and pests, Reporting and recordkeeping requirements.

Dated:_____

_____

Director, 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 180.601 is added to read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on the following commodities:

Commodity	Parts per million
Cucurbit vegetables (Group 9)	0.10
Grape, wine,* import	1.5
Potato	0.02
Tomato	0.20

*No domestic registrations.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 04–21931 Filed 9–29–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0298; FRL–7678–7]

Octanal; 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 octanal on growing crops or raw agricultural commodities (RAC) when used as an inert ingredient in pesticide formulations applied to growing crops, RAC after harvest, or to animals. Firmenich 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 octanal.

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

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–2004–0298. 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., Confidential Business Information (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 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 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 (6E4757) by Firmenich, P.O. 5880, Princeton, NJ 08543.

Firmenich requested that octanal, also known as caprylic aldehyde, or 1-octanal, be approved for use as an inert ingredient in pesticide formulations applied to growing crops, RACs after harvest, or to animals at an amount that was not to exceed 0.2% of the formulated product. This notice included a summary of the petition prepared by the petitioner Firmenich.

The petition requested that 40 CFR 180.1001, (c) and (e), newly re-designated as § 180.910 and § 180.930 April 28, 2004 (69 FR 23113) (FRL–7335–4), be amended by establishing an exemption from the requirement of a tolerance for residues of octanal, (CAS Registration No. 124–13–0). There were no comments received in response to the notice of filing.

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. 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 octanal are discussed in this unit.

A. Toxicity data

Table 1 below summarizes the toxicological aspects of octanal (C_8 aldehyde), and its surrogates, heptanal (C_7 aldehyde) and nonanal (C_9 aldehyde). All three chemicals belong to a group of short-chained linear (unbranched) aliphatic acyclic aldehydes. Based on their structural similarities, and the fact that studies indicate that these aldehydes are biochemically similar, toxicity data can be used almost interchangeably as surrogate data for these three substances. These aliphatic aldehydes are oxidized in the body to form the corresponding fatty acids. Thus, the corresponding fatty acids, octanoic and nonanoic acid, which are essentially metabolites of the original aldehyde can also be used as surrogate data. The Agency used the surrogate data from heptanal, nonanal, octanoic acid, and nonanoic acid as discussed in table 1 below, to supplement the available information on octanal.

TABLE 1.—COMPARATIVE TOXICITY DATA FOR OCTANAL, HEPTANAL, AND NONANAL

Study Type	Octanal	Heptanal	Nonanal
Acute oral toxicity - rat	LD_{50} = 5.63 mL/kg *LD_{50} = 4,616 mg/kg	*LD_{50} > 5,000 mg/kg	LD_{50} > 5,000 mg/kg
Acute dermal toxicity - rabbit	*LD_{50} = 5,207 mg/kg	*LD_{50} > 5,000 mg/kg	*LD_{50} > 5,000 mg/kg
Acute eye irritation - rabbit	0.01 mL is irritating, 0.5 mL severe burn	NA	NA
Acute dermal irritation - rabbit	At 0.5 mL moderate dermal reaction (irritant)	NA	NA
Acute dermal irritation - human	Non-irritant at 500 mmol, irritant at 1,000 and 2,000 mmol	NA	NA
14 day dermal (5 days per week for two weeks with a two week recovery period)	NA	In this single dose study, at 500 mg/kg/day there was local dermal irritation that healed after a 2 week recovery period *The NOAEL would be less than 500 mg/kg/day	Rabbit/New Zealand White M/F NOAEL < 500 mg/kg/day (nonanoic acid surrogate data) i.e., 28 day dermal toxicity assay
Acute inhalation toxicity	NA	*LC_{50} = 4.7 mg/L	LC_{50} between 0.46 - 3.8 mg/L Rats/Sprague - Dawley M/F (Data from nonanoic acid)
Gene mutation-Ames test-with and without S-9 activation, strains used TA98, TA100, TA1535, and TA 1537	*There was no increase in the frequency of reverse mutations with or without S9 activation	Included strain TA97 *Negative results in all strains with and without S9 activation	Activation at 3 units = mmol/plate *(486 g/plate) non-mutagenic

TABLE 1.—COMPARATIVE TOXICITY DATA FOR OCTANAL, HEPTANAL, AND NONANAL—Continued

Study Type	Octanal	Heptanal	Nonanal
Developmental toxicity - rat dose levels of 0, 1,125 or 1,500 mg/kg/day	Maternal NOAEL undetermined but likely to be less than 1,125 mg/kg/day LOAEL= 1,125 mg/kg/day based on decreased body weight in dams Developmental NOAEL = 1,125 mg/kg/day LOAEL = 1,500 mg/kg/day based on significant decrease in the number of live pups. (Data from octanoic acid)	NA	NA
Embryo-fetotoxicity	NA	NA	Rat/Sprague-Dawley M/F NOAEL (maternity toxicity 1,500) mg/kg/day (nonanoic acid)
Reproduction (1-generation) - rat	This single-dose study was used as a range finding study to design another study. 2,050 mg/kg/day *No evidence of reproductive toxicity although only a limited number of parameters measured (octanoic acid)	NA	NA
Mammaliam mutation assay - mouse lymphoma forward mutation assay		*Did not result in any evidence of mutagenicity	L5178Y mouse lymphoma cell with metabolic activation Aroclor 1,245 from Fisher N334 male rats. Conc. Up to 25 nl/ml without activation non-mutagenic. 60 to 120 nl/ml with activation weak mutagenic
Teratogenesis			Low to moderate hazard (surrogate data for octanal and nonanal from nonanoic acid)

*Source of Data is a submission by the Flavor Extract Manufacturers Association (FEMA), Washington, DC, under EPA's High Production Volume (HPV) Challenger Program (*http://www.epa.gov/chemrtk/opptsrch.htm*)

B. Structure Activity Relationship

Toxicity for octanal was assessed, in part, by a process called structure-activity relationship (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.

Octanal is absorbed via all routes. It is expected that oxidation of the aldehyde group to a carboxylic acid group would occur. There is concern for irritation to all tissues, especially at a high percentage in a product. There is uncertain concern for dermal sensitization based on analogs, and developmental toxicity based on aldehydes.

C. Conclusions

Octanal is a member of a class of chemicals (aldehydes) which are metabolized in the body to the corresponding fatty acids. The mammalian body has a demonstrated pathway to process octanal. Octanal is metabolized to octanoic acid.

There are developmental studies on octanoic acid performed as part of two investigations on the developmental effects of valproic acid. Unlike octanoic acid which is an eight carbon chain linear (unbranched) aliphatic acid that exhibits low toxicity, valproic acid is an eight carbon (branched chain) aliphatic acid. Valproic acid is teratogenic in humans and rodents. Based on results of these investigations, however, octanoic acid was not even included in the list of chemicals that were considered to have caused developmental effects.

The toxicity data from octanoic acid, was used to assess the toxicity of octanal. Even though as a group the staliphatic aldehydes and acids, which include octanoic acid and octanal, can exhibit developmental toxicity, the toxicity data for octanoic acid indicate that developmental effects were seen only at very high doses (1,125 milligrams/kiligram/day (mg/kg/day)). Also there was no evidence of reproductive toxicity for octanoic acid, even at very high doses (2,050 mg/kg/day).

The petitioner has accepted the Agency's limitation of 0.2% octanal in the formulated pesticide product. At this low percentage in the formulated products the residues from the use of

octanal as an inert ingredient will be much lower than the amounts which can possibly cause developmental or reproductive toxicity.

The SAR also indicated concerns for dermal sensitization, and irritation to mucous membranes. These concerns can be appropriately addressed through labeling and the use of protective equipment.

IV. 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

Octanal has been used in foodstuffs as a flavoring agent since the 1900's. The FDA has approved octanal for use as a direct food additive as a flavoring agent (21 CFR 172.515-Synthetic flavoring substances and adjuvants) and it is sponsored by EPA and the Flavor and Fragrance High Production Volume Consortia as a high production volume chemical. The Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Expert Committee on Food Additives concluded that linear aliphatic alcohols, aldehydes, and acids, which include octanal and octanoic acid, are ubiquitous in nature. In fact, low molecular weight alcohols and acids such as octanal and octanoic acid have been detected in almost every known fruit and vegetable. Given the natural occurrence, there is a background (naturally occurring) level of exposure to octanal that cannot be regulated, and cannot be decreased.

At its twenty-eighth meeting (1984), the Expert Committee established a group ADI (Acceptable Daily Intake) of 0–0.1 mg/kg bwt for octanal and nonanal singly or in combination. The Agency interprets this as an ADI of 0–0.1 mg/kg bwt for octanal alone. The use of octanal and octanoic acid was re-evaluated by the Expert Committee in 1998 (http://www.inchem.org/documents/jecfa/jecmono/v040je10.htm) as part of a group of flavoring agents. Using 1987 production volumes and other available information, JECFA estimated the exposure to octanal from use as a flavoring agent to be 0.0015 mg/kg bwt and for octanoic acid to be 0.011 mg/kg bwt. The available data indicates that consumption of octanal and octanoic acid as naturally occurring in fruit and vegetables is much greater than consumption as a flavoring agent. Exposure resulting from the use of octanal in only herbicide formulations at less than 0.2 % in the formulated product is anticipated to be much smaller than either the ADI, the naturally occurring background level of exposure, or exposure from its use as a flavoring agent.

2. *Drinking water exposure*. Due to its rapid volatilization octanal's half life in rivers is 2 hours and in lakes is 5 days. Because of this high volatility there would be only very low drinking water exposure and consequently no concern for risk to human health.

B. Other Non-Occupational Exposure

Octanal is used as a fragrance for soaps, detergents, and perfumes. Because it constitutes such a low percentage of the formulation exposure is likely to be minimal.

V. 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. Octanal 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/*.

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

FFDCA section 408 provides that EPA shall apply an additional 10-fold 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 octanal, based on an understanding of the metabolic pathway, the expected low oral toxicity, the available toxicity data which indicates low toxicity, and especially considering the developmental toxicity no observed adverse effect level of 1,125 mg/kg/day for octanoic acid, a metabolite of octanal, EPA has not used a safety factor analysis to assess the risk. For the same reasons a 10-fold safety factor is unnecessary.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of octanal, and that under reasonably forseeable circumstances aggregate exposure to octanal will pose no appreciable risk to human health. Accordingly, EPA finds that exempting octanal (CAS Registration No. 124–13–0) from the requirement of a tolerance will be safe.

VII. 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 octanal for endocrine effects may be required.

B. Analytical Method(s)

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

C. Existing Tolerances

There are no existing tolerance exemptions for octanal.

D. International Tolerances

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

VIII. Conclusions

The mammalian body has a demonstrated pathway to process

octanal. Octanal is metabolized to the corresponding fatty acid, octanoic acid, so there are no concerns for dietary exposure. Given that the petitioner will use octanal at levels not to exceed 0.2% of the formulation, and its metabolic transformation to octanoic acid, its use as an inert ingredient would not significantly increase the levels of octanal in the food supply, and should result in human exposure far below any dose level that could possibly produce an adverse effect

Based on the information discussed in this preamble, the expected low oral toxicity, and the developmental toxicity data for the metabolite (octanoic acid), EPA concludes that there is reasonable certainty of no harm from aggregate exposure to residues of 1-octanal. Therefore, EPA is establishing a tolerance exemption for 1-octanal (CAS Reg. No. 124–13– 0) with a limitation in the pesticide formulation of not more than 0.2%.

IX. 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 Identification (ID) number OPP–2004–0298 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 November 29, 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 (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 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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0298, 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).

X. 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.

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: September 23, 2004.

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; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* *	* *	*
1-Octanal (CAS Reg. No. 124–13–0)	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; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* *	* *	*
1-Octanal (CAS Reg. No. 124–13–0)	Not more than 0.2% of the pesticide formulation	Odor masking agent
* *	* *	*

[FR Doc. 04–21937 Filed 9–29–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0313; FRL–7678–8]

Mesotrione; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on cranberry. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cranberry. This regulation establishes a maximum permissible level for residues of mesotrione in this food commodity. The tolerance will expire and is revoked on December 31, 2007.

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0313. 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 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal