solution of alpha-cyclodextrin induced no signs of sensitization in the dermally induced animals.

Short-term (28-day and 90-day) studies of toxicity indicated that alpha-cyclodextrin has little effect when given orally to rats and dogs. Alpha-cyclodextrin is not digested in the gastrointestinal tract but is fermented by the intestinal micro flora. Absorbed alpha-cyclodextrin is excreted rapidly in the urine.

Studies conducted with mice, rabbits, and rats with alpha-cyclodextrin at concentrations of up to 20% did not indicate teratogenic effects.

Beta-cyclodextrin of 0.5 g moistened with 0.5 ml saline was applied to shaved dorsal skin of 3 white rabbits under occlusion for 24 hours. The mean primary irritation score was 0.50 (minimally irritating), and there were no

eschar or oedema and the treatment sites were normal by 24 hours after removal of the pad containing the chemical. A primary dermal irritation study in albino rabbits used an abraded skin protocol, and the index of primary cutaneous irritation which was obtained (0.01) classified beta-cyclodextrin as non-irritant.

In an ocular irritancy/corrosion test in albino rabbits, beta-cyclodextrin was classified as slightly irritating.

Gamma-cyclodextrin was not irritating or corrosive to the eyes of albino rabbits. In a skin sensitization assay in guinea-pigs, a 30% solution induced no signs of sensitization.

Short term (28-day and 90-day) studies of toxicity indicate that gamma-cyclodextrin has little toxicity when given orally to rats or dogs. Studies conducted in rats and rabbits with gamma-cyclodextrin at doses up to 20% of the diet did not indicate any teratogenic effects. Similarly, the results of a battery of studies of genotoxicity were negative. Long-term studies of toxicity, carcinogenicity, and reproductive toxicity have not been conducted, but, given the rapid metabolism of this substance to glucose and its lack of genotoxicity, such studies were not required for an evaluation.

VI. Aggregate Exposure

1. *Food.* Alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin are naturally occurring and are used as food additives. The following was taken from the WHO INCHEM (Food Additives Series 32, 42, 48). Alpha-cyclodextrin is used as a carrier for flavors, colors, and sweeteners in foods such as dry mixes, baked goods, and instant teas and coffee, as a stabilizer for flavors, colors, vitamins, and polyunsaturated fatty acids in dry mixes and dietary supplements (< 1% of the final product), as a flavor modifier in soya milk (< 1%), and as an absorbent (breath freshener) in confectionery products (10–15% of the final product).

Beta-cyclodextrin may serve as a stabilizer of food flavors, food colors and some vitamins.

Gamma-cyclodextrin is used as a carrier for flavors, sweeteners, and colors, and it has been proposed for use in this manner in dry mixes for beverages, soups, dressings, gravies and fillings. It is also used in instant coffee, tea, chewing gum, crackers, and spices. It is also proposed for use as a carrier for vitamins and polyunsaturated fatty acids in dry food mixes and in dietary supplements.

2. *Drinking water exposure.* Alpha-, beta-, and gamma-cyclodextrins are highly soluble in water, non-volatile,

have a low air: water partition coefficient, and will not be mobile in soils and sediments. Cyclodextrins will rapidly biodegrade with primary degradation occurring in a matter of hours and ultimate degradation occurring in days. No significant exposure to alpha-, beta-, and gamma-cyclodextrins via drinking water is anticipated.

Due to the high molecular weight of the alpha-, beta-, and gamma-cyclodextrins, absorption through the skin is expected to be negligible. Therefore, no significant systemic exposure is anticipated for these chemicals from residential use as inert ingredients in pesticide products.

VII. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, the Agency consider "available information" concerning the cumulative effects of a particular chemical's residues and other substances that have a common mechanism of toxicity.

Unlike other pesticides chemicals for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to alpha-, beta-, and gamma-cyclodextrins and any other substances and they do not appear to produce a toxic metabolite produced by other substances. For the purpose of this tolerance action, therefore, EPA has not assumed that alpha-, beta-, and gamma-cyclodextrins have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determination and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

VIII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. The Agency believes that alpha-, beta-, and gamma-cyclodextrins

to be of low toxicity. EPA has not used a safety factor analysis to assess the risk, and therefore the additional tenfold safety factor is unnecessary.

IX. Determination of Safety for U.S. Population, Infants and Children

Based on the available information demonstrating that alpha-, beta-, and gamma-cyclodextrins are of low toxicity, EPA concludes there is a reasonable certainty no harm will result to the general population including infants and children from aggregate exposure to alpha-, beta-, and gamma-cyclodextrin residues when used as inert ingredients in pesticide products.

X. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . ." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing alpha-, beta- and gamma-cyclodextrins for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes because the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for alpha, beta, and gamma-cyclodextrins.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for alpha, beta, or gamma-cyclodextrins nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

E. Response to Comment

No comments were received regarding the Notice of filling (67 FR 220) (FRL-7279-3).

XI. Conclusions

Based on the available information on alpha-, beta-, and gamma-cyclodextrin, there is a low likelihood of concern for substantial exposures to non-target organisms from the use of these

chemicals as inert ingredients in pesticide products. EPA concludes that there is a reasonable certainty of no harm from aggregate exposure from residues of alpha-, beta-, and gamma-cyclodextrin. Accordingly, EPA finds that exempting alpha-, beta-, and gamma-cyclodextrins from the requirement of tolerance will be safe to the general population and infants and children.

XII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0294, in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 6, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the

information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2002-0294, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XIII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the

development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final

rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: June 27, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180 —[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.950 table in paragraph (e) is amended by adding alphabetically the following entries to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

Chemical Name	CAS No.
* * * *	*
Alpha - cyclodextrin	10016-20-3
* * * *	*
Beta - cyclodextrin	7585-39-9
* * * *	*
Gamma - cyclodextrin	17465-86-0
* * * *	*

[FR Doc. 05-13263 Filed 7-5-05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2005-0109; FRL-7721-1]

Dimethyl Ether; Exemption from the Requirement of a Tolerance; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of May 18, 2005, establishing a tolerance exemption for dimethyl ether (methane, oxybis-). This document is being issued to correct the CAS Reg. No. for dimethyl ether.

DATES: This final rule is effective on July 6, 2005.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of May 18, 2005.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under the **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET at <http://www.epa.gov/edocket/>, you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. What Does this Correction Do?

A tolerance exemption for dimethyl ether (methane, oxybis-) was established in the **Federal Register** of May 18, 2005, (70 FR 28436), (FRL-7711-4). In that document the CAS Reg. No. in the tolerance exemption expression was given as 115-10-06. It should be 115-10-6 as expressed in the preamble.

III. Why is this Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's technical correction final without prior proposal and opportunity for comment, because EPA is merely correcting a typographical error in a previously-published final rule in the Chemical Abstracts Service (CAS) numerical designation for a chemical. Notice and public procedures

are unnecessary for such a minor change. The initial notice for the final rule and the final rule clearly identified the chemical by name. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

This final rule implements a technical correction to the CFR., and it does not otherwise impose or amend any requirements. As such, the Office of Management and Budget (OMB) has determined that a technical correction is not a "significant regulatory action" subject to review by OMB under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Nor does this final rule contain any information collection requirements subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

Since the Agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the APA or any other statute (see Unit III.), this action is not subject to provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

This action will not result in environmental justice related issues and does not, therefore, require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since this action is not a "significant regulatory action" as defined by Executive Order 12866; it does not require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), and is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).