name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

The Agency has issued REDs for the pesticide active ingredients listed in this document. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1988, EPA is conducting an accelerated reregistration program to reevaluate existing pesticides to make sure they meet current scientific and regulatory standards. The data base to support the reregistration of each of the chemicals listed in this document is substantially complete, and each pesticide's risks have been mitigated so that it will not pose unreasonable risks to people or the environment when used according to its approved labeling. In addition, EPA is reevaluating existing pesticides and reassessing tolerances under the Food Quality Protection Act (FQPA) of 1996. The pesticides included in this notice also have been found to meet the FQPA safety standard.

All registrants of pesticide products containing one or more of the active ingredients, listed in this document, have been sent the appropriate REDs, and must respond to labeling requirements and product–specific data requirements (if applicable) within 8 months of receipt. Products also containing other pesticide active ingredients will not be reregistered until those other active ingredients are determined to be eligible for reregistration.

The reregistration program is being conducted under Congressionally-mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing these REDs as final documents with a 60–day comment period. Although the 60–day public comment period does not affect the registrant's response due date, it is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the REDs. All comments will be carefully considered by the Agency. If any comment significantly affects a RED, EPA will amend the RED by publishing the amendment in the **Federal Register**.

B. What is the Agency's Authority for Taking this Action?

The legal authority for these reregistration eligibility decisions falls under FIFRA, as amended in 1988 and 1996. FIFRA section 4(g)(2)(A) directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product–specific data on individual end–use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection, pesticides.

Dated: December 8, 2000.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 00–32037 Filed 12–19–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–981; FRL–6751–9]

Notice of Filing Pesticide Petitions to Establish Tolerances for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–981, must be received on or before January 19, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–981 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin C. Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8380; e-mail address: gandhi.bipin@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–981. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is

available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–981 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–981. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of these petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 8, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summary of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petitioner's summaries verbatim without editing it in any way. The petitioner's summaries announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemicals residues or an explanation of why no such method is needed.

Firmenich Incorporated

1. PP 6E4757

EPA has received a pesticide petition (PP 6E4757) from Firmenich Incorporated, P.O. 5880, Princeton, NJ 08543 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, to establish an exemption from the requirement of a tolerance for octanal when used as an inert ingredient in the pesticide formulations applied to growing crops or to raw agricultural commodities (RACs) after harvest under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001(e). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Since this petition is for an exemption from the requirement of a tolerance, an analytical method is not required.

B. Toxicological Profile

As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL –3190–1), the Agency set forth a list of studies which generally are used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from

the requirement of a tolerance for an inert ingredient.

The data that Firmenich believes supports establishing an exemption from tolerance is summarized below. More detailed information has been provided to the Agency.

Octanal has been used in foodstuffs as a flavoring agent since the 1900's and is approved by the Food and Drug Administration (FDA) as generally recognized as safe (GRAS) (21 CFR 172.515) and by the Council of Europe as in the list of substances granted ''A status''— may be used in foodstuffs (COE No. 97). It is recognized by the flavor and extract manufacturer's association as GRAS (GRAS 3 (2797)).

1. *Acute toxicity*. The LD_{50} of octanal has been determined to be 5.63 grams/kilogram (g/kg) for the rat. In an acute inhalation toxicity study with rats, no mortality was found after 8 hours of exposure to a concentrated vapor of octanal. The dermal LD_{50} in rabbits was found to be 6.35 milligram/Liter/kilogram (mg/L/kg) using a 24 hour occluded patch.

The LC_{50} of octanal was found to be 7.9 mg/L in fish (*Poecilia reticulata*) and >111 mg/kg in the bird (redwing blackbird). These values are in agreement with the ECOSAR calculated values of 6.1 mg/L for fish, 2.3 mg/L for *Daphnia*, and 13.0 mg/L for green algae.

2. *Genotoxicty*. An Ames test with and without S–9 using strains TA 98, TA 100, TA 1535, and TA 1537 at 3 µmol/plate produced no adverse effects.

3. *Reproductive and developmental toxicity*. Toxicity and teratogenicity of octanal was evaluated in chickens by injecting 50 chick embryos suprablastodermally at 72 hours of incubation with 0.05M octanal in olive oil. The teratogenicity reproductive effect for octanal was 4.16% versus 7.9% for the solvent alone.

4. *Subchronic toxicity*. In a 12–week subchronic study with 12 rats per sex per dose using a mixture of aldehydes from C–8 to C–12, there were no adverse effects at 12.4 mg/kg.

5. *Endocrine disruption*. Octanal is not structurally similar to any substances known to be an endocrine disrupter.

C. Aggregate Exposure

Consistent with section 408(c)(2)(B) of FFDCA, Firmenich believes that, based on this submission, the Agency has sufficient information to assess the hazards of octanal and make a determination on aggregate exposure, consistent with section 408(b)(2) for tolerance exemption for the residues of octanal on growing crops, RACS after harvest, and animals.

Dietary exposure. For the purpose of assessing the potential dietary exposure under these exemptions, Firmenich Incorporated considers that octanal could be present in all raw and processed agricultural commodities.

1. *Food*. Octanal is a GRAS substance 21 CFR 172.515 and is included by the Council of Europe in the list of substances granted ''A status''—may be used in foodstuffs (COE No. 97). The flavors and extract manufacturer's association states: Generally recognized as safe as a flavor ingredient—GRAS 3, (2797). The Joint Expert Committee on food additives has established an allowable daily intake (ADI) of 0.1 mg/kg (with nonanal) (1984). Therefore, no concerns for risk associated with any potential exposure scenarios are reasonably foreseeable.

2. *Drinking water*. Due to the low water solubility (estimated 91 mg/L by ECOSAR), only very low drinking water exposure is expected and would not contribute significantly to the ADI. Therefore, no concerns for risk associated with any potential exposure scenarios are reasonably foreseeable.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of particular chemical's residues and ''other substances that have a common mechanism of toxicity''. Octanal has been in public use since the 1900's and the lack of observed toxicity after acute and chronic exposure would suggest that a cumulative risk assessment is therefore not necessary.

E. Safety Determination

1. *U.S. population*. Octanal has been granted self-affirmed GRAS status in the United States, is approved for food use in Europe, and by the World Health Organization (WHO) Joint Expert Committee on food additives, with an ADI of 0.1 mg/kg (based on nonanal). Based on this material's low-risk profile, there is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to octanal.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply a 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 base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessment either directly through the margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

Due to the extensive available toxicological data base including subchronic toxicity studies and the expected low toxicity of this compound, Firmenich Incorporated does not believe a safety factor analysis is necessary in assessing the risk of these compounds. For the same reasons, Firmenich believes the additional safety factor is unnecessary.

F. International Tolerances

There are no known international tolerances for octanol.

2. PP 6E4758

EPA has received a pesticide petition (PP 6E4758) to establish an exemption from the requirement of a tolerance for ethyl maltol when used as an inert ingredient in the pesticide formulations applied to growing crops or to RAC after harvest under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001 (e). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Since this petition is for an exemption from the requirement of a tolerance an analytical method is not required.

B. Toxicological Profile

As a part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL –3190–1), the Agency set forth a list of studies which generally are used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient.

The data that Firmenich believes supports establishing an exemption from tolerance is summarized below. More detailed information has been provided to the Agency.

Ethyl maltol has been used in foodstuffs as a flavoring agent since the

1950's and is approved by the FDA as GRAS (21 CFR 172.515) and by the Council of Europe as in the list of substances granted ''A status''—may be used in foodstuffs (COE No. 692). It is recognized by the flavor and extract manufacturer's association as GRAS (GRAS 10 (3487)).

1. *Acute toxicity*. The LD_{50} of ethyl maltol has been determined to be 1.15 g/kg for the rat, 0.78 g/kg in the mouse, and 1.27 g/kg in the chicken. While there is no known aquatic testing, the ECOSAR program predicts that ethyl maltol would be practically non toxic to fish (LC_{50}= 2.3 g/L), *Daphnia* (LC_{50}= 1.1 to 3 g/L) and green algae (EC_{50}= 0.6 to 1.4 g/L).

2. *Genotoxicty*. An Ames test with and without S–9 using strains TA 1535, TA 1537, TA 1538, TA 1539 and TA 100 at up to 3.6 mg/plate in DMSO or water produced no adverse effects.

In a micronucleus test with male and female NMRI mice, no adverse effects were observed at 24, 48, or 72 hours at 980 mg/kg.

In a study with *Drosophila melangaster* the number of sex-linked lethal (SRL) chromosomes was counted. The no effect level was 14 millimolar ethyl maltol.

3. *Reproductive and developmental toxicity*. Toxicity and teratogenicity of ethyl maltol was evaluated in chickens by injecting 50 chick embryos suprablastodermally at 72 hours of incubation with 0.05M ethyl maltol in olive oil. The teratogenicity reproductive effect for ethyl maltol was 4.16% versus 7.9% for the solvent alone.

4. *Subchronic toxicity*. In a 90–day study with male and female Beagle dogs, no effects were observed when the animals were fed 500 mg/kg ethyl maltol orally. In a study with weanling Albino rats feed concentrations of ethyl maltol for 90 days, effects were noted in the kidney at 1,000 mg/kg. No mortality occurred.

5. *Chronic toxicity*. A 2–year rat reproduction study with ethyl maltol involving two separate litters of offspring was conducted at levels up to 200 mg/kg. No adverse effects on the parents or offspring were observed. Similarly in a 2–year study with Beagle dogs, no adverse effects were seen in the parents or offspring at up to 200 mg/kg.

6. *Animal metabolism*. The excretion rate of ethyl maltol was measured in the dog by both oral and intravenous routes of administration. Beagle dogs were fed 200 mg/kg of ethyl maltol daily for 99 days and the urine and feces collected for 24 hours after day 98, and 99. Urinary excretion of the test substance averaged 0.13% of the daily dose, while excretion of the sulfate and glucuronide conjugates averaged 64.0%. Similarly, 64.5% of a single intravenous 10 mg/kg dose of ethyl maltol was excreted as the conjugates in 24 hours and 66.3% in 72 hours.

7. *Endocrine disruption*. Ethyl maltol is not structurally similar to any substances known to be an endocrine disrupter.

C. Aggregate Exposure

Consistent with section 408(c)(2)(B) of FFDCA, Firmenich Incorporated believes that, based on this submission, the Agency has sufficient information to assess the hazards of ethyl maltol and make a determination on aggregate exposure, consistent with section 408(b)(2) for tolerance exemption for the residues of ethyl maltol on growing crops, RACs after harvest, and animals.

Dietary exposure. For the purpose of assessing the potential dietary exposure under these exemptions, Firmenich Incorporated considers that ethyl maltol could be present in all raw and processed agricultural commodities.

1. *Food*. Ethyl maltol is a GRAS substance 21 CFR 172.515 and is included by the Council of Europe in the list of substances granted ''A status''—may be used in foodstuffs (COE No. 692). The flavors and extract manufacturer's association states: Generally recognized as safe as a flavor ingredient—GRAS 3, (3487). The Joint Expert Committee on food additives has established an ADI of 0.2 mg/kg) (1974). Therefore, no concerns for risk associated with any potential exposure scenarios are reasonably foreseeable.

2. *Drinking water*. While ethyl maltol is soluble in water, it has been used since the 1950's in beverages, candies, and other food items. The lack of observed toxicity after acute and chronic exposure would indicate that the presence of trace amounts of ethyl maltol in drinking water would pose no appreciable risk to humans.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of particular chemical's residues and ''other substances that have a common mechanism of toxicity''. Ethyl maltol has been in public use since the 1950's and the lack of observed toxicity after acute and chronic exposure would suggest that a cumulative risk assessment is therefore not necessary.

E. Safety Determination

1. *U.S. population*. Ethyl maltol has been granted self-affirmed GRAS status in the United States, is approved for food use in Europe, and by the WHO Joint Expert Committee on food additives, with an ADI of 0.2 mg/kg. Based on this material's low-risk profile, there is reasonable certainty that no harm to the U. S. population will result from aggregate exposure to ethyl maltol.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply a 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 base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA's risk assessment either directly through the MOE analysis or through using uncertainty (safety) factors in calculating a dose level that pose no appreciable risk to humans.

Due to the extensive available toxicological data base including sub-chronic toxicity studies and the expected low toxicity of this compound, Firmenich Incorporated does not believe a safety factor analysis is necessary in assessing the risk of these compounds.

F. International Tolerances

There are no known international tolerances for ethyl maltol.

3. PP 6E4759

EPA has received a pesticide petition (6E4759), to amend 40 CFR part 180, to establish an exemption from the requirement of a tolerance for ethyl methylphenylglycidate when used as an inert ingredient in the pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001 (e). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Since the petition is for an exemption from the requirement of a tolerance, an analytical method is not required.

B. Toxicological Profile

As a part of the EPA policy statement on inert ingredients published in the

Federal Register of April 22, 1987 (52 FR 13305) (FRL –3190–1), the Agency set forth a list of studies which can generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient.

The date that Firmenich believes supports establishing an exemption from tolerance is summarized below. More detailed information has been provided to the Agency.

Ethyl methylphenylglycidate has been used in foodstuffs as a flavoring agent since the 1930's and is approved by the FDA as GRAS (21 CFR 182.60) and by the Council of Europe as in the list of substances granted ''A status''— may be used in foodstuffs (COE No. 6002). It is recognized by the flavor and extract manufacturer's association as GRAS (GRAS 3 (2444)).

1. *Acute toxicity*. The LD_{50} of ethyl methylphenylglycidate has been determined to be 5.47 g/kg for the rat, 5.6 mL/kg for the mouse, and 4.05 g/kg for the guinea pig.

Due to the very low water solubility of ethyl methylphenylglycidate and the octanol/water coefficient (estimated Kow 3.0), acute aquatic toxicity testing is thereby precluded.

2. *Genotoxicty*. An Ames tests with S–9 fractions from Aroclor-pretreated rats at doses up to 3.6 mg/plate with and without S–9 gave no adverse effect. Similarly, an Ames test, with strains TA98, TA 100, TA1535, TA1537 and TA97, also gave no adverse effects. A *Drosophila melagaster* and micronucleus test on mouse bone marrow appeared weakly mutagenic in the *Drosophila* only.

A chinese hamster ovary (CHO) cell study with ethyl methylphenylglycidate treated 8–12 hours without rat S–9 and 2 hours with S–9, gave positive sister chromatid exchange effects without S–9 over the full range of doses tested, 16 – 160 µg/mL, and no effect with S–9 over the whole range. Similarly, there were significant increases in chromosome aberrations over the range 50–500 µg/mL with and without S–9.

3. *Reproductive and developmental toxicity*. Toxicity and teratogenicity of ethyl methylphenylglycidate was evaluated in chickens with mortality and structural & functional defects being evaluated. The teratogenicity NOEC was 25 mg/egg and the LD_{50} was 8.16 mg/egg.

A mouse carcinogenicity and mutagenesis study was conducted in 15/sex/dose male and female mice by intraperitoneal injection 3X per weeks for 8 weeks at the maximum tolerance dose (MTD) and 0.20X MTD of ethyl methylphenylglycidate. There were 10 deaths at 0.45 g/kg and 4 deaths at 2.15 g/kg. Similarly, an intraperitonile ethyl methylphenylglycidate study with male and female mice showed no effects at the highest dose treated, 1,856 mg/kg.

4. *Subchronic toxicity*. In a 16–week rat study with male and female Osborne-Mendel rats at 10,000 parts per million (ppm) ethyl methylphenylglycidate weight changes, reproductive effects, growth retardation in males, and marked testicular atrophy was observed. In a 1–year study with male and female Osborne-Mendel rats, no effects were observed at 2,500 ppm of ethyl methylphenylglycidate on growth, haematology or macroscopic/microscopic tissue examination. In a second study, ethyl methylphenylglycidate, was fed to male and female rats for 15 weeks at 0.0, 0.02, 0.1, and 0.5% in the diet. No effect was observed on the growth rate, food consumption, or water consumption of the animals. The only effect attributable to the test substance were increased organ weight changes in the animals fed at the 0.5% level. The no observed adverse effect level was 0.1% ethyl methylphenylglycidate, corresponding to 150 and 60 mg/kg/day respectively at the beginning and end of the study.

5. *Chronic toxicity*. In a rat study, male and female rats were fed for 1.5 to 2 years at 0.1% and 0.5% ethyl methylphenylglycidate in their diet. No effects were observed at the 0.1% level. At 0.5% in the diet, neurotoxic effects, body weight (bwt) changes, pareses of the rear extremities with histological degeneration of the ischia nerve, and growth inhibition were observed. In a second study with 48 Wistar rats/sex at 0, 0.02, 0.1, and 0.5 EMPG in the diet for 2 years, no effects were observed at 0.1% (EMPG intake of approximately 35 mg/kg/day ethyl methylphenylglycidate for the males and 60 mg/kg/day ethyl methylphenylglycidate for the females). At 0.5%, weight changes, liver, micropathology in other organs, significant decrease in body weight in females, increased incidents of histopathology changes in lymph nodes, pancreas, adrenal glands, and liver were noted. No differences in mortality, hematology, serum chemistry, renal function, organ weights, or motor coordination were observed at any dose.

6. *Endocrine disruption*. Ethyl methylphenylglycidate is not structurally similar to any substances know to be an endocrine disrupter.

C. Aggregate Exposure

Consistent with section 408(c)(2)(B) of FFDCA, Firmenich Incorporated believes that, based on this submission, the Agency has sufficient information to assess the hazards of ethyl methylphenylglycidate and make a determination on aggregate exposure, consistent with section 408(b)(2) for tolerance exemption for the residues of ethyl methylphenylglycidate on growing crops, RACs after harvest, and animals.

Dietary exposure. For the purpose of assessing the potential dietary exposure under these exemptions, Firmenich Incorporated considers that ethyl methylphenylglycidate could be present in all raw and processed agricultural commodities.

1. *Food*. Ethyl methylphenylglycidate is a GRAS substance 21 CFR 182.60 and is included by the Council of Europe in the list of substances granted''A status''—may be used in foodstuffs (COE No. 6002). The flavors and extract manufacturer's association states: Generally recognized as safe as a flavor ingredient—GRAS 3, (2444). The Joint Expert Committee on food additives has established an ADI of 0.5 mg/kg (1984). Therefore, no concerns for risk associated with any potential exposure scenarios are reasonably foreseeable.

2. *Drinking water*. Due to the low water solubility (estimated 87 mg/L by ECOSAR), only very low drinking water exposure is expected and would not contribute significantly to the ADI. Therefore, no concerns for risk associated with any potential exposure scenarios are reasonably foreseeable.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of particular chemical's residues and ''other substances that have a common mechanism of toxicity''. Ethyl methylphenylglycidate has been in public use since the 1930's and the lack of observed toxicity after acute and chronic exposure would suggest that a cumulative risk assessment is therefore not necessary.

E. Safety Determination

1. *U.S. population*. Ethyl methylphenylglycidate has been granted self-affirmed GRAS status in the United States, is approved for food use in Europe, and by the WHO Joint Expert Committee on food additives, with an

ADI of 0.5 mg/kg. Based on this material's low-risk profile, there is reasonable certainty that no harm to the U. S. population will result from aggregate exposure to ethyl methylphenylglycidate.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply a ten–fold MOE for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA's risk assessment either directly through the MOE analysis or through using uncertainty (safety) factors in calculating a dose level that pose no appreciable risk to humans.

Due to the extensive available toxicological data base including chronic toxicity studies and the expected low toxicity of this compound, Firmenich Incorporated does not believe a safety factor analysis is necessary in assessing the risk of these compounds. For the same reasons, Firmenich believes the additional safety factor is unnecessary.

F. International Tolerances

There are no known international tolerances for ethyl methyl-phenylglycidate

[FR Doc. 00–32152 Filed 12–19–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–987; FRL–6760–6]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–987, must be received on or before January 19, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–987 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6379; e-mail address: gairola.indira@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–987. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–987 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file