

exemption from the requirement of a tolerance for the active ingredient, methyl anthranilate for cherries, blueberries and grapes under 40 CFR 180.1143 became effective on April 26, 1995 as published in the **Federal Register** (60 FR 20432) (FRL-4941-8).

The mode of action is physical whereby the repellent irritates the bird's taste buds, olfactory sensors and skin. For this petition, methyl anthranilate is sprayed in a water solution at a rate of 0.2862 pounds (lbs.) per acre to corn twice and may be reapplied at 5 to 10 day intervals until harvest. Applications to the crop can be applied up to 2 days before harvest.

#### B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Methyl anthranilate is a common component of concord and other red grapes as well as neroli, ylang-ylang, bergamot, jasmine and other essential oils. It is synthetically obtained by esterifying anthranilic acid with methanol in the presence of hydrochloric acid. In its crystalline form it is slightly soluble in water and freely soluble in alcohol or ether. Methyl anthranilate is commonly used as a perfume for ointments and cosmetics, and a flavoring agent in confectionary products, drugs and beverages. Methyl anthranilate readily volatilizes under ultraviolet (uv) light and elevated temperatures.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* Residue studies, using gas chromatograph and mass spectrometry, show no residues at the time of harvest. No residues of methyl anthranilate are expected to occur at the time of harvest and thus the purpose for proposing an exemption from the requirement of a tolerance.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* The analytical method for detecting and measuring the levels of the residue is described above.

#### C. Mammalian Toxicological Profile

Methyl anthranilate is approved by the FDA for food use as an artificial flavoring and fragrance agent. Bird Shield Repellent Corporation has reviewed the acute toxicological studies associated with these approvals and conducted additional studies for verification. Summaries of these studies are presented below:

1. *Mammalian.* Methyl anthranilate exhibits little or no mammalian toxicity. Methyl anthranilate metabolizes in the intestine when consumed. The LD<sub>50</sub> values for methyl anthranilate were

estimated to be greater than 5,000 mg/kg in an acute oral toxicity study in rats (Toxicity category IV) and greater than 2,000 mg/kg in an acute dermal toxicity study in rats (Toxicity category III). The LC<sub>50</sub> value in an acute inhalation study in rats was determined to be greater 2.24 mg/L (Toxicity category IV). Methyl anthranilate was found to cause moderate irritation in a rabbit skin irritation assay and corneal effects that cleared in 8 to 21 days in a rabbit eye irritation assay.

2. *Avian.* Methyl anthranilate exhibits little or no avian toxicity. Methyl anthranilate's irritating properties to avian species preclude ingestion. In an acute oral avian toxicity study, methyl anthranilate was found to be practically non-toxic to bobwhite quail. In a dietary study, methyl anthranilate was determined to be practically non-toxic to mallard ducks. Based on these studies, Bird Shield Repellent Corporation concludes that methyl anthranilate poses no unique or additional risk to avian species.

#### D. Aggregate Exposure

1. *Dietary exposure* —i. *Food.* The active ingredient in Bird Shield Repellent Concentrate, methyl anthranilate, is applied at a rate of 0.2862 lbs per acre. Because of the low use rates, no active ingredient residues are detectable using available methods on treated crops even immediately after application. Because of its volatility, and degradation when exposed to ultraviolet light and elevated temperatures, no residues are expected at harvest. Dietary exposure to methyl anthranilate, via consumption of the treated food or feed, is expected to be low to negligible.

ii. *Drinking water.* The active ingredient is unlikely to be found in drinking water given the very low application rate and rapid degradation in soil.

2. *Non-dietary exposure.* Bird Shield Repellent Corporation believes that the potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use is primarily to the external, non-edible portions of the crop. This mode of application would not be expected to pose any quantifiable risks due to lack of residues of toxicological concern. Increased non-dietary exposure of methyl anthranilate is not considered likely because of the low use rates and the lack of persistence of the active ingredient.

#### E. Cumulative Exposure

Consideration of a common mode of toxicity is not appropriate given there is

no indication of mammalian toxicity of methyl anthranilate and no information that indicates that the toxic effects would be cumulative with any other compounds. Moreover, methyl anthranilate does not exhibit a toxic mode of action in its target species.

#### F. Safety Determination

1. *U.S. population.* Methyl anthranilate's lack of toxicity has been demonstrated by the results of acute toxicity testing in mammals in which the chemical caused no adverse effects when dosed orally and via inhalation at the limit dose for each study. Thus the aggregate exposure to methyl anthranilate over a lifetime should pose negligible risks to human health.

2. *Infants and children.* Based on the lack of toxicity and low exposure there is reasonable certainty of no harm to infants, children or adults from aggregate exposure to the chemical's residues. Exempting methyl anthranilate from the requirement of a tolerance should pose no significant risk to human health or the environment.

#### G. Effects on the Immune and Endocrine Systems

Bird Shield Repellent Corporation has no information to suggest that methyl anthranilate will adversely affect the immune or endocrine systems.

#### H. Existing Tolerances

An exemption from the requirement of a tolerance for the active ingredient, methyl anthranilate for cherries, blueberries and grapes under 40 CFR 180.1143 became effective on April 26, 1995 (60 FR 20432).

#### I. International Tolerances

Bird Shield Repellent Corporation is not aware of any tolerance, exemption from tolerance or MRL's issued for methyl anthranilate outside the United States.

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## ENVIRONMENTAL PROTECTION AGENCY

[PF-910; FRL-6484-9]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals 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-910, must be received on or before February 23, 2000.

**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-910 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8077; e-mail address: Cerrelli.susanne@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:

Cat-egories	NAICS	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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" 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-910. 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 (CM 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-910 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, Ariel Rios Bldg., 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, CM 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](mailto: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-910. 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 a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

### List of Subjects

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

Dated: January 5, 2000.

**Janet L. Andersen,**

Director, Registration Division, Office of Pesticide Programs.

### Summary of Petition

#### Prophyta Biologischer Pflanzenschutz GmbH

##### Pesticide Petition 9F6038

EPA has received a pesticide petition (PP) 9F6038 from Prophyta Biologischer Pflanzenschutz GmbH, Inselstrabe 12, D-23999 Malchow/Poel, Germany, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the microbial pesticide *Coniothyrium minitans* strain CON/M/91-08.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Prophyta Biologischer Pflanzenschutz GmbH has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Prophyta Biologischer Pflanzenschutz GmbH and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

### A. Product Name and Proposed Use Practices

*Coniothyrium minitans* strain CON/M/91-08 is proposed for use to control *Sclerotinia* species in the soil of any agricultural crop. The end-use product, CONTANS®WG, is applied as a spray to the soil, which is followed with mechanical incorporation (i.e., rotating) into the first one to two inches of the top soil layer. The product is applied as a preplant treatment, 3 to 4 months prior to planting the crop, or as a postharvest treatment to plant residues.

### B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* *Coniothyrium minitans* strain CON/M/91-08 is the active ingredient in the proposed end-use product CONTANS® WG. CONTANS® WG is currently registered for use in Germany and Switzerland. An application for inclusion of the active ingredient (*Coniothyrium minitans* strain CON/M/91-08) in Annex I of Council Directive 91/414/EEC on the marketing of plant-protection products was sanctioned in 1998 and was published in the European Union Gazette.

*Coniothyrium minitans* was first described after isolation from *sclerotia* of *Sclerotinia sclerotiorum* in California in 1947 and has been investigated as a pesticide over the last 20 years. The occurrence of *Coniothyrium minitans* in the soil has been reported from many countries all over the world.

*Coniothyrium minitans* strain CON/M/91-08 is a naturally occurring soil fungus that primarily attacks and infects *sclerotia*. When the host organism (*sclerotia*) is present, *Coniothyrium minitans* starts to develop a vegetative organism and infects the host. The *Coniothyrium minitans* population decreases when the number of vital *sclerotia* drops. The vegetative organism disappears and the fungus rests in a spore stage. The spores of *Coniothyrium minitans* can survive ungerminated in disintegrated *sclerotia* for at least 1 year, and the fungus can be recovered from soil in *sclerotia* for up to 18 months following application. However, at soil temperatures above 25 °C, isolation of *Coniothyrium minitans* from *sclerotia* is not possible after 6 months.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* An analytical method for detecting and measuring the levels of residues is not applicable. *Coniothyrium minitans* strain CON/M/91-08 is applied to the soil and immediately mixed into the top soil layer prior to planting the crop, or after harvest. It is

not applied to growing crops directly. Residues of *Coniothyrium minitans* strain CON/M/91-08 are not expected on agricultural commodities.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for detecting and measuring the levels of residues is not applicable. *Coniothyrium minitans* strain CON/M/91-08 is applied to the soil and immediately mixed into the top soil layer prior to planting the crop, or after harvest. It is not applied to growing crops directly. Residues of *Coniothyrium minitans* strain CON/M/91-08 are not expected on agricultural commodities.

### C. Mammalian Toxicological Profile

CONTANS® WG, the end-use product which contains 5.3% active ingredient, was evaluated for acute toxicity through oral, dermal, inhalation and eye routes of exposure. The results of the studies indicated Toxicity Category III or IV, which pose no significant human health risks.

The acute oral toxicity of *Coniothyrium minitans* strain CON/M/91-08 in rats is greater than 2,500 milligrams per kilograms (mg/kg) (Toxicity Category III), the highest dose tested. The acute dermal toxicity of *Coniothyrium minitans* strain CON/M/91-08 in rats is greater than 2,500 mg/kg (Toxicity Category III), the highest dose tested. The acute intraperitoneal toxicity of *Coniothyrium minitans* strain CON/M/91-08 to rats is greater than 2,000 mg/kg, the highest dose tested. The acute inhalation of *Coniothyrium minitans* strain CON/M/91-08 in rats is greater than 12.74 milligrams per liter (mg/L) of air (Toxicity Category IV). Eye irritation in rabbits was not observed at a dose of 0.1 milliliter (ml) (Toxicity Category IV). Skin irritation in rabbits was not observed at a dose of 0.5 ml (Toxicity Category IV). No dermal sensitization was observed in guinea pigs (Toxicity Category IV). Since its discovery in 1947, no incidents of hypersensitivity have been reported by researchers, manufacturers, or users.

A waiver is being requested for acute oral toxicity/pathogenicity, acute dermal toxicity/pathogenicity and acute pulmonary toxicity/pathogenicity data requirements, based on the fact that the active ingredient is not able to grow at temperatures above 32 °C, and thus would not be pathogenic or infective to humans. A growth temperature study has been submitted to support the waiver request. Additionally, acute toxicity studies have determined the end-use product containing the organism is not toxic, irritating or

sensitizing to test animals. Finally, the organism has never been reported as a pathogen of humans, or as causing any type of adverse effect to humans, in published literature or through commercial use.

**D. Aggregate Exposure**

1. *Dietary exposure* —i. *Food*. Dietary exposure from use of *Coniothyrium minitans* strain CON/M/91-08, as proposed, is minimal. *Coniothyrium minitans* strain CON/M/91-08 is applied to the soil and immediately mixed into the top soil layer prior to planting the crop, or after harvest. It is not applied to growing crops directly. Residues of *Coniothyrium minitans* strain CON/M/91-08 are not expected on agricultural commodities.

ii. *Drinking water*. Exposure to humans from residues of *Coniothyrium minitans* strain CON/M/91-08 in consumed drinking water would be unlikely. In a study to investigate the leaching behavior of *Coniothyrium minitans* strain CON/M/91-08, it was determined that there is no motility of the organism in the soil. Thus, it would not be possible for the organism to leach into drinking water. Also, due to the specific requirements for growth of *Coniothyrium minitans* strain CON/M/91-08, it is not likely that the organism could survive or persist in water.

2. *Non-dietary exposure*. The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are commercial, agricultural and horticultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

Personal protective equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in commercial, agricultural and horticultural settings.

**E. Cumulative Exposure**

It is not expected that, when used as proposed, *Coniothyrium minitans* strain CON/M/91-08 would result in residues that would remain in human food items.

**F. Safety Determination**

1. *U.S. population*. *Coniothyrium minitans* strain CON/M/91-08 does not grow at temperatures above 32 °C, and thus would not be pathogenic or infective to humans. There have been no reports of toxins or secondary metabolites associated with the organism, and acute toxicity studies have shown that *Coniothyrium minitans* strain CON/M/91-08 is nontoxic, nonirritating and nonsensitizing when applied to test animals.

*Coniothyrium minitans* strain CON/M/91-08 is applied to soil and immediately mixed into the top soil layer prior to planting the crop, or after harvest. It is not applied to growing crops directly. Residues of *Coniothyrium minitans* strain CON/M/91-08 are not expected on agricultural commodities, and therefore, exposure to the general U.S. population, from the proposed uses, is not anticipated.

2. *Infants and children*. As mentioned above, residues of *Coniothyrium minitans* strain CON/M/91-08 are not expected on agricultural commodities. There is a reasonable certainty of no harm for infants and children from exposure to *Coniothyrium minitans* strain CON/M/91-08 from the proposed uses.

**G. Effects on the Immune and Endocrine Systems**

*Coniothyrium minitans* strain CON/M/91-08 is a naturally occurring, nonpathogenic soil organism. To date there is no evidence to suggest that *Coniothyrium minitans* strain CON/M/91-08 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

**H. Existing Tolerances**

There are no existing tolerances for this ingredient.

**I. International Tolerances**

A Codex Alimentarium Commission Maximum Residue Level (MRL) is not required for *Coniothyrium minitans* strain CON/M/91-08.

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BILLING CODE 6560-50-F

**ENVIRONMENTAL PROTECTION AGENCY**

[OPP-181072; FRL-6485-7]

**Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. These exemptions or denials were issued during the period between January 1, 1999, through December 15, 1999, to control unforeseen pest outbreaks. The actions detailed in this document do not represent every FIFRA section 18 emergency exemption decision issued by EPA during the above time period.

**FOR FURTHER INFORMATION CONTACT:** See each emergency exemption or denial for the name of a contact person. The following information applies to all contact persons: Team Leader, Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (703) 308-9366.

**SUPPLEMENTARY INFORMATION:** EPA has granted or denied emergency exemptions to the following State and Federal agencies. The emergency exemptions may take the following form: Crisis, public health, quarantine, or specific. EPA has also listed denied emergency exemption requests in this notice.

**I. General Information**

**A. Does This Action Apply to Me?**

You may be potentially affected by this action if you petition EPA for authorization under section 18 of FIFRA to use pesticide products which are otherwise unavailable for a given use. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
State and Territorial government agencies charged with pesticide authority	9241	State agencies that petition EPA for section 18 pesticide use authorization

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be

regulated by this action. Other types of entities not listed in the table in this unit could also be regulated. The North

American Industrial Classification System (NAICS) codes have been provided to assist you and others in