''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.

IX. 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: June 21, 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.

§ 180.532 [Amended]

■ 2. In § 180.532, in the table to paragraph (a)(2), amend the entries for ''Onion, dry bulb''; ''Onion, green''; and ''Strawberry'' by revising the expiration date ''12/31/04'' to read ''12/31/07.''

[FR Doc. 05–12921 Filed 6–29–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0153; FRL–7717–1]

Ethyl Maltol; 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 2-ethyl-3-hydroxy- 4H-pyran-4-one, also known as ethyl maltol when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Firmenich Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethyl maltol.

DATES: This regulation is effective June 30, 2005. Objections and requests for hearings must be received on or before August 29, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0153. 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: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; e-mail address: *campbell.princess@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 December 20, 2000 (65 FR 79834) (FRL–6751–9), 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 (PP 6E4758) by Firmenich Incorporated, P.O. 5880, Princeton, NJ 08543. The petition requested that 40 CFR 180.1001(c) and (e), re-designated as 40 CFR 180.910 and 40 CFR 180.930, respectively (69 FR 23113, April 28, 2004 (FRL–7335–4)), be

amended by establishing an exemption from the requirement of a tolerance for residues of ethyl maltol (CAS Reg. No. 4940–11–8) when used as an inert ingredient. This notice included a summary of the petition prepared by the petitioner, Firmenich Incorporated. There were no comments received in response to the notice of filing.

In later correspondence with the Agency, the petitioner, Firmenich Incorporated, offered to accept a limitation for ethyl maltol of not more than 0.2% of the formulated product. The tolerance exemption established today includes that limitation.

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 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.

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. 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 nature of the toxic effects caused by ethyl maltol are discussed in this unit.

A. Toxicity Data

The following table summarizes the toxicological aspects of ethyl maltol. Even though the studies which yielded the data were not conducted in accordance with the Agency guidelines, and lacked some experimental details, the studies appear to be well conducted. Thus, the results of these studies can be used for regulatory purposes. In addition to using the toxicity data, the Agency also conducted a Structure Activity Relationship (SAR) analysis for ethyl maltol. This analysis supports the conclusions suggested by the toxicity data, namely, that ethyl maltol poses a low concern for adverse effects on human health.

TOXICITY DATA FOR ETHYL MALTOL

Study	Result
Acute oral toxicity mice (male) Dose= 5%	Lethal Dose (LD) $_{50}$ = 780 milligram/kilogram/day (mg/kg/day)
Acute oral toxicity rats (male) Dose = 10%	LD $_{50}$ = 1,150 mg/kg/day
Acute oral toxicity rats (female) Dose = 10%	LD $_{50}$ = 1,200 mg/kg/day
90–Day subchronic oral toxicity (rats) Dose = 0, 250, 500, or 1,000 mg/kg/day	NOAEL = 250 mg/kg/day LOAEL = 500 mg/kg/day

TOXICITY DATA FOR ETHYL MALTOL—Continued

Study	Result
90–Day subchronic oral toxicity (dogs) Dose = 0, 125, 250, or 500 mg/kg/day	NOAEL ≥ 500 mg/kg/day (highest dose tested (HDT)) LOAEL = not observed but would be > 500 mg/kg/day
2–year chronic oral toxicity (rats) Dose= 0, 50, 100, or 200 mg/kg/day	NOAEL ≥ 200 mg/kg/day LOAEL = not observed but would be > 200 mg/kg/day
2–year chronic toxicity (dogs) Dose= 0, 50, 100, or 200 mg/kg/day	NOAEL ≥ 200 mg/kg/day LOAEL = not observed but would be > 200 mg/kg/day
Reproduction and fertility effects	Parental/Systemic NOAEL ≥ 200 mg/kg/day Parental/Systemic LOAEL = not observed but would be > 200 mg/kg/day No significant treatment related effects on fertility, gestation, parturition, lactation, or fetal development.
Carcinogenicity rats	no evidence of carcinogenicity
Carcinogenicity mice	no evidence of carcinogenicity
Gene Mutation - Ames (5 strains of *S. typhimurium*)	non-mutagenic
Gene Mutation-Drosophila	no increase in sex linked recessive lethal mutations
Gene Mutation-mouse micronucleus	no increase in polynucleated cells
Metabolism and pharmacokinetics	64% of the 10 mg/kg total dose excreted within 24 hours

B. Structure Activity Relationship

Toxicity for ethyl maltol was assessed, in part, by a process called SAR. In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess

absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high.

Ethyl maltol is not absorbed from the skin if it is not in solution, and moderately absorbed from the skin if it is in solution based on physio-chemical properties (pchem). It is absorbed from the lung and GI tract based on data from surrogate chemicals. There is an uncertain concern for mutagenicity. Overall, health concern is rated as low.

C. Regulatory Characterizations of Toxicity by Other Governmental Organizations

The Food and Drug Administration has classified ethyl maltol as GRAS (generally recognized as safe) for use as a direct food additive as a flavoring agent (21 CFR 172.515-Synthetic Flavoring Substances and Adjuvants). In 1970, the Joint Food and Agricultural Organization of the United Nations/World Health Organization (FAO/WHO) Expert Committee on Food Additives established a group ADI (Acceptable Daily Intake) of 0-2mg/kg-bodyweight (bw) for ethyl maltol (*http://www.inchem.org/documents/jecfa/jecmono/v048aje01.htm*)

D. Conclusions

Ethyl maltol is a member of a class of chemicals known as flavor enhancers. It is almost completely absorbed from the gut and appears in the urine as gluconamide or sulfate within two hours. The toxicity data in the previous Table was used to assess the toxicity of ethyl maltol. The acute oral LD_{50} values which ranged from 780 mg/kg and 1,270 mg/kg place ethyl maltol in Toxicity Category III. EPA categorizes acute toxicity as I, II, III, or IV, with Category IV being the Agency's lowest level of acute toxicity. Also, there were no effects observed on the skin of rabbits when ethyl maltol was used at a dose of 5,000 mg/kg.

The report from the structure activity team (SAT) cites an uncertain concern for mutagenicity. This uncertainty was based on positive dose-related activity against only one *Salmonella* strain (TA 100), but the mutagenic effects were not reproducible. Given the lack of reproducibility, ethyl maltol was classified as non-mutagenic in the Ames test.

The SAR assessment did not indicate any concerns for carcinogenicity, developmental or reproductive concerns. The available repeated dose toxicity studies have NOAELs that are equal to or greater than 200 mg/kg/day.

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 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

1. *Food*. Ethyl maltol has been used in foodstuffs as a flavoring agent since the 1950's. Ethyl maltol is estimated to have a per capita daily intake of 0.0045 mg/kg from use as a food additive (*http://www.inchem.org/documents/jecfa/jecmono/v048aje01.htm*). Using a 60 kg person the daily intake becomes 0.27 mg/day, based on ethyl maltol's use as a food additive. The use of ethyl maltol as an inert ingredient in a pesticide product, especially considering the limitation of no more than 0.2% of the formulated product, should not significantly increase this estimate.

2. *Drinking water exposure*. The SAT report states that migration of ethyl maltol to ground water is moderate to rapid. Ethyl maltol has an estimated water solubility of 1.5 to 24 grams/Liter (g/L), a volatilization half-life of 81 hours in rivers and 41 days in lakes, and biodegrades rapidly. Based on biodegradation models and on the SAT's professional judgement, ethyl maltol undergoes primary (partial) aerobic biodegradation in days to weeks, and is completely biodegraded in weeks. The biodegradability estimate and Henry's Law Constant suggest that the residence time of ethyl maltol in surface waters is controlled by the biodegradation rate and not the rate of volatilization. Ethyl maltol has the potential to be mobile in soil, but if released to aerobic soils its migration would be mitigated by biodegradation. If it enters anaerobic soils (as in a landfill leachate scenario) biodegradation would be expected to be somewhat slower but still relatively rapid. Therefore, significant concentrations of ethyl maltol are very unlikely in sources of drinking water.

B. Other Non-Occupational Exposure

Ethyl maltol is used as a flavor enhancer for cigarettes, antiseptics, and perfumes. Because use as a flavoring substance generally constitutes such a low percentage of the formulation exposure is likely to be minimal.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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.''

Unlike other pesticides 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 the above chemical substances and any other substances. Ethyl maltol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that this chemical substance has 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 determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VII. 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 unless EPA concludes that a different margin of safety will be safe for infants and children. For ethyl maltol, based on the expected minimal oral toxicity, as demonstrated by toxicity studies with NOAELs greater than 200 mg/kg/day, the available toxicity data which indicates no significant treatment related effects on fertility, gestation, parturition, lactation, or fetal development, EPA has not used a safety factor analysis to assess the risk. For the same reasons a tenfold safety factor is unnecessary.

VIII. Determination of Safety for U.S. Population

Based on its review and evaluation of the available data on toxicity and exposure, and considering the 0.2% limitation in the formulation offered by the petitioner, EPA finds that exempting ethyl maltol (CAS Reg. No. 4940–11–8)

from the requirement of a tolerance will be safe for the general population including infants and children.

IX. 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 ethyl maltol for endocrine effects may be required.

B. Analytical Method

An analytical method is not required for tolerance enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance.

C. Existing Tolerances

There are no existing tolerance exemptions for ethyl maltol.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for ethyl maltol nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Therefore, EPA is establishing a tolerance exemption for ethyl maltol (CAS Reg. No. 4940–11–8) with a limitation in the pesticide formulation of not more than 0.2%.

XI. 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–2005–0153 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 August 29, 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 XI.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–2005–0153, 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).

XII. 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.

XIII. 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: June 20, 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. In § 180.910 the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemption from the requirement of a tolerance.

* * *

Inert ingredients	Limits	Uses
* * * *	*	* *
Ethyl maltol (CAS Reg. No.4940–11–8)	Not more than 0.2 % of the pesticide formulation	Odor masking agent
* * * *	*	* *

* * * * *

■ 3. In § 180.930 the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.930 Inert ingredients applied to animals; exemption from the requirement of a tolerance.

* * *

Inert ingredients	Limits	Uses
* * * *	*	* *
Ethyl maltol (CAS Reg. No.4940–11–8)	Not more than 0.2 % of the pesticide formulation	Odor masking agent
* * * *	*	* *

* * * * *

[FR Doc. 05–12920 Filed 6–29–05; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0143; FRL–7722–3]

Extension of Tolerances for Emergency Exemptions (Multiple Chemicals)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in Unit II. of the **SUPPLEMENTARY INFORMATION**. These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish