

Proposed Regulatory Decision Document PRDD2000-01

Avigon 14.5 Canada Goose Repellent for Turf Methyl Anthranilate

The active ingredient methyl anthranilate, and its associated end-use product Avigon 14.5 Canada Goose Repellent for Turf, are proposed for full registration under Section 13 of the Pest Control Products Regulations (PCP Regulations). Both products have been reviewed under the Pest Management Regulatory Agency's (PMRA) user requested minor use registration (URMUR) program.

Avigon 14.5 is the first product to be registered under the *Pest Control Products Act* (PCP Act) to repel Canada geese (*Branta canadensis*) from feeding and utilizing turf.

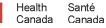
This proposed regulatory decision document (PRDD) provides a summary of data reviewed and the rationale for the proposed full registration of these products. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address listed below.

(publié aussi en français)

June 7, 2000

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Foreword

The submissions for the minor use registration of the active ingredient methyl anthranilate and its associated end-use product Avigon 14.5 Canada Goose Repellent for Turf were considered under the PMRA's URMUR program. This program:

- enables sponsor or user groups to encourage pesticide companies to seek registration for products already registered in the United States (U.S.) or other Organisation for Economic Co-operation and Development countries that, due to potential low volume of sales, might otherwise not be registered; and
- allows for the most efficient technical review of URMUR applications because of the opportunity to make use of foreign reviews completed by reliable regulators.

Avigon 14.5 is registered in the U.S. under the name of ReJeX-iT AG 36. The sponsoring group for the registration of methyl anthranilate was the Ontario Ministry of Agriculture, Food and Rural Affairs.

Currently, no chemical products are registered under the PCP Act for repelling Canada geese from turf. Available alternative methods include habitat modification (e.g., buffer strips around ponds), harassment techniques (e.g., scare-guns, trained dogs) and electronic sound-emitting devices (Squawker, Reg. No. 25560).

Because methyl anthranilate is a food-grade product that is classified by the U.S. Food and Drug Administration as "Generally Recognized As Safe," and because no issues had been identified during the evaluation of these products, a time-limited registration has been granted by the PMRA for these products until December 31, 2000 to allow users access to this low-risk product, while providing concerned Canadians an opportunity to provide input into the final decision through this PRDD.

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1.0 The active substance, its properties, uses, proposed classification and labelling

1.1 Identity of the active substance and preparation containing it

Common name:	methyl anthranilate
Function:	biochemical pesticide to be used as a bird repellent
Chemical name: (International Union of Pure and Applied Chemistry):	methyl 2-aminobenzoate
(Chemical Abstract Services (CAS)):	methyl 2-aminobenzoate
CAS number:	134-20-3
Molecular formula:	$C_8H_9NO_2$
Molecular weight:	151.2
Structural formula:	O Č-O-CH ₃ NH ₂

Nominal purity of active:

98.5%

Identity of relevant impurities of toxicological, environmental and other significance:

The technical grade methyl anthranilate does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track-1 substances

1.2 Physical and chemical properties of active substance

Technical product: Avigon MA

Property	Result	Comment
Colour and physical state	white to light yellow solid	
Odour	reminiscent of concord grape	
Melting point or range	24–25°C	
Specific gravity	1.161–1.169	
Vapour pressure at 20°C	0.012 mm Hg	Methyl anthranilate has a potential to be volatile under field conditions
Henry's law constant at 20°C (<i>K</i>)	$8.34 \times 10^{-2} \text{ Pa} \cdot \text{m}^{3} \cdot \text{mol}^{-1}$ (1/H = 2.95 × 10 ⁴)	Methyl anthranilate has a potential to be slightly volatile from moist soil and water surfaces
UV and visible spectrum	maximum at 370 nm at pH 7	Methyl anthranilate has a potential for phototransformation in the environment
Solubility in water at 23°C	0.29 g/100 mL	Methyl anthranilate is very soluble in water and has a potential for leaching in soil
Solubility in organic solvents	soluble in one volume or more of 60% alcohol, in most fixed oils and in propylene glycol	
<i>n</i> -Octanol–water partition coefficient (log K_{ow})	1.6–1.9	Methyl anthranilate has a low potential for bioconcentration and bioaccumulation
Dissociation constant $(-\log pK_a)$	1.7×10^{-12}	Methyl anthranilate exists in a molecular non-polar form in the environment
Stability (metal)	noncorrosive	

End-use	product:	Avigon	14.5
Linu-usc	product.	11 Hgon	14.0

Property	Result
Colour	Light blue to tan
Odour	Reminiscent of concord grape
Physical state	Thick, liquid slurry
Formulation type	Microencapsulated suspension
Guarantee	14.5% (nominal)
Container material and description	8.89 L plastic jugs
Density	1.02 g/mL at 25°C
рН	5.6
Oxidizing or reducing action	None
Storage stability	Stable for one year at room temperature

2.0 Methods of analysis

2.1 Method for analysis of the active substance as manufactured

A gas chromatographic (GC) method was used for the determination of the active substance and the significant structurally related impurities (content \$ 0.1%) in the technical product. The method has been shown to have satisfactory specificity, linearity, precision and accuracy.

2.2 Method for formulation analysis

A GC method was used for the determination of the active substance in the formulation. The method has been shown to have satisfactory specificity, linearity, precision and accuracy and is suitable for use as an enforcement analytical method.

Conclusion

The product chemistry data for methyl anthranilate technical and the end-use product Avigon are complete. The technical material was fully characterized and the specifications were supported by the analysis of 10 batches for active and impurities using a specific and validated method of analysis. The technical material is not expected to contain any impurities or microcontaminants known to be TSMP Track-1 substances. The required chemical and physical properties of the technical material and the end-use product were determined using acceptable methods. A fully validated GC method for the determination of the active ingredient in the formulation was provided.

3.0 Impact on human and animal health

3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities in the active substance or to their transformation products

No toxicokinetic data were provided; however, literature references show that methyl anthranilate readily undergoes enzymatic hydrolysis to form methyl alcohol and anthranilic acid. Methyl alcohol is readily metabolized via well known pathways to carbon dioxide and water. Anthranilic acid is a normal metabolite in humans, being a precursor for the amino acid tryptophan.

On the basis of the results of studies and literature references, the test material was found to be slightly toxic via the oral route and non-toxic via the dermal route. Studies show the test material to be non-irritating to rabbit skin and mildly irritating to rabbit eye and not to demonstrate any dermal sensitization potential. Inhalation toxicity could not be adequately addressed.

On the basis of the results of studies, the end-use formulation, Avigon 14.5, was found to be of low toxicity via the oral, dermal and inhalation routes. The end-use formulation was found to be practically non-irritating to rabbit eyes and non-irritating to rabbit skin; however, slight to moderate dermal irritation was noted in the acute dermal toxicity study. When tested in guinea pigs, no dermal sensitization potential was demonstrated.

In a short-term feeding study in rats, the study authors determined a no observable effect level (NOEL) of 1000 mg/kg body weight [bw]/day. In the report of the United Nations World Health Organization (WHO) and Food and Agriculture Organization Expert Committee on Food Additives, a 115-day rat feeding study is discussed. The NOEL is stated to be 3000 parts per million (ppm) (150–300 mg/kg bw/day) and further, at the highest dose level tested, 10 000 ppm, the only effects noted were "increases in average weights of the liver and kidneys, and slight (minimal) histological changes in the kidneys." Both studies confirm that the short-term NOEL for methyl anthranilate is relatively high.

Methyl anthranilate was considered to be negative for lung tumorigenicity in mice following intraperitoneal injection. This study is limited in that the purpose was to develop a screening assay rather than investigate the tumorigenic potential of methyl anthranilate. Although carcinogenicity data for methyl anthranilate are lacking, there is sufficient information available for the metabolite, anthranilic acid. The U.S. National Cancer Institute determined that under conditions of the bioassay, anthranilic acid was not carcinogenic for either Fischer 344 rats or B6C3F1 mice.

In a battery of mutagenicity assays, methyl anthranilate was found to be negative when tested in the in vitro hepatocyte – DNA repair assay, the *Salmonella* assay (TA1535, TA1537, TA98 and TA100) with and without metabolic activation and in a mutation test

with *Escherichia coli*. Positive results were reported in a Rec-Assay with *Bacillus subtilis* (strains M45, H17) as well as a chromosome aberration assay in Chinese hamster cells. The metabolite, anthranilic acid was negative for mutagenicity in the *Salmonella* assay (TA98, TA100, TA1535 and TA1537) in the presence and absence of liver S9 homogenate. No other studies testing other mutagenicity end points could be found for the metabolite.

No reliable information regarding the reproductive toxicity of methyl anthranilate or its metabolite, anthranilic acid, could be found. Although information provided suggests potential teratogenicity in mice receiving oral doses of methyl anthranilate, the data are extremely limited and results from a teratogenicity study in rats with the metabolite, anthranilic acid, suggest otherwise.

3.2 Toxicology end-point selection for handles and bystander risk assessment

Occupational exposure to methyl anthranilate when used on golf courses and municipal parks is expected to be repeated and intermittent in nature.

The toxicological database submitted for the registration of methyl anthranilate was limited; however, available information suggests a low order of toxicity. A 115-day rat feeding study, used by the WHO to determine an acceptable daily intake, is considered the most relevant study on which to base the occupational risk assessment. In this study, a NOEL of 150 mg/kg bw/day was established on the basis of increased liver and kidney weight and histological changes in the kidneys observed at the next dose level (1000 mg/kg/bw). The other established NOEL values were all higher than 150 mg/kg bw/day. Although the information on reproductive toxicity is limited, the general toxicological profile of methyl anthranilate and its metabolite does not suggest that reproductive parameters would be affected at dose levels significantly lower than those established for other end points.

3.3 Drinking water limit

No food uses are proposed; therefore, a drinking water limit has not been established.

3.4 Impact on human and animal health arising from exposure to the active substance or to impurities contained in it

Avigon 14.5 is a microencapsulated suspension with a guarantee of 14.5% methyl anthranilate. The maximum application rate recommended on the proposed label is 2.5 kg a.i./ha. The proposed label for Avigon 14.5 instructs users to allow material to dry before permitting human activity on the treated area, and to repeat application in three days or as warranted by goose activity. The product is to be applied to golf courses and municipal parks only. Application to residential lawns and recreational areas of parks is prohibited by use restrictions on the label. The label instructs users to apply the product using appropriate spray equipment. Typically in golf courses and parks, either

groundboom or truck mounted hand help sprayer is used for application. Precautionary statements include the following: "When handling, wear safety glasses, and dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

On the basis of information provided by the applicant each golf course would treat its own turf, and this would be performed by one worker. A range of 1–10 hectares (ha) can be treated per day. Treatment of two hectares per day is the most likely scenario for hand wand equipment. Therefore, typically, five kilograms a.i. would be handled per day. However, according to information provided by turf grass specialists, approximately eight hectares could be treated by groundboom in a day for golf courses resulting in 20 kg a.i. handled per day. Municipal parks would likely have a smaller area treated in a day. According to the applicant, one operator would spray several small areas of a park. A range of less than one to 2.5 ha may be treated per day, with 0.4 ha/day being the most likely scenario. Typically, therefore, one kilogram active ingredient would be handled per day.

An in-house exposure estimate was conducted by the Occupation Exposure Assessment Section using the Pesticides Handlers Exposure Database (PHED) 1.1 for the golf course scenario. It was felt that the golf course scenario would be the worst case and therefore an exposure estimate for this scenario would cover off the exposure for the municipal park scenario.

PHED subsets were created from the mixer and loader (MLOD) and applicator (APPL) files. The PHED subsets generated compare well with the product and use scenario. The MLOD subsets included dry flowable formulation, open mixing, A and B grade data. The exposure estimates were derived for persons wearing long pants, long-sleeved shirts and gloves. A dry flowable (DF) formulation was used to subset the MLOD file instead of a microencapsulated (ME) formulation because the ME formulation had only two replicates. It was felt that the DF formulation was the most similar to a ME formulation. Two subsets were created from the APPL file: one each for groundboom and hand wand application. The subset for groundboom application included open cabs and A and B grade data. The exposure estimates were derived for persons wearing long pants, longsleeved shirts and no gloves. The hand wand subset included both the lawn and greenhouse type high pressure hand wands and A, B and C grade data. Exposure estimates were derived for persons wearing long pants, long-sleeved shirts and gloves. All PHED subsets except the hand wand application subset met the North American Free Trade Agreement (NAFTA) acceptability criteria as outlined in the draft "NAFTA Guidelines for Using and Reporting PHED." The hand wand subset yielded only nine replicates from one study, using grades A, B and C data. Further, the one study in PHED for this subset contained only the greenhouse type of hand wand, which may result in different exposure from the lawn type of hand wand.

Scenario specific exposure estimates are presented in Table 3.1. The exposure estimates assume that in a typical day eight hectares of turf will be treated by groundboom and two

hectares will be treated by hand wand, all at the maximum application rate specified on the label. A dermal absorption value of 100% was assumed.

Scenario	Scenario		PHED unit exposure (Fg a.i./kg a.i. handled)		Exposure pattern	Daily dose (Fg ai/kg bw/d) ¹		
			Inhaled	Total	(kg a.i. handled/day [d])	Dermal	Inhaled	Total
Turf, dry flowable	Mixer and loader	163.8	1.7	165.5	Application to 8 ha/d at 2.5 kg a.i./ha = 20 kg a.i. handled/d	46.8	0.49	47.29
formulation groundboom	Applicator	33	1.6	34.6		9.43	0.46	9.89
application	Mixer, loader and applicator	196.8	3.3	200.1		56.23	0.94	57.17
Turf, dry flowable	Mixer and loader	163.8	1.7	165.5	Application to 2 ha/d at 2.5 kg a.i./ha = 5 kg a.i. handled/d	11.7	0.12	11.82
formulation, hand wand	Applicator	1517.5	200	1717.6		108.39	14.29	122.69
application	Mixer, loader and applicator	1681.3	202	1883.1		120.09	14.41	134.51

Table 3.1	Scenario specific exposure estimates on the basis of best fit statistical
	measure

1 Calculated as Fg a.i./kg a.i. handled × application rate/area × area treated/kg body weight

On the basis of the NOEL of 150 mg/kg bw/day from a 115-day rat feeding study, the margins of exposure (MOE) for a worker mixing, loading and applying Avigon with a boom sprayer and a hand held sprayer to golf courses would be 2620 and 1110, respectively. The MOE for the use of Avigon on turf in parks is expected to be higher. These MOEs are considered adequate by the PMRA.

3.4.1 Bystander exposure

A quantitative exposure assessment for post-application exposure to methyl anthranilate was not provided by the applicant. In the absence of characterization of bystander exposure (e.g., children playing) and given the limited toxicity data, restriction of the use of Avigon 14.5 on residential lawns and recreational areas of parks is required. This restriction should limit the potential for re-entry exposure. Further, on golf courses and other areas of parks, re-entry of people is not to occur until after residues have dried.

4.0 Integrated food residue chemistry summary

Not applicable.

5.0 Fate and behaviour in the environment

With the exception of the studies described below, additional studies are not required for this use site category (i.e., turf) or are waived.

5.1 Fate and behaviour in soil

The results of phototransformation in water indicated that, although phototransformation occurred, it will not be an important route of transformation in the environment.

The data on biotransformation were generated using a mixture of sewage effluent and soil extract (half-life less than two days), which does not represent aerobic soil.

The proposed maximum application rate is 2.48 kg a.i./ha. Assuming a soil bulk density of 1.5 g/cm^3 and a depth of 15 cm, the expected environmental concentration (EEC) in soil is 1.1 mg a.i./kg soil.

5.2 Fate and behavior in aquatic systems

Studies on hydrolysis indicated that no more than 10% of the initial methyl anthranilate concentration was hydrolysed by the end of 38 days in buffer solutions at pH 5, 7 and 9. Hydrolysis of methyl anthranilate is, therefore, not an important route of transformation in the environment.

Irradiation of methyl anthranilate in sterile aqueous solution buffered at pH 7.0 indicated that 44% of the initial concentration was phototransformed at the end of 384 hours (h) (equivalent to 32 days of 12 h light). No major transformation products were detected during this process. Phototransformation is, therefore, not an important route of transformation of methyl anthranilate in the aquatic environment.

On the basis of the proposed maximum application rate of 2.48 kg a.i./ha to turf and a water depth of 30 cm, the EEC in water is 0.83 mg a.i./L.

5.3 Fate and behavior in air

No data were submitted on the fate of methyl anthranilate in air. The vapour pressure of 0.012 mm Hg (1.6 Pa) at 20°C and the Henry's law constant, *K*, of 8.34×10^{-2} Pa·m³·mol⁻¹, indicate that methyl anthranilate has a potential to be volatile under field conditions and slightly volatile from moist soil or water surfaces, respectively. As the submission was made under URMUR, however, no data on fate in air are requested for the proposed use.

6.0 Effects on non-target species

Organism	Test	No observable effect concentration (NOEC) or NOEL	Lethal dose 50% (LD ₅₀) or concentration 50% (LC ₅₀)	Toxicity
Terrestrial organisms				
Bobwhite quail (Colinus virginianus)	14-d acute oral	1350 mg a.i./kg bw	$LD_{50} > 2250 \text{ mg a.i./kg bw}$ (mortality)	non-toxic
Mallard duck (Anus platyrhynchos)	5-d subacute dietary	4470 mg a.i./kg diet (body weight)	LC ₅₀ > 5000 mg a.i./kg diet (mortality)	non-toxic
Rats	acute oral		$LD_{50} = 2910 \text{ mg a.i./kg}$ bw/d	non-toxic
	acute dermal		LD ₅₀ >2000 mg a.i./kg bw	non-toxic
Rats (Osborne–Mendal rats)	Short-term dietary (150 d)	NOEC = 10 000 mg a.i./kg diet		
Honeybees (Apis mellifera)	48-h acute contact	lowest observed effect concentration (LOEC) = 0.25 Fg a.i./bee (3% mortality)	$LD_{50} > 25$ Fg a.i./bee	non-toxic
Aquatic organisms				
Water fleas (Daphnia magna)	48-h acute	6.2 mg a.i./L (immobilization)	$LC_{50} = 31.3 \text{ mg a.i./L}$ (mortality)	slightly toxic
Rainbow trout (Oncorhynchus mykiss)	96-h acute	7.36 mg a.i./L (sublethal effects)	$LC_{50} = 25.4 \text{ mg a.i./L}$ (mortality)	slightly toxic
Bluegill sunfish (Lepomis macrochirus)	96-h acute	11.6 mg a.i./L (sublethal effects)	$LC_{50} = 42.6 \text{ mg a.i./L}$ (mortality)	slightly toxic

Table 6.1Summary of toxicity of methyl anthranilate to biota

6.1 Environmental risk assessment

6.1.1 Terrestrial organisms

Risk to birds was assessed using the acute oral NOEL for bobwhite quail and dietary NOEC for mallard duck (Table 6.2). The major route of exposure of wild birds to methyl anthranilate is through dietary sources. Dietary intake (DI = food consumption \times EEC) of methyl anthranilate for the two bird species were estimated following application at the maximum application rate.

Bobwhite quail acute risk assessment: The EEC in the bobwhite diet, on the basis of the maximum application rate, is 298 mg a.i./kg dw. Bobwhite food consumption in the control group was 26.5 g dw per individual per day. The DI of methyl anthranilate is, therefore, 7.9 mg a.i./ind/d. The NOEL for bobwhite is 1350 mg a.i./kg bw, which is

equivalent to 263 mg a.i./ind. The number of days of methyl anthranilate intake required to reach the NOEL is 33 days (NOEL/DI). Wild birds exposed to the proposed maximum application rate of methyl anthranilate are, therefore, not at risk on an acute basis.

Table 6.2	Summary of risk assessment of methyl anthranilate to terrestrial and aquatic
	organisms

Species	NOEL or NOEC	EEC	Margin of safety	Risk			
Terrestrial organism	Terrestrial organisms						
Bobwhite quail	263 mg a.i./individual (ind) (acute)	dietary intake (DI) = 7.9 mg a.i./ind/d	days to reach NOEL = 33	no acute risk			
Mallard duck	4470 mg a.i./kg dry weight (dw) (dietary)	84.04 mg a.i./kg dw	53	no dietary risk			
Rat	$LD_{50} = 2910 \text{ mg a.i./kg}$ bw (acute)	DI = 74.6 mg a.i./ind/d	days to reach $LD_{50} = 14$	no acute risk			
Rat	10 000 mg a.i./kg dw (dietary)	1244 mg a.i./kg dw	8	no dietary risk			
Honeybees	LOEC = 0.28 kg a.i./ha (3% mortality)	application rate 2.48 kg a.i./ha	0.1	potential risk to bees with the proposed high application rate			
Aquatic organisms							
Waterflea	6.2 mg a.i./L	0.83 mg a.i./L	7.5	no acute risk			
Fish (rainbow trout)	7.36 mg a.i./L	0.83 mg a.i./L	9	no acute risk			

Mallard duck short-term dietary risk assessment: The EEC in the mallard duck diet, on the basis of the maximum application rate, is 84.04 mg a.i./kg dw. The NOEC for mallard is 4470 mg a.i./kg dw. The margin of safety value (53) indicates that the environmental concentration of methyl anthranilate is lower than the NOEC, and that ingestion of this compound at the indicated levels will not pose a dietary risk to birds.

Rat acute oral risk assessment: The EEC in the rat diet, on the basis of the maximum application rate, is 1244 mg a.i./kg dw. On the basis of standard food consumption of 0.06 kg dw/ind/d and body weight of 0.35 kg bw/ind, the daily intake of methyl anthranilate is 74.6 mg a.i./ind/d. The LD₅₀ for rat is 2910 mg a.i./kg bw, which is equivalent to 1002 mg a.i./ind. The number of days of methyl anthranilate intake required to reach the LD₅₀ is 14 days. On the basis of an expected short half-life in the environment, methyl anthranilate is not expected to pose a risk to rats on an acute basis.

Rat short-term dietary risk assessment: The EEC in the rat diet, on the basis of the maximum application rate, is 1244 mg a.i./kg dw. The dietary NOEC for rat is 10 000 mg a.i./kg dw. The margin of safety value (8) indicates that the environmental

concentration of methyl anthranilate is lower than the NOEC, and that ingestion of this compound at the indicated levels will not pose a dietary risk to rats.

Honeybees: The LOEC (3% mortality) is 0.25 Fg a.i./bee, which is equivalent to 0.28 kg a.i./ha. The proposed maximum application rate, 2.48 kg a.i./ha, is much greater than the LOEC. Although methyl anthranilate is classified as non-toxic on an acute contact basis, the margin of safety value (0.1) indicates that the proposed high application rate may pose a risk to honeybees.

6.1.2 Aquatic organisms

The risk to aquatic organisms was assessed with the most sensitive fish and invertebrate species (Table 6.2). The EEC in water from direct overspray at the maximum label rate is 0.83 mg a.i./L. The NOEC for rainbow trout is 7.36 mg a.i./L. The margin of safety value (9) indicates that the environmental concentration of methyl anthranilate is lower than the NOEC. The proposed maximum application rate for turf will, therefore, not pose a risk to fish.

The NOEC for *Daphnia magna* was 6.2 mg a.i./L. The margin of safety value (7.5) indicates that the environmental concentration of methyl anthranilate is lower than the NOEC. The proposed maximum application rate for turf will, therefore, not pose a risk to aquatic invertebrates.

Methyl anthranilate may pose a risk to honeybees if there is a direct exposure to the proposed maximum application rate.

To support any expansion beyond the current use, data addressing aerobic soil biotransformation, aerobic aquatic biotransformation, mobility and toxicity to algae, terrestrial and aquatic non-target plants will be required. The review of these data will determine the need for additional data (toxicity to earthworms, predators and parasites, and field dissipation and accumulation).

6.2 Risk mitigation

To protect the honeybees, the following label statement is required:

"Avoid direct exposure of honeybees to this product. Do not apply this product in the vicinity of hives."

7.0 Integrated efficacy summary

Four field studies were evaluated to support the registration of the proposed commercial class product called Avigon 14.5 (14.5% methyl anthranilate), which has the label claim of repelling Canada geese from turf (i.e., in golf courses and municipal parks) for at least three days when applied at a rate of 19.4 L product/ha (2.87 kg a.i./ha). Two of the

submitted studies were conducted using Canada geese, and the other two were conducted using snow geese.

Regarding the Canada goose studies, the only study that directly supports the three-day efficacy claim is a study conducted in Colorado where enclosed grass plots (blade height of 2.54 cm) were treated with a single application of methyl anthranilate at a rate of 13 kg of 14.5% a.i. product/ha (1.89 kg a.i./ha, approximately one third lower than the proposed label rate) and the activity of Canada geese was monitored at each site, both by goose count and fecal weight data. Acceptable repellency (over 80%) was achieved during the first three days after treatment. The other Canada goose study, also conducted in Colorado, evaluated whether turf areas treated with methyl anthranilate would have reduced goose activity. Grass plots (blade height not provided) were treated with a single application of methyl anthranilate at a rate of 2.47 kg a.i./ha (approximately 15% lower than the proposed label rate). The activity of Canada geese was monitored at each site at weekly intervals for a period of three weeks by collecting and quantifying the amount of feces along sample transects within control and experimental plots. The evaluation of the repellency of methyl anthranilate on geese was only initiated one week after treatment application, with the result that the repellency achieved after this length of time was minimal (i.e., 37–68%) at three sites and acceptable (80%) at one site.

The two studies on snow geese conducted in New Jersey evaluated the repellency effect of methyl anthranilate when applied at a rate of 3.4 kg a.i./ha (approximately 15% higher than the label rate) to turf (blade height not provided) and winter wheat plots. In the 1995 study, it was demonstrated that methyl anthranilate significantly reduced feces from wild populations of snow geese within plots for 16 days after treatment compared with unsprayed plots, with acceptable levels of repellency (\$80%) being achieved within the first four days after treatment. The applicability of these data to Canada geese is unknown. If these species did react similarly when exposed to areas treated with methyl anthranilate, however, these data lend support to the three-day claim of repellency against Canada geese at the experimental rate of application. In the 1996 study, examination of feces weight per transect metre was only initiated seven days after treatment, with the result that, although test plots treated with methyl anthranilate had reductions in snow goose activity when compared with the control plots, the repellency achieved at seven days after treatment was minimal (only 41%).

• On the basis of the Canada goose study where acceptable repellency (over 80%) of Canada geese from turf was achieved during the first three days after treatment with a 14.5% methyl anthranilate formulation applied at a rate of 1.89 kg a.i./ha to turf (2.5 cm high), the registration of the proposed product can be supported, provided that the label rate of 19.4 L product/ha be reduced to 13 L product/ha, and a blade height of 2.5 cm be specified on the label.

8.0 Toxic substances management policy

During the review of methyl anthranilate, the PMRA has considered the implications of the federal TSMP and the PMRA regulatory directive DIR99-03 (*The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*) and has concluded that:

- Methyl anthranilate is not bioaccumulative. Studies have shown that the octanol–water partition coefficient (log K_{ow}) is 1.9 or lower, which is below the TSMP Track-1 cut-off criterion of 5.0 or higher.
- The formulated product, Avigon 14.5, does not contain any by-products or microcontaminants that meet the TSMP Track-1 criteria. Impurities of toxicological concerns are not expected to be present in the raw materials nor are they expected to be generated during the manufacturing process.
- The toxicity of methyl anthranilate is descried in detail in Sections 3.0 to 6.0 of this document. The formulated product does not contain any formulants that are known to contain TSMP Track-1 substances.

9.0 Proposed regulatory decision

The Agency has established, interim registrations (time limited to December 31, 2000) of the technical grade active ingredient Avigon MA (Technical Methyl Anthranilate) and its associated end-use formulation, Avigon 14.5 Canada Goose Repellent for Turf, and is proposing full registration, pursuant to Section 13 of the PCP Regulations. This proposed decision for full registration is open to comments.

List of Abbreviations

a.i.	active ingredient
APPL	applicator
bw	body weight
CAS	Chemical Abstract Services
CEPA	Canadian Environmental Protection Act
d	day
DF	dry flowable
DI	dietary intake
dw	dry weight
EEC	expected environmental concentration
GC	gas chromatography
h	hour
ind	individual
Κ	Henry's law constant at 20°C
$K_{ m ow}$	<i>n</i> -octanol–water coefficient
LC ₅₀	lethal concentration 50%
LD_{50}	lethal dose 50%
LOEC	lowest observed effect concentration
ME	microencapsulated
mg	milligram
MLOD	mixer and loader
MOE	margin of exposure
NAFTA	North American Free Trade Agreement
nm	nanometre
NOEC	no observable effect concentration
NOEL	no observable effect level
PCP Act	Pest Control Products Act
PCP Regulations	Pest Control Products Regulations
PHED	Pesticides Handlers Exposure Database
pK _a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRDD	proposed regulatory decision document
TSMP	Toxic Substances Management Policy
URMUR	user requested minor use registration
U.S.	United States World Health Organization
WHO	World Health Organization