

(c) \* \* \*

(7) Commercial and industrial solid waste incineration units.

■ 3. Subpart T is amended by adding a new undesignated center heading and a new §§ 62.4670 and 62.4671 to read as follows: Existing Commercial and Industrial Solid Waste Incineration Units

#### § 62.4670 Identification of sources.

The plan applies to the following existing commercial and industrial solid waste incineration units:

- (a) BASF Corporation, Geismar, Louisiana.
- (b) DSM Copolymer, Baton Rouge, Louisiana.
- (c) LA Skid & Pallet Co., Baton Rouge, Louisiana.
- (d) Shell Chemicals, Norco, Louisiana.

#### § 62.4671 Effective date.

The effective date of this portion of the State's plan applicable to existing commercial and industrial solid waste incineration units is May 3, 2004.

[FR Doc. 04-4622 Filed 3-2-04; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2003-0403; FRL-7343-9]

#### Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*; 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 for residues of the biochemical pesticide Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* on all food commodities when applied/used for the management of plant diseases. Morse Enterprises, Limited, Inc. 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 Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*.

**DATES:** This regulation is effective March 3, 2004. Objections and requests for hearings, identified by docket ID number OPP-2003-0403, must be received on or before May 3, 2004.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Diana M. Horne, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8367; e-mail address: [horne.diana@epa.gov](mailto:horne.diana@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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0403. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* 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 [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=694b82a50366afdfc121f3c76cc00405&c=ecfr&tpl=/ecfrbrowse/Title40/40cfrv21\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=694b82a50366afdfc121f3c76cc00405&c=ecfr&tpl=/ecfrbrowse/Title40/40cfrv21_02.tpl), a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

##### II. Background and Statutory Findings

In the **Federal Register** of August 6, 2003 (68 FR 46613) (FRL-7316-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (2E6383) by Morse Enterprises, Limited, Inc., Brickell East Floor Ten, 151 South East 15 Road, Miami, Florida. This notice included a summary of the petition prepared by the petitioner Morse Enterprises. One commenter requested information on the identity and mechanism of action of the active ingredient, which is provided and/or addressed in this rule.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*.

##### III. Risk Assessment

New 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) of the FFDCA 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. Section of the FFDC (b)(2)(C) 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....” Additionally, section 408(b)(2)(D) of the FFDC requires that the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. 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.

#### IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDC, 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.

An acute oral study was conducted with the end use product KeyPlex 350 at the limit value of 5 g/kg, a single high dose required by the Agency’s testing guidelines to determine whether any adverse effects are noted at this extremely elevated exposure level. No deaths or adverse effects occurred during this test, placing this product in Toxicity Category IV (the least toxic) via the oral route of exposure. A primary dermal irritation study has shown KeyPlex 350 to be very slightly irritating to non-irritating, placing the product in Toxicity Category IV (again, the least toxic) for skin irritation. An eye irritation study indicated that the product is slightly irritating to rabbit eyes, placing the product in Toxicity Category III for primary eye irritation. There have been no reported incidents of hypersensitivity to Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* in individuals exposed during the manufacture or use of this

product, which has been used as a plant micronutrient product for over 20 years. Nevertheless, to comply with the Agency’s requirements under FIFRA section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

All other acute and subchronic toxicity studies were waived based upon all or some combination of the following rationales: First, no effects were observed in an acute oral study on the end use product, KeyPlex 350 containing 0.063% Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*, at the limit value of 5 g/kg. Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* is made from Brewer’s (Baker’s) yeast extract, which is the water soluble portion of autolyzed yeast (*Saccharomyces cerevisiae*), and contains protein, peptides, free amino acids, vitamins, minerals and trace elements. Brewer’s yeast extract is already widely used as a flavor enhancer for soups, soy sauce, sausage, fruits, etc., and is also used as a nutritional supplement, since it is rich in B-vitamins. Brewer’s yeast extracts are used in hundreds of food products at levels up to 2.0%, as consumed, which is approximately 32 times higher than levels of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* found in the end use product (0.063%). Third, Brewer’s yeast extract is affirmed as “generally recognized as safe”, or GRAS (21 CFR 184.1983), which means that it may be applied to food as a direct additive. Fourth, all inerts used in the end use product KeyPlex 350 are either already exempted from the requirement of a tolerance under 40 CFR 180.1001 (c) or (d), or common fertilizer ingredients cleared by FDA as direct food additives (GRAS). Fifth, KeyPlex 350 containing 0.063% Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* has been sold as a plant micronutrient product for over 20 years, with no adverse effects ever reported. Sixth, label directions allow a minuscule amount (a maximum of 7.1 milliliters) of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* to be applied per acre per year, and the literature indicates that the components of yeast hydrolysate degrade rapidly in the environment. Finally, Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* has a non-toxic mode of action by eliciting a systemic acquired resistance response in plants, and has no direct antimicrobial effect on plant disease organisms.

#### V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDC directs EPA

to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

#### A. Dietary Exposure

Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* is already cleared for use in food products at concentrations greater than that found in the end use product KeyPlex 350. Additional dietary exposure to Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* resulting from labeled uses is unlikely to occur because of extremely low use rates and rapid degradation in the field. Further, the lack of demonstrable toxicity in acute studies and the long history of safe use as a component of food products support the establishment of an exemption from the requirement of a tolerance for Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*.

1. *Food.* The use of KeyPlex 350 is not expected to result in any increase in dietary exposure to Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* against the background of Brewer’s yeast extract normally consumed in the diet. Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* is made by hydrolyzing Brewer’s yeast extract, which is the water soluble portion of autolyzed yeast (*Saccharomyces cerevisiae*) and contains protein, peptides, free amino acids, vitamins, minerals and trace elements. Brewer’s yeast extract is classified as Generally Recognized as Safe (GRAS) under 21 CFR 184.1983 and is used as a flavor enhancer for soups, soy sauce, sausage, fruits, and other food products at concentrations in the range of 0.1%–2.0%, as consumed, which is significantly higher than the levels found in the end use product KeyPlex 350 (0.063%). Brewer’s yeast is also used as a human nutritional supplement since it is rich in B-vitamins. Further, all inerts in the formulation of KeyPlex 350 are either already exempted from the requirement of a tolerance under 40 CFR 180.1001 (c) or (d), or common fertilizer ingredients cleared by FDA as direct food additives (GRAS). Finally, when used according to label directions, an extremely small amount (a total of 7.1 milliliters) of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* may be applied per acre per year, and the literature indicates that the components

of yeast hydrolysate are rapidly degraded in the environment.

2. *Drinking water exposure.* Brewer's yeast extract, the starting material for the manufacture of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*, is classified as GRAS under 21 CFR 184.1983. Further, the other ingredients used in the production of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* are either already exempted from the requirement of a tolerance under 40 CFR 180.1001 (c) or (d), or common fertilizer ingredients cleared by FDA as direct food additives (GRAS). The concentration of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* allowable in food products is significantly higher than that found in the end use product KeyPlex 350. Finally, because KeyPlex 350 is applied at extremely low rates and rapidly degrades in the environment, it poses no concern as a drinking water contaminant.

#### B. Other Non-Occupational Exposure

With the sole exception of turf uses, the label use sites are commercial agricultural and horticultural, as opposed to domestic settings. In addition, KeyPlex 350 is applied at extremely low rates and rapidly degrades after application. As a result, the approved uses of KeyPlex 350 for field crops and commercial application to turf and ornamentals will not likely result in exposures in residences, schools or day care institutions to Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*. Thus non-occupational exposure to the general population is expected to be minimal to non-existent.

1. *Dermal exposure.* KeyPlex 350 is classified as a Toxicity Category IV product, the least toxic category, with regard to dermal irritation. This combined with the lack of toxicity via the oral route, suggests that risks due to dermal exposure are of no concern.

2. *Inhalation exposure.* KeyPlex 350 is classified as a Toxicity Category IV product, the least toxic category, via the oral route, and will not likely pose any risk via inhalation.

#### VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* and to other substances that have a common mode of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Because of the lack of toxicity, lack of information indicating that any toxic

effects, if they existed, would be cumulative with any other compounds, extremely low use rates, and common occurrence in hundreds of food products, the Agency does not expect any cumulative or incremental effects from exposure to residues of this product when used as directed on the label.

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

Key Plex 350 has an oral LD<sub>50</sub> greater than 5 g/kg, placing the product in Toxicity Category IV, the least toxic category. Further, Brewer's yeast extract, from which Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* is derived, is a common component of hundreds of food products and is used as a human nutritional supplement because of its high B-vitamin content. Therefore, EPA concludes that there is a reasonable certainty that no harm to the United States population in general, and to infants and children, specifically, will result from aggregate exposure to residues of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. Accordingly, exempting Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* from the requirement of a tolerance is considered safe and pose no risk. FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. Here, based on all the available information and for all the reasons already set forth above in this final rule, the Agency finds that there are no threshold effects of concern to infants, children, and adults when Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* is used as labeled, and that the provision requiring an additional margin of safety is not necessary to protect infants and children. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*.

#### VIII. Other Considerations

##### A. Endocrine Disruptors

EPA is required under the FFDCA as amended by FQPA to develop a

screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on available data, no endocrine system-related effects have been identified with consumption of Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*. To date, there is no evidence to suggest that Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

##### B. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons enumerated in this preamble, including Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*'s lack of toxicity. Accordingly, the Agency has concluded that an analytical method is not needed for enforcement purposes for Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* residues.

##### C. Codex Maximum Residue Level

There is currently no CODEX Maximum Residue Limit set for food use of this active ingredient.

## IX. Objections and Hearing Requests

Under section 408(g) of the FFDCFA, 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 FFDCFA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCFA 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) of the FFDCFA, as was provided in the old sections 408 and 409 of the FFDCFA. 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-2003-0403 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 May 3, 2004.

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 (1900C), 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 Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0403, 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 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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).

## X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCFA 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 section 408(d) of the FFDCFA, 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 foodretailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCFA. 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.

#### XI. 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 recordkeeping requirements.

Dated: February 18, 2004.

**James Jones,**

*Director, Office of Pesticide Programs.*

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

#### PART 180—[AMENDED]

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

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

■ 2. Section 180.1246 is added to subpart D to read as follows:

#### **§ 180.1246 Yeast Extract Hydrolysate from *Saccharomyces cerevisiae*: exemption from the requirement of a tolerance.**

This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* on all food commodities when applied/used for the management of plant diseases.

[FR Doc. 04-4706 Filed 3-2-04; 8:45am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2004-0003; FRL-7344-1]

#### Gellan Gum; 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 for residues of gellan gum when used as an inert ingredient in a pesticide product. CP Kelco submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCFA), 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 gellan gum.

**DATES:** This regulation is effective March 3, 2004. Objections and requests for hearings, identified by docket ID number OPP-2004-0003, must be received on or before May 3, 2004.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit X. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0371; e-mail address: [parker.james@epa.gov](mailto:parker.james@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