

turf by professional lawn care applicators or on sod farms. The product is rarely, if ever, used on homeowner turf due to the fact that the diseases it controls (Brown patch, Fairy ring, and snow molds) occur in high-fertility, high-maintenance turf (e.g., golf courses), not in homeowner lawns. Thus, non-dietary exposure to flutolanil would be minimal. Furthermore, no dermal toxicity endpoints of concern have been identified for flutolanil. Thus, an assessment of non-dietary exposure and risk is not considered to be necessary.

#### D. Cumulative Effects

Flutolanil has demonstrated only minimal toxicity in animal studies. The mechanism of this toxicity is unknown. Furthermore, there are no available data to indicate that flutolanil has a common mechanism of toxicity with other substances. Thus, only the potential risks from flutolanil are being considered in this document.

#### E. Safety Determination

1. *U.S. population.* Based on the existing and proposed tolerances in potatoes, rice, peanuts and, secondary commodities, the Theoretical Maximum Residue Contribution (TMRC) of the current action is estimated to be 0.001353 mg/kg/day for the U.S. population in general. This exposure would utilize less than 1% of the RfD. There is generally no concern for exposures below 100% of the RfD since the RfD represents the exposure level at or below which daily exposure over a lifetime will not pose any appreciable risks to human health. Therefore, there is a reasonable certainty that no harm will result in the U.S. population in general from aggregate exposure to flutolanil.

2. *Infants and children.* Data from reproductive and developmental toxicity studies are generally used to assess the potential for increased sensitivity of infants and children. No evidence of developmental toxicity was noted in rats or rabbits, even at the limit dose of 1,000 mg/kg/day. Reduced pup weights in the absence of parental toxicity were noted at the high-dose level (10,000 ppm) in a 3-generation rat reproduction study. However, no such effects were noted in a subsequent reproduction study, even at a higher dose level (20,000 ppm). Furthermore, the reduced weight gain in the first study began late in the lactation period, at a time when the pups were likely ingesting significant quantities of diet. Feed intake is much higher in young animals than in adults and the apparent increase in sensitivity may simply

reflect the higher test material intake in these pups on a mg/kg basis compared to the adults. Thus, AgrEvo believes that the overall weight of evidence does not indicate any special concern for infants and children, and that no additional safety factor is necessary.

Based on the existing and proposed tolerances in rice, potatoes, peanuts, and secondary commodities, the TMRC from the current petition is estimated to be 0.006498 mg/kg/day for the most highly exposed subpopulation, non-nursing infants (less than 1 year old). This exposure would utilize approximately 1% of the RfD. Therefore, there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to flutolanil.

#### F. International Tolerances

No Codex Alimentarius Commission (CODEX) tolerances have been established for flutolanil.

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### ENVIRONMENTAL PROTECTION AGENCY

[PF-911; FRL-6485-5]

#### 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 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-911, 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-911 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Judy Loranger, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-8056; e-mail address: loranger.judy@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 codes	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-911. 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-911 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, 401 M St., SW., 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*," 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-911. 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 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 10, 2000.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

#### **Summaries of Petitions**

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

#### **I. Bird Shield Repellent Corporation**

*9F5055*

EPA has received a pesticide petition 9F5055 from Bird Shield Repellent Corporation, P.O. Box 785, Pullman, WA 99163, 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 biochemical pesticide methyl anthranilate in or on sunflower.

#### *A. Product Name and Proposed Use Practices*

The commercial name for the end use product containing methyl anthranilate (MA) is Bird Shield Repellent, EPA Reg. No. 66550-1. The product was approved for use as a bird repellent on cherries, blueberries and grapes on October 3, 1995. The active ingredient, methyl anthranilate, is a natural constituent of concord and heavy red grapes. It is listed by the U.S. Food and Drug Administration (FDA) as a flavoring compound under 21 CFR 182.60 and is classified as a Generally Recognized as Safe (GRAS) compound by the Expert panel of the Flavoring and Extract Manufacturer's Association (FEMA No. 2682). 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, 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 sunflowers twice at 7-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 chromatography 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 lethal dose<sub>50</sub> (LD<sub>50</sub>) values for methyl anthranilate were estimated to be greater than 5,000 milligrams/kilograms (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/liters (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 in the **Federal Register** of April 26, 1995 (60 FR 20432).

#### I. International Tolerances

Bird Shield Repellent Corporation is not aware of any tolerance, exemption from tolerance or maximum residue levels (MRLs) issued for methyl anthranilate outside the United States.

## II. Bird Shield Repellent Corporation 9F5056

EPA has received a pesticide petition 9F5056 from Bird Shield Repellent Corporation, P.O. Box 785, Pullman, WA 99163, proposing pursuant to section 408(d) of the FFDC, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide methyl anthranilate in or on corn.

#### A. Product Name and Proposed Use Practices

The commercial name for the end use product containing methyl anthranilate is Bird Shield Repellent, EPA Reg. No. 66550-1. The product was approved for use as a bird repellent on cherries, blueberries and grapes on October 3, 1995. The active ingredient, methyl anthranilate, is a natural constituent of concord and heavy red grapes. It is listed by the FDA as a flavoring compound under 21 CFR 182.60 and is classified as a GRAS compound by the Expert panel of FEMA No. 2682. 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 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