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Proposed Re-evaluation Decision

PRVD2018-06

Methyl Anthranilate and Its Associated End-use Products

Consultation Document

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca

Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada 

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Proposed Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Methyl anthranilate is a natural component in a variety of plants and fruits. It is registered as a commercial product to repel birds on blueberries, cherries and turf (golf courses and municipal parks only). Birds repelled include American robins, house finches, sparrows and European starlings from blueberries and cherries, and Canada geese from turf. Methyl anthranilate is applied using conventional ground application equipment and applied as necessary.

This document presents the proposed regulatory decision for the re-evaluation of methyl anthranilate including the proposed risk mitigation measures to further protect human health and the environment, as well as the science evaluation on which the proposed decision was based. All products containing methyl anthranilate registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public including the pesticide manufacturers and stakeholders may submit written comments and additional information to the PMRA. The final re-evaluation decision will be published taking into consideration the comments and information received.

Outcome of Science Evaluation

Methyl anthranilate is registered to repel birds. The use of methyl anthranilate as a repellent offers a treatment option that can be used in an integrated pest management program.

Methyl anthranilate is a naturally occurring substance in plants and fruits. With respect to human health, methyl anthranilate is of low acute toxicity by oral and dermal routes and is mildly irritating to the eyes, but is not a skin irritant or potential dermal sensitizer.

Risk from occupational exposures to workers mixing, loading and applying the repellent or re-entering treated sites are not of concern under the current conditions of use. Exposure to bystanders is not expected based on the registered use pattern.

Based on the current use pattern, dietary risk through consumption of treated food commodities is not of concern to the general population, including children and infants.

Methyl anthranilate repels birds by irritating the eyes, nostrils and mouths of birds. It is expected to dissipate rapidly via biotransformation. Under the current conditions of use, potential risk to terrestrial organisms is not expected to be of concern. To minimize the potential risk to aquatic organisms from spray drift, buffer zones are currently included on the label and these buffer zone statements are proposed to be updated to meet the current labeling standard.

Proposed Regulatory Decision for Methyl Anthranilate

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, products containing methyl anthranilate are being proposed for continued registration in Canada, provided that the updated label directions are in place to further protect human health and the environment.

Registered pesticide product labels include specific instructions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of methyl anthranilate, updated precautionary and buffer zone statements are being proposed.

International Context

Methyl anthranilate is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the European Union, Japan, New Zealand and the United States. As of 29 September 2017, no decision by an OECD member country to prohibit all uses of methyl anthranilate for health or environmental reasons has been identified.

Next Steps

The public, including the registrants and stakeholders, are encouraged to submit comments during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document.² The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with the PMRA's responses.

Additional Scientific Information

No additional data are required.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

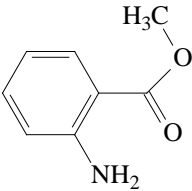
Science Evaluation

1.0 Introduction

Methyl anthranilate is registered as a bird repellent to repel a variety of birds including American robins, house finches, sparrows and European starlings from blueberries and cherries, and Canada geese from turf. Methyl anthranilate is registered as commercial products in Canada, formulated as solution, suspension and microcapsule suspension. It repels birds by irritating their eyes, nostrils and mouths. The product is applied directly on the fruit of blueberries and cherries and to turf (golf courses and municipal parks only) using ground equipment (such as pump, power-blast, and airblast sprayers) as necessary. Currently registered products containing methyl anthranilate are listed in Appendix I.

2.0 The Technical Grade Active Ingredient

Table 1 Identity of the technical grade active ingredient

Active substance:	methyl anthranilate	
Function:	biochemical pesticide to be used as a bird repellent	
Chemical name: International Union of Pure and Applied Chemistry (IUPAC): Chemical Abstract Services (CAS):	methyl 2-aminobenzoate 2-aminobenzoic acid, methyl ester	
CAS number:	134-20-3	
Molecular formula:	C ₈ H ₉ NO ₂	
Molecular weight:	151.17	
Structural formula:		
Purity of the active ingredient	Registration Number	Purity of methyl anthranilate
	26451	98.5 %
	30190	99.7%
	30793	99.9%

3.0 Human Health

Based on the registered use pattern, exposure to methyl anthranilate may occur through working as a mixer/loader/applicator, by entering treated sites, or by consuming food and drinking water. Two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having no health risks of concern.

3.1 Toxicological Summary

Methyl anthranilate is a natural component in a variety of plants and fruits. The technical grade active ingredient is of low acute toxicity by the oral, dermal and inhalation routes and is mildly irritating to the eyes. It is not a skin irritant or a potential skin sensitizer.

Methyl anthranilate is rapidly metabolized and the by-products are excreted. With the rapid metabolism of methyl anthranilate and based on the currently available information, methyl anthranilate is not known or suspected of being a developmental/reproductive toxic compound. Methyl anthranilate is not expected to be carcinogenic. For more details, please refer to Proposed Registration Decision PRD2011-11, *Methyl Anthranilate* and Registration Decision RD2012-04, *Methyl Anthranilate*.

No toxicology endpoints for quantitative risk assessment were established for methyl anthranilate. As a result, the PMRA has used a qualitative approach to assess the potential risks of methyl anthranilate to human health.

3.2 Occupational Exposure and Risk

Workers can be exposed to methyl anthranilate through mixing, loading, and/or applying the product as well as through clean-up and maintenance activities. Workers can also be exposed when entering a treated site to conduct any number of postapplication activities.

3.2.1 Mixer/Loader/Applicator Exposure and Risk

Commercial class methyl anthranilate end-use products can be applied using ground equipment, including groundboom, airblast or hand-held sprayers.

Occupational exposure for methyl anthranilate is expected to be short term and predominantly by the inhalation and dermal routes when workers are exposed during mixing, loading and application.

Risk from occupational exposure to methyl anthranilate (mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities) is not expected to be of concern based on the low toxicity profile of the active ingredient. Current risk reduction measures on the labels, (for example, eye protection), are adequate. No additional risk mitigation measures are proposed. However, updated label statements related to eye protection is proposed (Appendix II).

3.2.2 Postapplication Exposure and Risk

Potential postapplication exposure of workers entering treated sites is not expected to be of concern given the low toxicity profile of this active ingredient and current conditions of use. The product labels currently require the material to dry before permitting human activity in the treated areas. No additional risk mitigation measures are proposed.

3.3 Non-occupational Exposure

3.3.1 Bystander Exposure and Risk

To prevent bystander exposure when used on golf courses and municipal parks, the current labels of the end-use products registered for use on turf prohibit application to residential lawns or recreational areas of parks. Further, on golf courses and other areas of parks, re-entry of people is prohibited until after residues have dried.

For all end-use products, a standard statement is proposed, based on current labelling practices, to minimize spray drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas. The proposed label statement is listed in Appendix II.

3.3.2 Dietary Exposure and Risk

Methyl anthranilate is a natural component in a variety of plants and fruits and it is used as a flavouring agent. Methyl anthranilate is volatile and is expected to transform rapidly when exposed to ultraviolet light and elevated temperatures. No residues or low residues (i.e., below natural levels occurring in commonly consumed foods, such as grapes) are expected at harvest of treated crops and any remaining residues are likely to be further decreased by washing and possible cooking of treated crop prior to consumption.

Based on the low toxicity profile, rapid metabolism, and the current conditions of use, potential dietary (food) risk to the general population, including children and infants, to methyl anthranilate is not expected to be of concern. No additional risk mitigation measures are proposed.

Due to its rapid dissipation, methyl anthranilate will not likely reach surface water through run-off or leaching through the soil profile and contaminate drinking water. Consequently, the use of methyl anthranilate according to label directions is not expected to result in residues in drinking water. No additional mitigation measures are proposed.

3.3.3 Aggregate Exposure and Risk

Based on the registered conditions of use, aggregate exposure of methyl anthranilate could occur through exposure to residues in food and drinking water or by coming into contact with treated turf. However, these exposures are not of concern based on the low toxicity profile of methyl anthranilate, the minimal residue levels in food and drinking water and the current label directions. On this basis, aggregate exposure and risk is not expected to be of concern.

3.4 Cumulative Exposure and Risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify information indicating that methyl anthranilate shares a common mechanism of toxicity with other pest control products. Therefore there is no requirement for a cumulative assessment at this time.

4.0 Environmental Assessment

4.1 Fate and Behaviour in the Environment

Methyl anthranilate is a naturally occurring substance, expected to transform rapidly via biotransformation. Even though methyl anthranilate will not be applied directly to water, this substance could reach surface water through run off and spray drift. However, once in the environment, methyl anthranilate will dissipate rapidly via biotransformation. 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.

Methyl anthranilate is not acutely toxic to non-target terrestrial organisms. 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 (PRD2011-11).

4.2 Environment Exposure and Risk Assessment

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are levels of pesticide in various environmental media, such as food, water, soil and air. The EECs are calculated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (such as, 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 (for example, 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 ($RQ = \text{exposure}/\text{toxicity}$), and the risk quotient is then compared to the level of concern (LOC). 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 to non-target habitats) and might consider different toxicity endpoints.

4.2.1 Risks to Terrestrial Organisms

Minimal exposure to vertebrate and invertebrate terrestrial organisms is expected when considering factors such as the properties of the repellent, rapid environmental dissipation, and the application timing (not applied during bloom). Considering the low toxicity profile (not acutely toxic to birds, mammals and honeybees (contact)), fate characteristics and current conditions of use, potential risk to non-target terrestrial vertebrate and invertebrate species is not expected to be concern from the use of methyl anthranilate. Methyl anthranilate may cause phytotoxicity in certain non-target plants. However, it is not expected that the overall health of terrestrial habitats would be affected by drift (PRD2011-11).

4.2.2 Risks to Aquatic Organisms

Potential risk to aquatic organisms from use of methyl anthranilate on turf and on blueberries at the lower application rate was below the level of concern based on a screening level assessment (PRD2011-11).

Potential risk to aquatic organisms from spray drift was above the level of concern when methyl anthranilate was applied to cherries, and, to blueberries at higher rates and frequency (PRD2011-11). Therefore, for these uses, buffer zones are included on the current label (Reg. No. 30189) to protect aquatic organisms from spray drift. These buffer zone statements are proposed to be updated to meet the current labeling standard (Appendix II).

Due to the rapid dissipation of methyl anthranilate, runoff to water bodies is not expected to occur. Thus the risk from this route of exposure was not characterized further.

Environmental precautions and disposal statements are proposed to be included on Reg. No. 26452 to meet current labelling standards.

5.0 Value

Methyl anthranilate is applied directly to the fruit of blueberries and cherries and to turf (golf courses and municipal parks only) to reduce damage by birds. It is registered to repel birds including American robins, house finches, sparrows and European starlings from blueberries and cherries, and Canada geese from turf.

Bird control requires several techniques used in an integrated pest management program to be effective. Bird problems are usually controlled by trapping, exclusion, the use of noisemakers or the use of toxic baits. The use of methyl anthranilate as a repellent offers another treatment option that can be used in an integrated pest management program.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

In accordance with the PMRA Regulatory Directive DIR99-03,³ the assessment of methyl anthranilate against Track 1 criteria of Toxic Substances Management Policy (TSMP) under *Canadian Environmental Protection Act* was conducted. It determined that:

- Methyl anthranilate does not to meet all Track 1 criteria, and is not considered a Track 1 substance, as it dissipates rapidly in the environment.

³ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical grade active ingredient 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*.⁴ The list is used as described in the PMRA Notice of Intent NOI2005-01⁵ and is based on existing policies and regulations including DIR99-03 and DIR2006-02,⁶ 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 sources of methyl anthranilate products do not contain impurities of human health or environmental concern as identified in the *Canada Gazette*.

7.0 Incident Reports

Since 26 April 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. As of 28 June 2017, no incident reports have been submitted to the PMRA for the active ingredient methyl anthranilate.

8.0 Conclusion

Methyl anthranilate has value in providing a pest management option that can be used in an integrated pest management program. Methyl anthranilate is a naturally occurring substance in a variety of plants and fruits. With respect to human health, methyl anthranilate has a low toxicity profile, and when used as a bird repellent according to the proposed label directions, the potential risk to human health and the environment is not expected to be of concern.

On this basis, Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing methyl anthranilate for sale and use in Canada. Updates to label directions are being proposed to meet the current labelling standards.

⁴ *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.*

⁵ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

⁶ DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

Appendix I Registered Methyl anthranilate Products as of 7 December 2017

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
26451	T	Engage Agro Corporation	Avigon MA (technical methyl anthranilate)	Liquid	98.5
26452	C		Avigon 14.5 Canada Goose Repellent for Turf	Microcapsule Suspension	14.5
30189	C	Avian Enterprises Limited LLC	Avian Migrate for Agriculture and Turf Bird Repellent	Suspension	14.5
30190	T		Methyl Anthranilate Technical	Solid	99.7
30793	T	1578549 Ontario Limited	MA Technical	Solid	99.9
32233	C	Avian Enterprise LLC	Avian Control	Solution	20

Appendix II Proposed Label Amendments for Products Containing Methyl Anthranilate

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

The following label statements are proposed:

- I) The following statement is proposed to be included under the **PRECAUTIONS section for all end-use product labels:**

Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

- II) Under the **PRECAUTIONS section:**

Replace the term “safety glasses”

With the term “goggles or face shield”

- III) The following statements are proposed to be included **for Reg. No. 26452:**

Add to **ENVIRONMENTAL PRECAUTIONS:**

To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Add to **DIRECTIONS FOR USE:**

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

IV) For Reg. No. 30189 replace the existing buffer zone related statements with the following (for use on blueberries at a rate of 6.4 to 8.3 kg a.i./ha and for use on cherries):

DIRECTIONS FOR USE:

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Airblast	Cherry	Late growth stage	5	0	1	0
	Blueberry	Late growth stage	2	0	0	0

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.

References

A. Registrant Submitted Studies/Information

A.1.0 Chemistry Assessment

PMRA Document Number	Reference
1633860	1981, Manufacturing Methods for the Technical Active Ingredients. Methyl Anthranilate Process Description, DACO: 2.11.
1632679	Technical Chemistry file [CBI Removed] ReJeX-iT MA Chemical and Physical Properties. Fenaroli's Handbook of Flavor Ingredients Second Edition Volume 2., DACO: 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, 2.16
1616027	1992, Physical/Chemical Characteristics - Basic Information and Waivers for 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
1616028	1992, Physical/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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1616025	1992, 2A - Product Identification, Manufacturing Process, Analytical Method Rejex-it MA, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1, 2.4,2.5, 2.6, 2.7, 2.8, 2.9 CBI.
2102211	2011, Chemistry-2.11.2-MA TGAI-Starting Materials, DACO: 2.11.2 CBI.
2102212	2010, Chemistry-Methyl Anthranilate tech-2 11 3 2 11 4-LH, DACO: 2.11.3, 2.11.4 CBI.
1634098	Quality Control Method ReJeX-iT MA, DACO: 2.13.3.
1616026	1994, Preliminary Analysis, DACO: 2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI.
2102213	2010, Methyl Anthranilate-Chemistry-2.13.3-5 batch, DACO: 2.13.1,2.13.2,2.13.3 CBI.

PMRA Document Number	Reference
1633798	1994, Chemical and Physical Properties and attached EPA DER April 29, 1994 Deficiency Reponse May 5, 1998, DACO: 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.9, 2.16.
1633779	1992, Physical and Chemical Characteristics of Methyl Anthranilate, ReJex-IT. Deficiency Reponse May 5, 1998, DACO: 2.14.14.
1634275	1993, ReJeX-iT MA Chemical and Physical Properties of Pure Active UV-Visible Absorption Spectrum. Degradation Studies of the Nonlethal Bird Repellent, Methyl Anthranilate, DACO: 2.14.12.
2102220	2010, Chemistry-2 13 3-five_batch_analysis_summary-LH, DACO: 2.13.3 CBI
1633784	1994, Manufacturing Methods for the TGAI - Discussion of Formation of Impurities of Toxicological Concern and Confidential Information - Deficiency Reponse May 5, 1998, DACO: 2.11.4, 2.13.4.

B. Additional Information Considered

B.1.0 Published Information

PMRA Document Number	Reference
654836	Proposed Regulatory Decision Document, PRDD2000-01, Avignon 14.5 Canada Goose Repellent for Turf - Methyl Anthranilate. Pest Management Regulatory Agency. 7 June 2000.
660789	Regulatory Decision Document, RDD2000-03, Avignon 14.5 Canada Goose Repellent for Use on Turf (Methyl Anthranilate). Pest Management Regulatory Agency. 16 August 2000.
2098257	Proposed Registration Decision, PRD2011-11, Methyl Anthranilate. Pest Management Regulatory Agency. 2 September 2011.
2201840	Registration Decision, RD2012-04, Methyl Anthranilate. Pest Management Regulatory Agency. 7 June 2012.