Proposed Registration Decision PRD2011-11

Methyl Anthranilate

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Overview

Proposed Registration Decision for Methyl Anthranilate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Methyl Anthranilate Technical and Rejex-It Migrate for Agriculture and Turf Bird Repellent, containing the technical grade active ingredient methyl anthranilate, to repel a variety of birds in cherries and blueberries, as well as Canada geese on turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of methyl anthranilate and Rejex-It Migrate for Agriculture and Turf Bird Repellent.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on methyl anthranilate, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on methyl anthranilate, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Methyl Anthranilate?

Methyl anthranilate repels birds when it comes in contact with eyes, nostrils and mouths. It has been registered in Canada to repel Canada geese from turf since 2000. In addition to this use, the end-use product Rejex-It Migrate for Agriculture and Turf Bird Repellent is also used to repel birds from cherries and blueberries.

Health Considerations

Can Approved Uses of Methyl Anthranilate Affect Human Health?

Methyl anthranilate is unlikely to affect your health when used according to label directions.

Methyl anthranilate is a natural component in a variety of plants and fruits. Potential exposure to methyl anthranilate may occur when handling and applying the end-use product or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, Methyl Anthranilate Technical, is of low acute toxicity by the oral and dermal routes and is mildly irritating to the eyes, but is not an irritant or potential sensitizer to the skin. Methyl Anthranilate Technical is expected to be of low acute toxicity via the pulmonary route. Therefore, precautionary statements alerting users to the eye irritation potential are required on the labels for Methyl Anthranilate Technical.

The end-use product, Rejex-It Migrate for Agriculture and Turf Bird Repellent, is of low acute toxicity by the oral and dermal routes, is minimally irritating to the eyes, and is not an irritant or potential sensitizer to the skin. Rejex-It Migrate for Agriculture and Turf Bird Repellent is expected to be of low acute toxicity via the pulmonary route.

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Requests to waive short-term dermal toxicity, prenatal development toxicity and genotoxicity studies were accepted by the PMRA. Waivers were based on the low toxicity profile, the rapid metabolism into excreted byproducts and on the strength of evidence that there is little indication of short or long term toxic effects resulting from methyl anthranilate's long history as an additive in food products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

At the time of harvest, the residue level of crops treated with methyl anthranilate is not expected to exceed the natural levels occurring in commonly consumed foods, such as grapes. Therefore, no crop residue data are needed and the establishment of an MRL will not be required.

While good hygiene practices, such as washing food prior to eating, are not considered in the assessment for the registration of a food-use pesticide, they are recommended as any remaining residues are likely to be further decreased by washing and possible cooking of treated crop before eating.

Occupational Risks from Handling Rejex-It Migrate for Agriculture and Turf Bird Repellent

Occupational risks are not of concern when Rejex-It Migrate for Agriculture and Turf Bird Repellent is used according to label directions, which include protective measures.

Occupational exposure to individuals mixing, loading, or applying Rejex-It Migrate for Agriculture and Turf Bird Repellent is not expected to result in unacceptable risk when the product is used according to label directions.

Inhalation and dermal exposures are likely for occupational workers and commercial applicators. Anyone entering the sprayed areas before the spray is dried may be exposed dermally. Therefore, personal protective equipment and a restricted entry statement (i.e., until sprays have dried) are required on the end-use product label to mitigate such exposure concerns.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible if the precautionary label statements are observed.

Precautionary (e.g., wearing of personal protective equipment) statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Methyl Anthranilate Is Introduced Into the Environment?

Environmental risks to non-target organisms are not of concern when Rejex-It Migrate for Agriculture and Turf Bird Repellent is used according to label directions, which include precautionary label statements and buffer zones.

Methyl anthranilate enters the environment when it is sprayed on turf, cherries, and blueberries to repel birds. It is not expected that methyl anthranilate will pose a risk to terrestrial species given its low toxicity to terrestrial organisms. However, methyl anthranilate has been shown to cause adverse effects in aquatic organisms. Because of the high application rates used in cherry and blueberry, a potential for concern for aquatic organisms has been identified in these crops should methyl anthranilate enter the aquatic environment through spray drift. Methyl anthranilate will not likely reach surface water through run-off or leach through the soil profile and contaminate groundwater due to its rapid dissipation.

Value Considerations

What Is the Value of Rejex-It Migrate for Agriculture and Turf Bird Repellent

Methyl anthranilate repels birds such as American robins, house finches, sparrows and European starlings from blueberries and cherries, and Canada geese from turf. It would be an additional product to use in a bird control program.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Rejex-It Migrate for Agriculture and Turf Bird Repellent to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words "CAUTION EYE IRRITANT" and the statement "May irritate eyes. Avoid contact with eyes." are present on the principal and the secondary display panels, respectively, of the label for Methyl Anthranilate Technical.

The precautionary statement "Avoid contact with skin, eyes or clothing" is present on the secondary display panel of the label for Rejex-It Migrate for Agriculture and Turf Bird Repellent. Also the label recommends the product be mixed outside or in a ventilated area.

The label for Rejex-It Migrate for Agriculture and Turf Bird Repellent requires applicators and other handlers to wear long-sleeved shirt and long pants, waterproof gloves, shoes plus socks. To prevent post-application exposure, the label for Rejex-It Migrate for Agriculture and Turf Bird Repellent states to "allow material to dry before permitting human activity in the treated areas".

To prevent bystander exposure when used on golf courses and municipal parks, the label restricts the use of Rejex-It Migrate for Agriculture and Turf Bird Repellent by stating "Do not apply the end-use product to residential lawns or recreational areas of parks."

Environment

To mitigate the risk to aquatic organisms from spray drift, buffer zones up to five metres for cherry and two metres for blueberry must be observed. No buffer zones are required for turf uses, as the application rate is lower and is not expected to cause adverse effects to non target aquatic organisms.

Next Steps

Before making a final registration decision on methyl anthranilate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

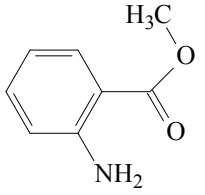
When the PMRA makes its registration decision, it will publish a Registration Decision on methyl anthranilate (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Methyl Anthranilate

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Methyl Anthranilate
Function	Bird repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Methyl 2-aminobenzoate
2. Chemical Abstracts Service (CAS)	2-Aminobenzoic acid, methyl ester
CAS number	134-20-3
Molecular formula	$C_8H_9NO_2$
Molecular weight	151.17
Structural formula	
Purity of the active ingredient	Methyl anthranilate at 99.7%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product— Methyl Anthranilate Technical

Property	Result
Colour and physical state	Pale yellow, bluish fluorescent solid
Odour	Reminiscent of concord grape odour
Melting range	23.8°C (product is a liquid above this temperature)
Boiling point	256°C

Property	Result
Specific gravity at 25°C	1.161-1.169
Vapour pressure at 20°C	Not required for food grade methyl anthranilate
Ultraviolet (UV)-visible spectrum	Not required for food grade methyl anthranilate
Solubility in water at 20°C	0.29 g / 100 mL
Solubility in organic solvents	Soluble in most fixed oils and propylene glycol.
n-Octanol-water partition cofficient (K_{ow})	log K_{ow} = 1.62
Dissociation constant (pK_a)	Not required for food grade methyl anthranilate
Stability (temperature, metal)	Not required for food grade methyl anthranilate

End-Use Product— Rejex-It Migrate for Agriculture and Turf Bird Repellent

Property	Result
Colour	Blue tan
Odour	Reminiscent of concord grape odour
Physical state	Thick slurry
Formulation type	Suspension
Guarantee	14.5%
Container material and description	3.78 – 9.46 L, plastic containers
Density	1.02 g/L
pH of 1% dispersion in water	5.6
Oxidizing or reducing action	The product does not contain any oxidizing or reducing components.
Storage stability	Outstanding requirement
Corrosion characteristics	The product is not corrosive to the container material.
Explodability	The product is not potentially explosive.

1.3 Directions for Use

Rejex-It Migrate for Agriculture and Turf Bird Repellent repels birds, including American robins, house finches, sparrows and European starlings, in cherries at 230 L product/ha (33 kg a.i./ha) without surfactant and in blueberries at 43-56 L product/ha (6.3 - 8.3 kg a.i./ha) with a non-ionic surfactant. The product is to be sprayed diluted with water using conventional ground application equipment. Application is to start just before fruit ripening and the product may be applied as necessary.

Rejex-It Migrate for Agriculture and Turf Bird Repellent also repels Canada geese from golf courses and municipal parks when applied using conventional ground application equipment using a dilution of one part product to 19 parts water. For turf grass at a height of approximately 2.5 cm, the diluted product is applied at a rate of 260 L/ha. The product may be re-applied after three days if warranted by Canada goose activity.

1.4 Mode of Action

Methyl anthranilate repels birds by irritating the eyes, nostrils and the mouths of birds.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The method provided for the analysis of the active ingredient and the impurities in Methyl Anthranilate Technical has not been validated. However, since this product meets the food grade criteria, the validation of the analytical method is not required.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for methyl anthranilate consisting of Tier I toxicity studies and waiver rationales was conducted. The scientific quality of the data is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure resulting from the intended use of this pest control product.

Acute toxicity (oral and dermal), irritation (ocular and dermal), and sensitization studies were submitted on Methyl Anthranilate Technical and Rejex-It Migrate for Agriculture and Turf Bird Repellent. These studies (Appendix 1, Tables 1 and 2) and information available from published literature were used to assess the toxicological effects of both the technical grade active ingredient and the end-use product.

Methyl Anthranilate Technical was of low acute toxicity by the oral route in rats and by the dermal routes in rabbits. The available acute toxicity information obtained from published literature supports low toxicity by these routes.

In irritation studies on rabbits, Methyl Anthranilate Technical was mildly irritating to the eye and not irritating nor sensitizing to the skin. The signal words "CAUTION EYE IRRITANT" that is on the principal panel of the proposed label for the technical grade active ingredient should remain.

A request to waive an inhalation study for Methyl Anthranilate Technical and for Rejex-It Migrate for Agriculture and Turf Bird Repellent was based on an assumption that pulmonary exposure by handlers would be minimized through the wearing of a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) as stated on the proposed label. However based on the U.S. EPA review of an acute inhalation study, Methyl Anthranilate Technical was determined to be of low toxicity by the inhalation route of exposure. As such no precautionary word statements or signal words are required on the label for Methyl Anthranilate Technical and for Rejex-It Migrate for Agriculture and Turf Bird Repellent.

Rejex-It Migrate for Agriculture and Turf Bird Repellent was of low acute toxicity by the oral route in rats and by the dermal routes in rabbits. The available acute toxicity information obtained from published literature supports low toxicity by these routes.

In irritation studies on rabbits, Rejex-It Migrate for Agriculture and Turf Bird Repellent was minimally irritating to the eye and not irritating nor sensitizing to the skin. No precautionary label statements are required. Consequently, neither irritation nor sensitizing signal words are required on the product label.

Methyl anthranilate is rapidly metabolized in the human intestine and liver and the by-products are excreted. Methyl anthranilate is hydrolyzed to an alcohol and either anthranilic acid or an N-alkyl anthranilic acid. In humans, anthranilic acid is a normal metabolite and is excreted in the urine.

Although a short-term toxicology study was not submitted to the PMRA, a short-term oral study in the rat (reviewed by the Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives) was reported to show no adverse effects. With the low toxicity profile seen in the acute studies on both the technical and end-use products, with the rapid metabolism of methyl anthranilate, and with the lack of reported toxicity in the published scientific literature, methyl anthranilate is not known or suspected of being carcinogenic, genotoxic, neurotoxic or a developmental/reproductive toxic compound. Therefore, requests to waive short-term and chronic toxicology studies were accepted.

3.2 Occupational and Bystander Risk Assessment

3.2.1 Use Description /Exposure Scenario

The commercial use of Rejex-It Migrate for Agriculture and Turf Bird Repellent is a spray application on cherries, blueberries and turf to repel bird species (including Canada geese, American robins, European starlings, sparrows, and house finches). Rejex-It Migrate for Agriculture and Turf Bird Repellent is to be applied by a pump sprayer or a power-blast sprayer at rates of 13L/ha, 230L/ha and 43–56L/ha to turf, cherries and blueberries, respectively. Application to fruit is proposed just before fruit ripening and may be applied as necessary.

3.2.2 Mixer, Loader and Applicator Exposure and Risk Assessment

Occupational exposure to Rejex-It Migrate for Agriculture and Turf Bird Repellent is expected to be short term and predominantly by the inhalation and dermal routes when workers are exposed during loading and mixing and when applicators are exposed to spray drift or to freshly treated wet plant surfaces. Occupational exposure to Rejex-It Migrate for Agriculture and Turf Bird Repellent will be minimal if workers follow label recommendations. The label has a number of exposure reduction statements (e.g., hygiene statement) to protect workers against any unnecessary risk from exposure. When handling and/or applying Rejex-It Migrate for Agriculture and Turf Bird Repellent and during clean-up/maintenance activities workers must wear long-sleeved shirt and long pants, waterproof gloves, shoes plus socks, safety glasses and dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Also, the Rejex-It Migrate for Agriculture and Turf Bird Repellent label requires that handlers and applicators avoid contact of the spray solution with skin, eyes or clothing and that mixing of the end-use product be performed in a well ventilated area.

Significant risk from exposure to Rejex-It Migrate for Agriculture and Turf Bird Repellent for the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities, is not anticipated due to the low toxicity of Rejex-It Migrate for Agriculture and Turf Bird Repellent and reduced occupational exposure when label directions are followed.

3.2.3 Bystander Exposure and Risk Assessment

Bystander exposure is expected to be negligible to non-existent because the product is to be applied by commercial applicators, and the end-use product label states to allow material to dry before permitting human activity in treated areas.

3.2.4 Post-Application Exposure

Post-application activities associated with Rejex-It Migrate for Agriculture and Turf Bird Repellent when used in cherry and blueberry applications include harvesting crop by workers, and when used on turf, entry by individuals using the golf courses and municipal parks. To prevent post-application dermal exposure from wet surfaces, the Rejex-It Migrate for Agriculture and Turf Bird Repellent label states to allow material to dry before permitting human activity in the treated areas.

3.3 Food Residue Exposure Assessment

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

Methyl anthranilate is volatile and is expected to transform rapidly when exposed to ultraviolet light and elevated temperatures. At the time of harvest, the residue level of crops treated with methyl anthranilate is not expected to exceed the natural levels occurring in commonly consumed foods, such as grapes. Therefore, no crop residue data are needed and the establishment of an MRL will not be required.

While good hygiene practices, such as washing food prior to eating, are not considered in the assessment for the registration of a food-use pesticide, they are recommended as any remaining residues are likely to be further decreased by washing and possible cooking of treated crop before eating.

Dietary risk to humans from the proposed use of Rejex-It Migrate for Agriculture and Turf Bird Repellent is not of concern. There is reasonable certainty that no harmful effects will result from dietary exposure to residues of methyl anthranilate based on its low toxicity and rapid metabolism in mammals.

Methyl anthranilate is exempt from the requirement of a food tolerance in the United States and there is no Codex MRL for this active ingredient.

3.4 Incident Reports Related to Human and Animal Health

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Incidents from Canada and the United States were searched and reviewed for products containing methyl anthranilate.

As of June 10, 2011, there were no health-related incident reports submitted to the PMRA, nor summarized by the U.S. EPA or the California Department of Pesticide regulation, for end-use products containing methyl anthranilate.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Methyl anthranilate will enter the terrestrial environment when it is sprayed on turf, cherries and blueberries to repel birds. Even though methyl anthranilate will not be applied directly to water, this substance could reach surface water through spray drift. Once in the environment, methyl anthranilate will dissipate rapidly via biotransformation. Available information on the biotransformation of methyl anthranilate indicates that this compound will dissipate with a half-life of less than two days. Other laboratory tests showed that hydrolysis and phototransformation are not important routes of transformation. Because of its rapid dissipation, methyl anthranilate will not likely reach surface water through run-off or leach through the soil profile and contaminate groundwater.

4.2 Environmental Risk Characterization

4.2.1 Risks to Terrestrial Organisms

The following information was taken into consideration when characterizing the risk of methyl anthranilate to non-target terrestrial organisms (see Appendix 1, Table 3):

- data on the acute toxicity of methyl anthranilate to one mammal and two bird species
- data on the acute toxicity of methyl anthranilate to honeybees
- waiver request for terrestrial vascular plants

Based on a qualitative risk assessment, it was determined that limited risk to non-target vertebrate and invertebrate terrestrial species is expected from the use of methyl anthranilate, as this substance is not acutely toxic to non-target terrestrial organisms. Furthermore, minimal exposure to vertebrate and invertebrate terrestrial organisms is expected when considering factors such as the repellent properties of methyl anthranilate, the application timing (not applied during bloom) and the rapid dissipation of methyl anthranilate in the environment.

Methyl anthranilate may cause phytotoxicity in certain crops (refer to Section 5.0 of this document). However, it is not expected that the overall health of terrestrial habitats would be affected by drift generated from uses of Rejex-It Migrate for Agriculture and Turf Bird Repellent. Observed phytotoxic effects are slight (brown spots on the leaves) and are not likely to adversely affect the overall growth of non-target plants. Other information provided by the applicant has indicated that the phytotoxicity of methyl anthranilate is known to vary depending on the formulation. Based on this information, minimal phytotoxicity is expected with the formulations used for Rejex-It Migrate for Agriculture and Turf Bird Repellent. In addition, the registrant reported that no phytotoxic effects are observed when methyl anthranilate is applied on other crops such as sunflower, sweet corn and wild rice. Finally, this conclusion is further supported by the fact that no incidents of crop damage have been reported in Canada and in the United States for methyl anthranilate (see Section 4.2.3 of this document).

4.2.2 Risks to Aquatic Organisms

The following information was taken into consideration when characterizing the risk of methyl anthranilate to non-target aquatic organisms (see Appendix 1, Table 3):

- data on the acute toxicity of methyl anthranilate to one invertebrate species
- data on the acute toxicity of methyl anthranilate to two fish species

Studies on the acute toxicity of methyl anthranilate to aquatic organisms have indicated that adverse effects can occur when aquatic invertebrates and fish are exposed to methyl anthranilate. A quantitative assessment was thus carried out to characterize the potential risk to aquatic organisms.

The environmental risk assessment integrates environmental exposure and ecotoxicology information by comparing estimated exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of the pesticide of interest in various environmental media (i.e., water in the context of this assessment). The EECs are estimated using standard models which take into consideration the application rate, chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information typically includes acute and chronic toxicity data for various organisms; only acute information was considered for methyl anthranilate given its short half-life. Acute toxicity endpoints used in the risk assessment are adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift and run-off to non-target habitats) and might consider different toxicity endpoints. Refinements may also include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

Risk quotients calculated at the screening level for methyl anthranilate did not exceed the level of concern for uses on turf (Appendix 1, Table 4). However, a potential for concern was identified for uses of methyl anthranilate on cherries and blueberries given the higher application rate for these crops. The level of concern was exceeded for freshwater fish (use in cherries) and for amphibians (use in cherries and blueberries). The level of concern was not exceeded for aquatic invertebrates.

Where the risk quotient exceeded the level of concern at the screening level, the risk was refined in order to consider drift to non-target habitats. Due to the rapid dissipation of methyl anthranilate, runoff to water bodies is not expected to occur and the risk from this exposure route was not further characterized.

To assess the risk from spray drift, the expected environmental concentrations in water from the screening level assessment were adjusted according to the projected percent drift that would be deposited one metre downwind from the site of application. When considering drift, risk quotients exceed the level of concern (Appendix 1, Table 5). Adverse effects to fish and amphibians are therefore expected should spray drift reach aquatic habitats when methyl anthranilate is applied to cherries and blueberries. Buffer zones are required to mitigate this risk.

4.2.3 Incident Reports

Incidents from Canada and the United States were searched and reviewed for products containing methyl anthranilate. As of May 30, 2011, no incident reports were found for this active ingredient. Specific information regarding the mandatory reporting system regulations that came into force April 26, 2007, under the *Pest Control Products Act* can be found at http://canadagazette.gc.ca/partII/2006/20061115/html/sor260-e.html.

5.0 Value

5.1 Effectiveness Against Pests

Blueberries:
In a small scale efficacy trial conducted in Missouri, the most common bird species present were American robins (76%) and European starlings (11%). Additional bird species identified in the trial included house finches and mourning doves. This trial demonstrated that Rejex-It Migrate for Agriculture and Turf Bird Repellent applied at 6.27 kg a.i./ha (5.6 lbs a.i./acre) repels birds from blueberries when used with a non-ionic surfactant. Efficacy began to decline immediately after treatment with the amount of undamaged fruit being 94% at three days after treatment to 68% at ten days after treatment. A second trial conducted in Washington demonstrated that methyl anthranilate reduced damage by 63% compared to the untreated control plots.

A third study conducted in Washington, Oregon and Michigan demonstrated no difference between methyl anthranilate treated blueberries and untreated blueberries, but these results may have been due to the absence of a spreader/sticker. Additional value information indicates that methyl anthranilate is volatile and, thus, the duration of effectiveness for this product to repel birds may be short. As such, Rejex-It Migrate for Agriculture and Turf Bird Repellent will need to be applied multiple times in a season and be used in conjuction with other methods of repelling birds.

Methyl anthranilate is known to cause phytotoxicity in plants. No phytotoxic effects were noted in the efficacy trial conducted in Missouri. Phytotoxicity (i.e., foliar discolouration and burning) was observed in three trials, but the formulations used in these trials are unknown. One of the trials demonstrated that the formulation plays a role in the severity of phytotoxicity observed in plants. To mitigate the potential for phytotoxicity, a warning statement on the potential for phytotoxicity is required on the product label.

Cherries:

In a trial conducted in New York, the most common bird species present were house finches (43%), American robins (12.5%) and sparrows (17.9%). Other species included cardinals, gray catbirds, Eastern mockingbirds and European starlings. The trial demonstrated that Rejex-It for Agriculture and Turf Bird Repellent applied at 26.8 kg a.i./ha resulted in significantly less bird damage to fruit compared to the untreated control for the entire duration of the trial, which was 13 days.

In a second efficacy trial conducted in Washington, there were three components: i) a study on early ripening varieties of cherry; ii) a small scale study on Bing cherries and iii) an operational trial on Bing cherries.

In the early ripening varieties of cherry trial, American robins were present in the orchard. A single application of methyl anthranilate reduced bird damage by 13% whereas, two treatments applied 7-days apart reduced overall bird damage by 54%.

In the small scale trial on Bing cherries, American robins were present in the orchard. Cherry trees were treated twice with a re-application interval of five days or ten days. At harvest (22 days post-treatment), bird damage was 25% in the untreated control. Bird damage was reduced by 74% and 98% compared to the untreated control when methyl anthranilate was applied at five and ten day re-application intervals, respectively.

In the operational trial on Bing cherries, robins, starlings and cedar waxwings were present in the orchard. No bird damage to fruit was noted prior to or 7-days after the first application. By the 14th day, bird damage to fruit had increased to 5.34% in the untreated control compared to 0.52% in the treated trees. At harvest 15-days later, the bird damage estimate had increased to 7.67% in the untreated control and 4.45% in the methyl anthranilate treatment. Total harvested weight of the treated trees was 43% greater than the untreated trees.

Leaf discolouration and leaf burning were noted in a laboratory trial conducted in Washington but no phytotoxicity concerns were raised in the trial conducted on cherries in New York. Given that there is a potential for phytotoxicity in cherries and a limited data set, a warning statement on the label of Rejex-It for Agriculture and Turf Bird Repellent is required.

5.1.1 Acceptable Efficacy Claims

Rejex-It Migrate for Agriculture and Turf Bird Repellent repels birds, including American robins, house finches, sparrows and European starlings, in cherries at 230 L product/ha (33 kg a.i./h) without surfactant and in blueberries at 43-56 L product/ha (6.3 - 8.3 kg a.i./ha) with a non-ionic surfactant. The product also repels Canada geese from turf grass on golf courses and municipal parks using a dilution of one part product to 19 parts water at a rate of 260 L dilution/ha in turf grass approximately 2.5 cm tall.

5.2 Sustainability

5.2.1 Survey of Alternatives

There are no alternative pest control products registered to repel birds from blueberries and cherries. Another product containing methyl anthranilate (Avigon 14.5 Canada Goose Repellent for Turf; Registration number 26452; 14.5% methyl anthranilate) is registered to repel Canada geese from turf grass on golf courses and municipal parks. Alternative methods for repelling birds include habitat modification, netting, spikes, bird scaring devices without sound (e.g., scare-eye balloons, predatory bird silhouettes, flashtape), bird scaring devices with sound (e.g., propane canons, electronic scaring devices, pyrotechnics) and falconry.

5.2.2 Compatibility with Current Management Practices Including Integrated Pest Management

A variety of techniques to reduce damage caused by birds is typically used to repel birds from blueberries and cherries. Rejex-It Migrate for Agriculture Migrate and Turf Bird Repellent would be an additional product to use in a program used to repel birds from these crops. Rejex-It Migrate for Agriculture and Turf Bird Repellent should be used in conjunction with other techniques used to repel birds because the duration of effectiveness for this product to repel birds may be short.

5.2.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Resistance to methyl anthranilate is not expected to occur. However, the effectiveness of this product will depend on a variety of external factors such as the bird species, habituation, availability of other food sources and the potential to be washed off by rain. In one of the submitted efficacy trials, it was reported that birds continued to consume treated blueberries by piercing the exterior of the treated skin and then eating the fruit inside.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, methyl anthranilate and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Methyl anthranilate does not meet the Track 1 criteria. Methyl anthranilate is a naturally occurring substance that is not persistent in the environment and is not expected to be bioaccumulative.
- Methyl anthranilate is not expected to form transformation products that are of concern.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Technical grade methyl anthranilate and the end-use product Rejex-It Migrate for Agriculture and Turf Bird Repellent do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

8 DIR2006-02, PMRA Formulants Policy.

7.0 Summary

7.1 Human Health and Safety

The available information for methyl anthranilate is adequate to qualitatively identify the toxicological hazards that may result from human exposure to methyl anthranilate. Methyl anthranilate is of low acute toxicity by oral and dermal routes. It is mildly irritating to eyes, but is not a skin irritant or a potential skin sensitizer.

Occupational exposure to Rejex-It Migrate for Agriculture and Turf Bird Repellent is expected to be minimal if the precautionary statements and recommended personal protective equipment on the product label, which are intended to minimize worker exposure, are observed. Bystander exposure is likely to be negligible. Post-application exposure can be minimized by restricted entry.

The dietary risk due to exposure to methyl anthranilate from the use of the proposed end-use product is considered negligible. The PMRA does not require an MRL for methyl anthranilate.

7.2 Environmental Risk

Methyl anthranilate may pose a risk to non-target aquatic organisms. Buffer zones up to five metres are required to protect sensitive aquatic habitats from spray drift.

7.3 Value

Rejex-It Migrate for Agriculture and Turf Bird Repellent repels birds, including American robins, house finches, sparrows and European starlings, in cherries at 230 L product/ha (33 kg a.i./h) without surfactant and in blueberries at 43-56 L product/ha (6.3 - 8.3 kg a.i./ha) with a non-ionic surfactant. The product also repels Canada geese from turf grass on golf courses and municipal parks using a dilution of one part product to 19 parts water at a rate of 260 L dilution/ha in turf grass approximately 2.5 cm tall.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Methyl Anthranilate Technical and Rejex-It Migrate for Agriculture and Turf Bird Repellent, containing the technical grade active ingredient methyl anthranilate, to repel a variety of birds in cherries and blueberries, as well as Canada geese on turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
cm^2	centimetre(s) squared
EEC	estimated environmental exposure concentrations
g	gram(s)
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
lbs	pound(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose to 50%
LOC	level of concern
MAS	maximum average score for 24, 48 and 72 hours
mg	milligram(s)
MIS	maximum irritation score
mL	millilitre(s)
MRL	maximum residue limit
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
RQ	risk quotient
TSMP	Toxic Substances Management Policy
U.S. EPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Acute Toxicity and Irritative Effects of Methyl Anthranilate Technical (98.5% Methyl Anthranilate)

Study Type	Species, Strain and Doses	Results	Significant Effects and Comments	Reference
Acute toxicity and irritative effects of Methyl Anthranilate				
Acute Oral toxicity 14-day observation	Rat- Crl: CD®BR (5/sex) A single oral dose of Rejex-it MA (98.5 % a.i.) undiluted by gavage at doses of 1000, 3000, and 5000 mg/kg bw for each of males and females.	LD_{50} (combined) = 3288 mg/kg bw LD_{50} (♀) = 3000 mg/kg bw LD_{50} (♂) = 3633 mg/kg bw **Low Toxicity**	All mortality occurred within two days of test material administration. Animals treated that died during testing showed dark brown areas of variable size in the glandular mucosa of the stomach.	1662480
Acute Dermal toxicity	Rabbit - Hra: (New Zealand White) SPF (5/sex) 14-day observation 24 hours to approximately 10% of the body surface at doses of 2,000 mg/kg bw	LD_{50} >2,000 mg/kg bw (Males and Females) **Low Toxicity**	Slight erythema and edema seen at initial exposure, returning to normal by day 14. No mortalities. No effect on body weight gain. No lesions seen from gross necropsy.	1865167
Inhalation	Waver rationale: pulmonary exposure will not result in toxic concentrations as the proposed label will require handlers to wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). However, an inhalation study for the technical grade active ingredient was submitted to the U.S. EPA, where the technical grade active ingredient was assessed to be of low toxicity such that the label did not require the wearing of a respirator. **Low Toxicity**			1865168
Eye Irritation	Rabbit - Hra: (New Zealand White) SPF (3/sex) 0.1 mL of methyl anthranilate into conjunctival sac 3-Day observation period post-exposure	MIS= 16.83/110 (at 1 hour) **Mildly irritating**	All observed effects were completely resolved by 72 hours after exposure.	1662483

Study Type	Species, Strain and Doses	Results	Significant Effects and Comments	Reference
Dermal Irritation	Rabbit- Hra: (New Zealand White) SPF (3/sex) 0.5 mL Rejex-It MA for 4 hours on 6.25 cm^2	Neither erythema nor edema observed **Not a dermal irritant**	None	1865170
Dermal Sensitization	Guinea pig- Haz: (Dunkin Hartley) fBR (8 ♀/ 20 ♂) using Buehler method	**Not a dermal sensitizer**	None	1662485

Table 2 Acute Toxicity and Irritative Effects of Rejex-It Migrate for Agriculture and Turf Bird Repellent (14.5% Methyl Anthranilate)

Study Type	Species, Strain, and Doses	Results	Significant Effects and Comments	Reference
Acute toxicity and irritative effects of Rejex-It Migrate for Agriculture and Turf Bird Repellent				
Acute Oral toxicity 14-day observation	Rat - Crl: CD®BR (5/sex) A single oral dose of Rejex-it Migrate (14.5 % a.i.) undiluted by gavage at one dose of 5000 mg/kg bw for each of males and females.	LD_{50} (♀♂) > 5000 mg/kg bw **Low Toxicity**	No treatment related clinical signs or necropsy findings. No mortality	1662589
Acute Dermal toxicity 14-day observation	Rabbit - Hra: (New Zealand White) SPF (5/sex) 24 hour exposure to a dose of 2,000 mg/kg bw Rejex-it Migrate applied at a rate of 0.05 g/cm^2	LD_{50} >2,000 mg/kg bw (♀♂) **Low Toxicity**	Dermal irritation showed slight to moderate erythema and slight edema, atonia and desquation. No mortalities. No effect on body weight gain. No lesions seen from gross necropsy.	1662590
Inhalation	Waver rationale: pulmonary exposure will not result in toxic concentrations as the proposed label will require handlers to wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). However, an inhalation study for the technical grade active ingredient was submitted to the U.S. EPA, where the technical grade active ingredient was assessed to be of low toxicity such that the label did not require the wearing of a respirator. **Low Toxicity**			1662591

Study Type	Species, Strain, and Doses	Results	Significant Effects and Comments	Reference
Eye Irritation 3-Day study	Rabbit – Hra: (New Zealand White) SPF (6 ♂) 0.1 mL of Rejex-It Migrate into conjunctival sac	MIS= 1.67/110 (at one hour) MAS= 0.11/110 (24, 48, 72 h) **Minimally irritating**	All observed effects were completely resolved by 48 hours after exposure.	1662592
Dermal Irritation 4-Day study	Rabbit- Hra: (New Zealand White) SPF (3/sex) 0.5 mL of Rejex-It Migrate for four hours to 6.25 cm^2 of intact skin	MIS= 0/8 (at one hour) **Not a dermal irritant**	None	1662593
Dermal Sensitization	Guinea pigs- Haz: (Dunkin Hartley) BR (10 ♂) using Buehler method	**Not a dermal sensitizer**	None	1662594

Table 3 Acute Toxicity to Non-Target Species

Organism	Test	Toxicity	Reference
Terrestrial organisms			
Honeybees (*Apis mellifera*)	Contact	LD_{50} > 25 µg a.i./bee	1662498
Bobwhite quail (*Colinus virginianus*)	Oral	LD_{50} > 2250 mg a.i./kg bw	1662501
Mallard duck (*Anas platyrhynchos*)	Dietary	LC_{50} > 5000 mg a.i./kg diet	1662506
Rat	Oral	LD_{50} = 3288 mg a.i./kg bw/day	1662480
Terrestrial vascular plants	Waiver request submitted by applicant.		1662508, 1662509
Aquatic organisms			
Water fleas (*Daphnia magna*)	48-hour	LC_{50} = 31.3 mg a.i./L	1662499
Rainbow trout (*Onchorynchus mykiss*)	96-hour	LC_{50} = 25.4 mg a.i./L	1971704
Bluegill sunfish (*Lepomis macrochirus*)	96-hour	LC_{50} = 42.6 mg a.i./L	1662500

Table 4 Screening Level Risk Assessment on Non-target Species

Organism	Toxicity	Applications [a]	EEC [a]	RQ [b]
Turf				
Invertebrates	Daphnia LC_{50}/2: 15.6 mg a.i./L	1x	80 cm: 0.24 mg a.i./L	0.02
		2x	80 cm: 0.31 mg a.i./L	0.02
Fish	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	80 cm: 0.24 mg a.i./L	0.09
		2x	80 cm: 0.31 mg a.i./L	0.12
Amphibians	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	15 cm: 1.27 mg a.i./L	0.50
		2x	15 cm: 1.67 mg a.i./L	0.66
Cherry				
Invertebrates	Daphnia LC_{50}/2: 15.6 mg a.i./L	1x	80 cm: 4.13 mg a.i./L	0.26
		10x	80 cm: 6.02 mg a.i./L	0.38
Fish	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	80 cm: 4.13 mg a.i./L	1.62
		10x	80 cm: 6.02 mg a.i./L	2.37
Amphibians	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	15 cm: 22.0 mg a.i./L	8.66
		10x	15 cm: 32.1 mg a.i./L	12.6
Blueberry				
Invertebrates	Daphnia LC_{50}/2: 15.6 mg a.i./L	1x	80 cm: 1.04 mg a.i./L	0.07
		10x	80 cm: 1.51 mg a.i./L	0.10
Fish	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	80 cm: 1.04 mg a.i./L	0.41
		10x	80 cm: 1.51 mg a.i./L	0.59
Amphibians	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	15 cm: 5.53 mg a.i./L	2.18
		10x	15 cm: 8.08 mg a.i./L	3.18

[a] The expected environmental concentrations (EEC) represents the exposure from a direct application to a water body (depth varies according to organism of interest). EECs were calculated considering both a single application and also a maximum number of applications. Two applications was chosen as a maximum for turf based on labelled directions for use. Ten applications was chosen as a maximum for cherry and blueberry based on an exploratory analysis (not shown) indicating that the cumulative application rate stabilized after ten applications (the label does not specify a maximum number of applications for these crops). Repeat applications were assumed to be made at a 3-day interval and it was considered that methyl anthranilate dissipated with a half-life of 1.8 days between applications.

[b] Risk Quotient = Exposure/Toxicity. Shaded cells indicate that the risk quotient exceeds the level of concern (LOC=1)

Table 5 Refined Risk Assessment on Non-Target Species (Drift)

Organism	Toxicity	Applications	EEC (59% drift) [a]	RQ [b]
Cherry				
Fish	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	80 cm: 2.43 mg a.i./L	0.96
		10x	80 cm: 3.55 mg a.i./L	1.40
Amphibians	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	15 cm: 13.0 mg a.i./L	5.11
		10x	15 cm: 18.9 mg a.i./L	7.46
Blueberry				
Amphibians	Rainbow trout LC_{50}/10: 2.54 mg a.i./L	1x	15 cm: 3.26 mg a.i./L	1.28
		10x	15 cm: 4.77 mg a.i./L	1.88

[a] The EEC was adjusted according to the projected percent drift that would be deposited 1m downwind from the site of application (59% for late season airblast applications with fine spray quality).

[b] Risk Quotient = Exposure/Toxicity. Shaded cells indicate that the risk quotient exceeds the level of concern (LOC=1)

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
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1616028	1992, Phystical/Chemical Characteristics Rejex-it MA, DACO: 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9 CBI
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1662585	1994, One Year Storage Stability Supplemental Report Rejex-it AG-36/Migrate, DACO: 3.5.10 CBI
1662587	1994, Accelerated Storage Stability Study Rejex-it AG-36/Migrate, DACO: 3.5.10 CBI
1739636	2009, DACO 3.5.10, DACO: 3.5.10 CBI
1783022	2009, 3.5.10 Storage Stability, DACO: 3.5.10 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
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1662481	1992, Acute Dermal Toxicity Study of Rejex-it MA in Rabbits, DACO: 4.2.2
1662482	1992, Acute Inhalation - Methyl Anthranilate Waiver Request, DACO: 4.2.3
1662483	1992, Primary Eye Irritation Study of Rejex-it MA in Rabbits, DACO: 4.2.4
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1662488	2008, Waiver Request - Toxicology Studies for Methyl Anthranilate, DACO: 4.3, 4.4, 4.5
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1662590	1993, Acute Dermal Toxicity Study of Rejex-it AG-36 in Rabbits, DACO: 4.6.2
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1662592	1993, Primary Eye Irritation Study of Rejex-it AG-36 in Rabbits, DACO: 4.6.4
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3.0 Environment

PMRA Document Number	Reference
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4.0 Value

PMRA Document Number **Reference**

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1622885 2008, Description of Pest Problem, DACO: 10.2.2
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B. Additional Information Considered

i) Published Information

1.0 Value

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