

### **Methyl Anthranilate Preliminary Work Plan and Summary Document**

Registration Review: Initial Docket September 2011

Case 6056

PC Code 128725

Approved by:

Keith Matthews Director, Biopesticides and

Pollution Prevention Division

20 Statute 2011 Date

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#### METHYL ANTHRANILATE REGISTRATION REVIEW TEAM

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his is the Registration Review Summary Document for the biochemical pesticide active agreement (a.i.) Mathyl Anthranilate, PC Code 128725.

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#### PRELIMINARY WORK PLAN

#### A. Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be registered by the U.S. Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on the product labeling. The Registration Review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the Registration Review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration\_review/.

The Agency is implementing the Registration Review program pursuant to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of Registration Review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a Registration Review decision. After reviewing and responding to comments and data received in the docket during this comment period, the Agency will develop and commit to a final work plan and schedule for the Registration Review.

This is the Registration Review Summary Document for the biochemical pesticide active ingredient (a.i.) Methyl Anthranilate, PC Code 128725.

#### B. Background and Regulatory Information

Methyl Anthranilate (MA) is a naturally occurring ester found in plants such as grapes, corn, cherries, cocoa and black tea. MA is a pale yellow liquid that is redolent of grapes. It has no known acute toxic endpoints for mammals, and biodegrades rapidly. MA is used as a flavoring in candy and sodas and is considered 'Generally Regarded as Safe' (GRAS) by FDA for consumption as a flavoring agent. It is also used in perfumes.

MA was first registered by the Agency in 1985 for use as a bird repellent. It is used on agricultural sites and on other sites where nuisance birds create hazard, such as at airports and on turf. MA works through a non-toxic mode of action by causing a pain response in the trigeminal nerve of birds. Birds are then conditioned not to return to the place of their discomfort. It is formulated as a liquid and is applied by foliar spray or

fogger. Human exposure is considered minimal because of low application rates and rapid biodegradability. MA has negligible acute toxicity to humans, nontarget insects, plants, birds and fish. In 1995, MA was exempted from the requirement of a tolerance for use on grapes, blueberries and cherries under 40 CFR 180.1143. The exemption was amended in 2001 to include corn and sunflowers and amended again in 2002 to include all agricultural use sites. There are currently seven registered products containing the active ingredient. One of these products is a manufacturing-use product (MPs); the remaining six are end-use products (EPs).

#### C. Anticipated Risk Assessment and Data Needs

Below is a discussion of how the current data requirements for MA are satisfied by available data. The pertinent data areas include: Product Analysis, Toxicology (human health), and Nontarget Organisms and Environmental Fate (ecotoxicology).

## 1. **Product Analysis** (40 CFR 158.2030)

The Agency has conducted a review of the available product chemistry data and information for MA and has concluded that all biochemical pesticide data requirements for the technical grade active ingredient have been satisfied. Table 1 provides information on chemical identity; and Table 2 reflects the fulfillment of the product chemistry data requirements.

Table 1. Methyl Anthranilate Chemical Identity

Common Name	Methyl Anthranilate	
Chemical Name, IUPAC	2-aminobenzoic acid methyl ester	ΩĒ3
Molecular Weight	151.2 g/mol	OES
PC Code	128725	088
CAS Registry Number	134-20-3	OF2
Empirical Formula	C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>	063
Chemical Structure	AsAscanias le, MANISTA Applicable	
	Data from MR1Ds 42608600, 42606801,42 990660	
	2. Human Health Risk Assessmen	
	(40 CFR 158,2050)	
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Table 2. Methyl Anthranilate Product Chemistry Data Requirements Summary

Guideline No.	Physical and Chemical Properties	Status	Value
830.1100	Product Identity and Composition	Α	Refer to Table 1.
830.1200	Description of starting materials, production and formulation process	ng esu-b	containing the active ingreIBO ( MPs); the remaining six are en
830.1400	Discussion of formation of impurities	A	CBI Natifi betsgiptinA
830.1700	Preliminary analysis	Α	CBI
830.6302	Color Color an emergen stab	A	Pale Yellow
830.6303	Physical state	Α	Liquid or crystals
830.6304	Odor	Α	Orange blossoms; Grapes
830.6313	Stability to normal and elevated temperatures, metals and metal ions	A redyesis (8.2030)	No degradation observed.
830.7000	Hq in per available product chemin	N/A	N/A; pH testing done on enduse products.
830.7050	UV/Visible light absorption λ <sup>al</sup> = 248, 341 nm	Α	5012 M <sup>-1</sup> cm <sup>-1</sup>
830.7200	Melting point/melting range	Α	24-25°C
830.7220	Boiling point/boiling range	Α	256°C
830.7300	Density	Α	1.168 g/mL
830.7520	Particle size, fiber length, and diameter distribution	N/A	N/A; water soluble
830.7550 830.7560 830.7570	Partition coefficient (n- Octanol/Water)	Α	Log K <sub>ow</sub> = 1.88
830.7840	Water solubility	Α	0.29 g/100mL
830.7950	Vapor pressure	Α	0.012 mm (20°C)

1. A=Acceptable, N/A=Not Applicable

Data from MRIDs 42608800, 42608801,42699800, 4269801 and 43036900.

## 2. Human Health Risk Assessment Status (40 CFR 158.2050)

Based on available data and information, the Agency does not foresee the need for new data or new human health risk assessments for this active ingredient. Hazard and exposure information as well as Agency risk assessments on MA were evaluated against current safety standards established by statute, the Agency's scientific policies and regulations, and it was determined that there is no need to conduct additional risk assessments. The active ingredient is a naturally occurring ester found in plants such as corn, grapes, cherries, cocoa and black tea. It is present in those commonly consumed foods at higher concentrations than in any pesticidal exposure scenarios. Data indicate that

when MA is consumed, it is metabolized easily in the intestines and liver, obviating any systemic dietary exposure (MRID 44786300). It is used as a flavoring in candy and sodas and is considered GRAS by FDA for consumption as a flavoring agent (21 CFR 182.60). It is also used in perfumes. No acute toxic endpoints have been established for MA; and it degrades rapidly into nontoxic components such as anthranilic acid.

All acute toxicity data requirements were fulfilled for MA per 40 CFR 158.2050. All data show that MA is virtually non-toxic to mammals through all routes of exposure.

Due to the low toxicity, metabolism, rapid degradation and long history of dietary exposure to this naturally occurring biochemical, chronic and subchronic data were waived. No other toxic endpoints were identified and, therefore, no reference dose and no observable effect level were established. Labels for all products containing MA require the following personal protective equipment (PPE) for applicators/handlers: long sleeve shirt, long pants, shoes, socks, and protective eyewear. Because of a lack of significant acute toxicity and minimal exposure due to low application rates and rapid degradation, EPA does not foresee the need for new data or for a new human health risk assessment for MA.

Table 3. Human Health Assessment Data Requirements for Methyl Anthranilate

Data Requirement	<u>LD<sub>50</sub></u>	Toxicity Category	MRID 42608802	
Acute Oral Toxicity/OPPTS 870.1100	3,633 mg/kg (males) 3,000mg/kg (females) 3,288 mg/kg (sexes combined)	d by Avery et al. als and Mirds foll ste. Based on the		
Acute Dermal Toxicity/OPPTS 870.1200	> 2,000 mg/kg*	e smailli*	42608803	
Acute Inhalation Toxicity/OPPTS 870.1300	> 2.8 mg/L	sobing fill crimeur	44740303	
Acute Eye Irritation/OPPTS 870.2400	Slight to moderate conjunctival irritation; all cleared by 72 hours after treatment	Fositives May rect ap Mication ( that toxicity stud	42608804	
Acute Dermal Irritation/OPPTS 870.2500	No irritation	oduct wyr applie	42608805	
Skin Sensitization/OPPTS 870.2600	Not a sensitizer	Not a sensitizer	42608806	

<sup>\*</sup> Highest tested dose.

## 3. Environmental Fates and Ecological Risk Assessment Status (40 CFR 158.2060)

in water following a fog application at maximum label use rates ((

MA is a naturally occurring substance in plants such as corn, sunflowers, grapes and cherries, as well as cocoa and black tea (EPA, 1994). Honey made from

citrus floral sources has been reported to contain from 3.60 to 5.04 mg/kg of MA (Ferreres et. a., 1994; White & Bryant, 1996, unpublished study). MA is extremely volatile and degrades rapidly into non-toxic components such as anthranilic acid. Numerous studies are available evaluating residues on crops and aquatic environments following application of MA at maximum label use rates for the respective use sites. In both terrestrial and aquatic exposure scenarios, the potential residues were well below the naturally occurring levels found in cherries (35 ppm) and grapes (33 ppm), and far below any level of concern for non-targets. Even in the event of exposure, toxicity data on nontarget organisms confirm that MA is virtually non-toxic to non-target plants, insects, mammals, and birds and slightly to moderately toxic to fish. It is slightly toxic to aquatic invertebrates, but at levels far in excess of any expected exposure scenario. In sum, use of MA as a bird repellent will not result in significant residues; and any residues are considered to be virtually non-toxic. (Table 4).

Terrestrial Residues: Data from magnitude of the residue studies on apples, corn (sweet), and sunflower confirm the rapid dissipation of the active ingredient. Residues on whole apples treated with a single foliar application at 2.29 lbs a.i./A declined from 1.79 ppm at 1-hour posttreatment to <0.055 ppm (non-detectable) by 14 days posttreatment (MRID 45065105). Sweet corn was treated twice at 0.573 lbs a.i./A with a 5-day interval; residues were 0.374 ppm 10-days after the second application (MRID 45065103). Avery et al. (1995) reported residues on rice as 11.7 ppm immediately following an application of ReJex-It AG-36 (14.5% a.i.) at 6.2 lb a.i./A, which rapidly declined over the next 14 days with a half-life of 7 days (interpolated by reviewer based on study author data). The residue value reported by Avery et al. (1995) was used to calculate Risk Quotients (RQs) for mammals and birds following terrestrial applications of MA at the maximum label used rate. Based on the highest respective application rates for terrestrial use sites, calculated RQs are all <0.05 for all taxa, indicating negligible risk for all non-target organisms exposed to MA residues (2011 EPA Methyl Anthranilate Eco Scoping Document and ESA).

Aquatic Residues: Magnitude of the residue studies have been conducted for both direct application and fogging applications of MA products to aquatic sites. In a catfish toxicity study (Dorr et al. 1998), a 40% liquid methyl anthranilate enduse product was applied directly to the surface of an aquaculture pond at an exaggerated rate of 80 lb a.i./A water surface (10X the maximum label rate for currently registered products). The maximum concentration of was 4.44 ppm at a depth of 24 inches following seven applications over a two-week period. If mathematically adjusted to a 1X rate, the calculated residues are estimated to be approximately 0.444 ppm. Fog application rates are an order of magnitude below that of direct spray applications (0.21 lb a.i/A vs. 8.0 lb a.i./A). The Tier I Rice Model equation (EPA, 2007) was used to estimate environmental concentrations in water following a fog application at maximum label use rates (0.21 lbs a.i./A or 0.24 kg a.i./ HA) and assuming a K<sub>oc</sub> of 250 for MA (HSDB, 2004). The calculated residues for fogger applications were 0.175 ppm. Given the low EEC

levels, the virtual non-toxicity of MA to aquatic organisms and the prohibition of use on fish-bearing waters, no risks are anticipated to result from applications of MA as a bird repellent.

Table 4. Summary of Non-Target Organism Data

Study Type/OCSPP Guideline	LD <sub>50</sub> /LC <sub>50</sub> /EC <sub>50</sub> Results	Toxicity Category	MRID
Acute Oral Toxicity /OCSPP 870.1100	>5000 mg/kg (rat)	Tox Category IV	42608702
90-day Feeding (rat) /OCSPP 870.	>500 mg/kg/day	No effects on growth or survival	42151904
Avian Acute Oral Toxicity /OCSPP 850.2100	>2036 ppm (Bobwhite quail)	Practically non-toxic	42966902
non-guidemia sindres not notamation for	>2250 ppm (Bobwhite quail)	Practically non-toxic	43610701
Avian Dietary Toxicity /OCSPP 850.	>5620 ppm (Mallard duck)	Practically non-toxic	42608808
	>2200 (White crowned sparrow)	Practically non-toxic	42966903
	>5259 ppm (Mallard duck)	Practically non-toxic	44741501
Freshwater Fish Acute Toxicity, 96 hr	9.12 ppm <sup>1, 2</sup> (Bluegill sunfish)	Moderately toxic	42718202
OCSPP 850.1075	42.56 ppm NOEC = 33.6 ppm (bluegill)	Slightly toxic	43610702
	22.91 ppm <sup>1</sup> (Rainbow trout)	Slightly toxic	42966901
	25.40 ppm <sup>2</sup> (Rainbow trout)	Slightly toxic	43610703
	16.23 ppm <sup>1</sup> (Channel catfish)	Slightly toxic	42699803
	32.25 ppm <sup>1</sup> (Atlantic salmon)	Slightly toxic	42995101
Freshwater Fish Dietary Toxicity,12-hr /Non-Guideline	>1000 mg/kg (striped bass & African cichlid)	No effects on growth or survival	Harpaz & Clark, 2006
Aquatic Freshwater	17.0 mg/L	Slightly toxic	41895207
Invertebrate Toxicity, 48-hr /OCSPP 850.1010	29.1 mg/L	Slightly toxic	42718203
Non-target Plants	>40000 ppm on blueberries, cherries, grapes, and raspberries <sup>3</sup>	Practically non-toxic	42740204

Study Type/OCSPP Guideline	LD <sub>50</sub> /LC <sub>50</sub> /EC <sub>50</sub> Results	Toxicity Category	MRID
Non-target Insects (Honey Bee Contact Toxicity, 48- hr)/OCSPP 850.3020	>25 ug/bee	Practically non-toxic	41623704

Static conditions

Flow-through conditions

Based on visual observations of foliar necrosis/desiccation

#### 4. Risk to Threatened and Endangered Species

A risk assessment was conducted with acute and dietary mammal and avian toxicity data; aquatic organism  $LC_{50}$  and  $EC_{50}$  data; and terrestrial plant and insect (honey bee) data obtained from guideline studies, non-guideline studies, and the open technical literature in conjunction with the label use information for Methyl Anthranilate from the product labels (2011 EPA Methyl Anthranilate Eco Scoping Document and ESA). Based on the results of this assessment, a "No Effect" finding is concluded for threatened and endangered Species. MA undergoes rapid biodegradation in the environment and the Agency's Levels of Concern (LOCs) are not exceeded for listed species.

Mammals: Mammalian acute oral toxicity is >5000 mg/kg. The subchronic (90-day) dietary No Observable Effects Level (NOEL) was >500 ppm. The non-definitive endpoints are respectively approximately 430X and 43X greater than the observed maximum environmental concentrations of 11.7 ppm for MA residues (Avery et. al., 1995) on terrestrial foliage. Based on the data and the Guidance for Using Non-Definitive Endpoints in Evaluating Risks to Listed and Non-listed Animal Species (EPA, 2010), there are no concerns for non-target mammals, including listed species.

<u>Birds</u>: Applications of MA are not expected to affect birds. Based on available avian toxicity data, the acute oral LD50 is >2250 mg/kg, and the sub-acute dietary LC50 is>5620 ppm. The non-definitive endpoints are, respectively, approximately 192X and 480X greater than the observed maximum environmental concentrations of 11.7 ppm for MA residues (Avery et. al., 1995) on terrestrial foliage. Based on the data and the *Guidance for Using Non-Definitive Endpoints in Evaluating Risks to Listed and Non-listed Animal Species* (EPA, 2010), there are no concerns for non-target birds, including listed species.

<u>Fish</u>: Applications of MA are not expected to affect fish. Using the most conservative endpoint for fish in laboratory testing (Bluegill sunfish; 9.12 ppm) and the measured calculated maximum EEC of MA in water (0.44 ppm), the RQ was calculated as 0.019. The RQ is well below the Level of Concern (LOC) for listed species of 0.05.

Aquatic Invertebrates: Applications of MA are not expected to affect aquatic invertebrates. Using the most conservative endpoint for aquatic invertebrates (17.0 ppm) in laboratory testing and the maximum estimated environmental concentration (EEC) of MA in water following a direct spray application to water (0.44 ppm), the RQ was calculated as 0.048. The slightly less than the the listed species LOC of 0.05. When applied at a 10X rate to the surface of an aquaculture pond, the maximum concentration of MA was 4.44 ppm at a depth of 24 inches following seven applications over a two-week period (Dorr et. al., 1998), approximately 4X less than that the most conservative endpoint for aquatic invertebrates (17.0 ppm).

If applied according to EPA-approved label use directions, environmental concentrations of MA in water are not expected to reach concentrations that would be harmful to aquatic invertebrates due to rapid biodegradation, high volatility, and low solubility in water (HSDB, 2004). Based on the low toxicity of MA to aquatic invertebrates (Table 4) and its rapid dissipation in the environment (Avery et. al., 1995; Dorr et. al., 1998; HSDB, 2004), there are no concerns for non-target aquatic invertebrates, included listed species.

Plants: MA is a naturally occurring substance found in many plant species such as corn, sunflowers, grapes (33 ppm) and cherries (35 ppm). It is extremely volatile and degrades rapidly into non-toxic components such as anthranilic acid. It has no known toxic effects when applied exogenously to plants at the proposed rates of application. In a field study using leaves of blueberries, cherries, and grapes, it was demonstrated that non-target terrestrial plants can tolerate >40,000 ppm of MA before exhibiting any observable, but minor foliar desiccation or necrosis (MRID 42740204). Using the most conservative non-definitive endpoint for plants (40000 ppm) and the maximum observable residues on plants following a foliar spray application at the maximum label use rate, the RQ was calculated as 0.002. The RQ is well below any LOC for non-target plants, including listed species.

<u>Insects</u>: The non-target insect contact toxicity  $LD_{50}$  (honey bee) was >25 ug/bee, which is categorized as practically non-toxic. No toxic effects were observed at the highest rate used in laboratory testing. Endogneous levels of MA reported for grapes and cherries are higher than residues measured on foliage (11.7 ppm) following an application at maximum label use rates (Avery et. al., 1995). Honey made from citrus floral sources has been reported to contain from 3.60 to 5.04 mg/kg of MA (Ferreres et al., 1994; White & Bryant, 1996, unpublished study) indicating regular dietary and contact exposure to naturally occurring methyl anthranilate by pollinators. Based on these data, the Agency has no concerns to non-target insects, including listed species.

Based on the fact that MA degrades rapidly and all RQs are less than LOCs for listed species, EPA has determined that MA will have "No Effect" on listed threatened or endangered species or any designated critical habitat.

#### 5. Endocrine Disruptor Screening Program

As required by the Administrator under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) and has begun to implement the screening program that is to be used to test all pesticides in order to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."

FFDCA section 408(p)(4), authorizes the Administrator, by order, to exempt from the requirements of the Estrogenic Substances Screening Program a biologic substance or other substance if a determination is made that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. MA, a bird repellent and naturally occurring ester, found in corn, grapes, cherries and tea, is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP.

The Agency, as part of this preliminary work plan, believes that MA, the active ingredient involved in this registration review case, likely is a substance that would not produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance. As such, pursuant to Section 408(p)(4), EPA will determine in the future whether it can exempt MA from the requirements of the Section 408(p) EDSP. In the event the Agency does determine to exempt this substance from the EDSP, an order will be issued.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

#### not happen A6. Incidents make a police of whote local in beau sign temper and

According to the Agency's Office of Pesticide Programs Incident Data System (IDS), there have been three reported incidents from the use of EPA-registered products containing Methyl Anthranilate. On January 1, 2001 a human respiratory problem was caused by exposure to drift, attributable to misuse by the applicator; no additional information was available concerning this incident. On April 1, 2002, a human miscarriage was attributed to an applicator's misuse of the pesticide inside a store. On May 11, 2004, there was another respiratory problem resulting from exposure to fumes; no additional information was available concerning this incident. The Agency is not requiring more information or a revised risk assessment based on these incidents because none of the preceding reported incidents are attributable to information unknown to the

Agency regarding the nature of Methyl Anthranilate; and all incidents appear to be associated with applicator error. Label language, including the requirement of PPE, for methyl anthranilate products are appropriate and sufficient to protect the users/handlers of these products. The Agency will consider any incident data or comments submitted to this docket in response to this preliminary work plan.

#### D. Timeline

The projected timeline for the Registration Review of Methyl Anthranilate, Case 6056, is shown in Table 5, below.

Table 5. Projected Timeline for the Registration Review of Case 6056

Activities	Estimated Month/Year
Open Public Comment Period for Methyl Anthranilate	September 2011
Close Public Comment Period	November 2011
Issue Final Work Plan (FWP)	March 2012
Open Public Comment Period for Proposed Reg. Review Decision	September 2012
Close Public Comment Period	November 2012
Final Decision	December 2012
Total (years)	1.25

#### E. Guidance for Commenters

The public is invited to comment on EPA's preliminary work plan and rationale. The Agency will consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the case.

#### F. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to MA compared to the general population. Please comment if you are aware of any subpopulations that may have atypical, unusually high exposure compared to the general population.

#### G. Water Quality

MA is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at: http://www.epa.gov/owow/tmdl/. In addition, no Total Maximum Daily Loads (TMDL) have been developed for MA based on information provided at: http://iaspub.epa.gov/tmdl\_waters10/text\_search.tmdl\_search\_form. More information on impaired water bodies and TMDL's can be found at: http://www.epa.gov/owow/tmdl/. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the Office of Pesticide Program's (OPP) Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process (see:

http://www.epa.gov/oppsrrd1/registration\_review/water\_quality\_sop.htm) to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

#### H. Trade Irritants

Through the Registration Review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRL's) or disparities between United States tolerances and MRL's in key export markets, providing as much specificity as possible regarding the nature of the concern. In the case of Methyl Anthranilate (Case 6056), there are currently no established residue tolerances. Additionally, there is no MRL established for MA. Therefore, the Agency does not anticipate that current uses of MA will pose concerns as trade irritants.

### I. Next Steps Next Steps

After the 60-day comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for Case 6056: Methyl Anthranilate.

#### II. FACT SHEET for METHYL ANTHRANILATE

#### A. Background Information

**Registration Review Case Number: 6056** 

PC Code: 128725 CAS #: 134-20-3

Common Name: Methyl Anthranilate

**Synonyms and Abbreviations:** Benzoic Acid, 2-Amino, Methyl Ester, Anthranilic Acid, methyl ester, Methyl-2-amonobenzoate, Methyl o-aminobenzoate, Neroli Oil, Nevoli Oil

and o-Carbomethoxyaniline, MA

First Registered: 1985 Products: 1 MP, 7 EPs

Physical Description: Pale yellow liquid

Mode of Action: Triggers a pain response in the trigemimal nerve of birds (The

trigemimal nerve is located in the head.)

**Use Sites:** For commercial food and non-food uses on agricultural areas, airports, turf, open spaces, landfills, commercial/industrial water impoundments, temporary pools and electrical substations.

Method(s) of Application: Spray and Fogger

Use Limitation: Not be applied to fish-bearing waters

Previous Regulatory Documents: Fact Sheet, Exemption from the Requirement of a

Tolerance

Registration Review Lead: Chris Pfeifer; pfeifer.chris@epa.gov

#### **Products Labels**

Labels for the MA products may be found at: http://oaspub.epa.gov/pestlab1/ppls.home, which is the Office of Pesticide Programs' Pesticide Product Label System (PPLS) website.

#### B. Description of Active Ingredient

MA is a bird repellent registered for use on agricultural sites and on sites where nuisance birds create hazard, sites such as at airports and on turf. It is a naturally-occurring substance found in plants such as corn, grapes, cherries, cocoa and black tea. It is used as a flavoring in candy and sodas and is considered 'Generally Regarded as Safe' (GRAS) by FDA for consumption as a flavoring agent. It is also used in perfumes. No toxic endpoints have been established for MA; and it degrades rapidly into non-toxic components such as anthranilic acid. It is applied as a foliar spray and through fogging. MA has a non-toxic mode of action, repelling birds by causing a pain response in a nerve located in their heads. The pain is temporary, but the birds associate the discomfort with the location and become conditioned to avoid that location. It was exempted from the requirement of a tolerance for use on grapes, blueberries and cherries in 1995 under 40 CFR 180.1143. The exemption was amended

in 2001 to include corn and sunflowers and amended again in 2002 to include all agricultural use sites.

#### C. Use Information

Agency screening estimates MA in 2011 indicate a minimal usage of 1000 pounds of active ingredient on cherries. No other usage data are available.

**Table 6. Products Containing Methyl Anthranilate** 

EPA Reg. #	Registration Name	Company Name	Current Status	% of Active Ingredient
33162-1	AVIAN CONTROL	STONE SOAP CO. INC.	Registered 2010	20
58035-7	REJEX-IT TP-40	CEANNARD INC.	Registered 1994	40
58035-8	REJEX-IT MA	CEANNARD INC.	Registered 1994	98.5
58035-9	REJEX-IT AG-36	CEANNARD INC.	Registered 1994	14.5
58035-15	REJEX-IT FOG FORCE AR20	CEANNARD INC	Registered 2008	20
66550-1	BIRD SHIELD BIRD REPELLENT CONCENTRATE	BIRD SHIELD BIRD REPELLENT CORPORATION	Registered 1995	26.4
72041-2	GOOSE REPELLENT	LIQUID FENCE CO.	Registered 2005	20.72
83359-4	AVEX	IMPEC, INC.	Registered 2009	26.4

<sup>\*</sup> The MP is highlighted.

#### D. Recent Actions

In July 2002, the Agency amended the 1995 exemption from the requirement of a tolerance to include all agricultural crops. A synopsis of the risk assessment supporting that decision can be found in Final Rule - 67 FR 51088, August 7, 2002.

#### E. Product Analysis

The Agency has conducted a review of the available product chemistry data and information for MA. Product chemistry data and information for MA, provided by the registrants, are sufficient to fulfill the respective product chemistry data requirements outlined in 40 CFR 158.2030.

#### F. Human Health Risk Assessment

Meeting the Current Data Requirements: Status

The Agency does not foresee the need to require new data or for a new human health risk assessment for methyl anthranilate. All data requirements as outlined in 40 CFR 158.2050 have been satisfied for methyl anthranilate.

#### **Exposure Assessment**

All occupational and non-occupational risk associated with MA end-use products (EPs) is expected to be insignificant because of the nontoxic mode of action and low exposure resulting from the low application rates of these products.

**Dietary** (Food and Water). Because of low use rates, pre-harvest intervals and rapid degradation, no significant MA residues are expected at harvest (MRIDs 45065102, 45065103, 45065104, 45065105, 43119401). Any residues would be below any naturally occurring levels found in commonly consumed foods such as grapes (MRID 44786301). Further, since MA has shown no mammalian toxicity and is rapidly metabolized in human intestines and liver, no dietary risks are anticipated. Likewise, residues of methyl anthranilateMA are very unlikely to be found in drinking water. In addition to the low use rates and the rapid photodegradation, MA is also prone to microbial degradation (MRID 43119401).

Residential exposure is expected to be minimal via the dermal and inhalation routes due to the largely commercial nature of the use patterns and the low application rates for Methyl Anthranilate EPs with residential uses. The residential labels prescribe a single use per season. Additionally, exposure is anticipated to be limited based on biodegradation and directions requiring household applicators to wear personal protective equipment - protective eyewear, long sleeved shirt and pants.

Occupational exposure is expected to individuals who handle this pesticide through mixing and loading and to those who apply the pesticide. The exposure is expected to be insignificant due to low application rates of these products, rapid biodegradation of the active ingredient and PPE requirements - protective eyewear and long-sleeved shirts and long pants.

#### **Tolerance Exemption**

40 CFR 180.1143: Methyl Anthranilate; exemption from the requirement of a tolerance. Residues of Methyl Anthranilate, a biochemical pesticide, are exempt from the requirement of a tolerance in or on all food commodities, when used in accordance with good agricultural practices. [67 FR 51088, August 7, 2002]

#### G. Environmental Fate and Ecological Risk Assessment

Meeting the Current Data Requirements: Status

The Agency considers the nontarget organisms and environmental fate biochemical data requirements, as outlined in 40 CFR 158.2060, to be satisfied for MA at this time.

#### **Exposure Assessment**

MA is a naturally occurring ester commonly found in fruits. It has a non-toxic mode of action, and is of low toxicity. It has no known toxicity to nontarget plants, mammals, insects and birds; and data confirm that the active ingredient is only slightly toxic to aquatic organisms. A screening level assessment was conducted to evaluate the risks posed by exposure to nontarget organisms. The risk quotients for all nontarget organisms were significantly below any LOC. Although MA is an effective repellent, EPA modeling demonstrates that indirect exposures to plants are not significant enough to elicit a response. The assessment determined that nontarget exposures to MA will have "No Effect" on any currently listed threatened or endangered species or any designated critical habitat.

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