Proposed Registration Document PRD2014-07

Thyme Oil and Wintergreen Oil

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Overview

Proposed Registration Decision for Thyme Oil and Wintergreen Oil

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 TyraTech Thyme Oil Technical and TyraTech Wintergreen Oil Technical and TyraTech Drain Fly Killer and TyraTech TechDust (end-use products), containing the technical grade active ingredients thyme oil and wintergreen oil. TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact.

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 TyraTech Thyme Oil Technical, TyraTech Wintergreen Oil Technical, TyraTech Drain Fly Killer, and TyraTech TechDust.

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.

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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."

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 (for example, children) as well as organisms in the environment (for example, 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 Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on thyme oil and wintergreen oil, 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 thyme oil and wintergreen oil, 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 Are Thyme Oil and Wintergreen Oil?

Thyme oil and wintergreen oil are the active ingredients in the end-use products, TyraTech Drain Fly Killer and TyraTech TechDust. Both products are used indoors and outdoors around structures. TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact.

Health Considerations

Can Approved Uses of Thyme Oil and Wintergreen Oil Affect Human Health?

Thyme oil and wintergreen oil are unlikely to affect human health when used according to label directions.

Exposure to thyme oil and wintergreen oil may occur when applying the end-use products 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 (for example, 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.

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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*.

The technical grade active ingredient thyme oil is expected to be of low acute toxicity by the oral, dermal, and inhalation routes; corrosive to eyes and skin, and a skin sensitizer.

The technical grade active ingredient wintergreen oil is expected to be moderately acutely toxic by the oral route, low toxicity by the dermal and inhalation routes, severely irritating to eyes, moderately irritating to skin, and is not a skin sensitizer.

Human exposure from the commercial uses of TyraTech Drain Fly Killer and TyraTech TechDust are not expected to be of concern due to the low toxicity of the end-use products, and the precautionary and hygiene statements present on the end-use product labels that are aimed at mitigating exposure.

Residues in Water and Food

Dietary risks from thyme oil and wintergreen oil on food and water are not of concern.

TyraTech Drain Fly Killer and TyraTech TechDust are not intended for application to food. Also, the end-use product labels instruct not to contaminate food and water with the end-use products; therefore, exposures to thyme oil and wintergreen oil through food from the proposed end-use product uses are anticipated to be negligible.

No risks due to exposure from drinking water are anticipated as thyme oil and wintergreen oil are unlikely to persist in the environment to the extent that it could be consumed in drinking water.

Risks From Handling Thyme Oil and Wintergreen Oil

Risks are not of concern when thyme oil and wintergreen oil are used according to label directions, which include precautionary statements.

TyraTech Drain Fly Killer and TyraTech TechDust are to be applied by commercial applicators for application indoors and outdoors around commercial, institutional, industrial and residential areas.

There is minimal occupational exposure concern from TyraTech Drain Fly Killer, which is a ready-to-use product. Occupational exposure can occur during loading, application, and clean-up activities for TyraTech TechDust. However, risks from exposure are not of concern when workers follow label directions which include exposure mitigation measures, such as personal protective equipment , cautionary, and hygiene statements on the end-use product label. Moreover, the end-use product labels have mitigative measures to minimize bystander exposure and post-application exposure.

Environmental Considerations

What Happens When TyraTech Thyme Oil Technical and TyraTech Wintergreen Oil Technical Are Introduced Into the Environment?

The active ingredients, thyme oil (containing thymol) and wintergreen oil (containing methyl salicylate), are naturally occurring constituents of common plant species, such as thyme (*Thymus vulgaris*) and teaberry (*Gaultheria procumbens*), respectively, but are also present in food and other personal care products. Therefore, it is unlikely that the use of TyraTech Drain Fly Killer and of TyraTech TechDust would increase the concentration of thyme oil and wintergreen oil above background levels. Due to the nature of the proposed use of these products potential for exposure of non-target terrestrial and aquatic organisms to TyraTech Thyme Oil Technical and TyraTech Wintergreen Oil Technical is expected to be low. Therefore, the risk associated with the use of these products at the accepted application rates and use pattern is expected to be negligible.

Value Considerations

What Is the Value of TyraTech Drain Fly Killer and TyraTech TechDust?

TyraTech Drain Fly Killer and TyraTech TechDust contain thyme oil and wintergreen oil to kill various pests found in and around structures.

TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact. It is unlikely that pests will develop resistance to thyme oil and wintergreen oil. They can be used in conjunction with other pest control practices and/or in situations where alternatives to conventional pest control products are desired.

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 TyraTech Drain Fly Killer and TyraTech TechDust to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Workers are required to wear a NIOSH approved respirator for prolonged exposure. However, taking into consideration the inhalation irritation potential of the end-use product, a dust mask to prevent short-term exposure to workers is also required.

Based on the hazard profile of the dust formulation, TyraTech TechDust label requires a personal protective equipment statement: When loading and applying the end-use product, and during cleanup/maintenance activities, workers must wear a long-sleeved shirt and pants, waterproof gloves, goggles, a dust mask, shoes, and socks.

To ensure bystander protection, label statements are required on both the end-use product labels to instruct that the end-use products must not be applied in a way that it will contact workers or other persons, either directly or through drift.

To minimize post-application exposure to children and pets especially in locations, such as hospitals, schools, daycare facilities, multi-family housing, veterinary clinics, and nursing homes, the labels must include the following statement: Do not apply in areas accessible to children and pets.

Next Steps

Before making a final registration decision on thyme oil and wintergreen oil, 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 thyme oil and wintergreen oil (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

Thyme Oil and Wintergreen Oil

1.0 The Active Ingredients, Their Properties and Uses

1.1 Identity of the Active Ingredients

1.1.1 Thyme Oil

Active substance	Thyme oil
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	8007-46-3
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	100%

1.1.2 Wintergreen Oil

Active substance	Wintergreen oil
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	68917-75-9
Molecular formula	Not applicable

Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	100%

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

Technical Product—TyraTech Thyme Oil Technical

Property	Result
Colour and physical state	Colourless, pale yellow to pale amber liquid
Odour	Characteristic warm, spicy-herbaceous, thymol odour
Melting range	Not applicable; the product is a liquid at room temperature.
Boiling point or range	190-195°C at atmospheric pressure
Specific gravity	0.90-0.92
Vapour pressure	Not applicable; the product is a mixture of several complex components.
Ultraviolet (UV)-visible spectrum	Not applicable
Solubility in water at 25°C	437.4 mg/L
Solubility in organic solvents	Soluble in alcohol
n-Octanol-water partition coefficient (K_{ow})	Not applicable; the product is a mixture of several complex components.
Dissociation constant (pK_a)	Not applicable; the product is a mixture of several complex components.
Stability (temperature, metal)	When heated to decomposition it emits carbon monoxide and carbon dioxide; no decomposition or hazardous reaction occurs if stored and handled as indicated; not known to be explosive; will ignite if heated; does not react with water, nor is it pyrophoric. Thyme oil should be stored protected from light at 15-25ºC.

Technical Product—TyraTech Wintergreen Oil Technical

Wintergreen oil consists mainly of methyl salicylate; some of the properties provided below are for methyl salicylate.

Property	Result
Colour and physical state	Colourless to pale-yellowish or reddish liquid
Odour	Wintergreen odour
Melting range	N/A
Boiling point or range	220-224°C at atmospheric pressure
Density	1.08-1.18 g/mL
Vapour pressure at 25°C	4.57 Pa
Ultraviolet (UV)-visible spectrum	Not expected to absorb above 300 nm
Solubility in water at 30°C	0.74%
Solubility in organic solvents	Soluble in chloroform and ether; miscible with alcohol and glacial acetic acid
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} = 2.55
Dissociation constant (pK_a)	9.8
Stability (temperature, metal)	Methyl salicylate is sensitive to light and heat; no decomposition or hazardous reactions if stored and handled as indicated; not known to be explosive; will ignite if heated; does not react with water, nor is it pyrophoric. Wintergreen oil should be stored protected from light at 15-25ºC.

End-Use Product— TyraTech Drain Fly Killer

Property	Result
Colour	Milky white
Odour	Wintergreen odour
Physical state	Liquid
Formulation type	Emulsion (EC)
Guarantee	Thyme oil …….. 3.1% Wintergreen oil…6.8%
Container material and description	High density polyethylene (HDPE) bottles (with trigger spray); 650 mL - 3.78 L
Density	1 – 1.1 kg/L
pH of 1% dispersion in water	5-8
Oxidizing or reducing action	No known oxidizing or reducing action
Storage stability	Stable for 2 years
Corrosion characteristics	Non-corrosive to the packaging material
Explodability	Not explosive

End-Use Product—TyraTech TechDust

Property	Result
Colour	White to off-white
Odour	Wintergreen odour
Physical state	Solid
Formulation type	Dust (DU)
Guarantee	Thyme oil……....4.1% Wintergreen oil…9.0%
Container material and description	High density polyethylene (HDPE) bottles (with dispenser tip); 454 g - 4.54 kg
Density	0.4-0.5 kg/L
pH of 1% dispersion in water	N/A
Oxidizing or reducing action	Product may react with strong oxidizing agents
Storage stability	Stable for 2 years
Corrosion characteristics	Non-corrosive to the packaging material
Explodability	Not explosive

1.3 Directions for Use

TyraTech Drain Fly Killer is a ready-to-use product that kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders (excluding black widow and brown recluse) and springtails on contact. It is for use indoors and outdoors around commercial, institutional and industrial structures to kill the listed pests when applied for thorough coverage to a maximum of 1.7 L product/m^2. The product should be applied directly to the pest where possible but may also be applied to areas where insects may be harboring. For further information, please refer to the product label.

TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders (excluding black widows and brown recluse), silverfish and wasps on contact. It is for use indoors and outdoors around commercial, institutional, industrial and residential structures to kill the listed pests when applied for thorough coverage to a maximum of 10 to 140 grams/m^2 depending on pest species. The product should be applied directly to the pest where possible but may also be applied to areas where insects may be harboring. For further information, please refer to the product label.

1.4 Mode of Action

The mode of action (MOA) of thyme oil and wintergreen oil is not clear. However, essential oils are known to suffocate pests and thyme oil may also have a toxic effect.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The active ingredients are mixtures of complex components and therefore no analytical method to determine the composition of these products is required.

2.2 Method for Formulation Analysis

The active ingredients are mixtures of complex components and therefore no analytical enforcement method is required.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Technical grade active ingredients

Acute toxicity

To address the data requirements for the technical grade active ingredients , the applicant submitted toxicology information from databases and published sources on the technical grade active ingredients, including toxicology information on methyl salicylate and thymol to meet the data requirements of wintergreen oil and thyme oil, respectively. Methyl salicylate is the primary constituent in wintergreen oil and thymol that of thyme oil.

Thyme oil is of low acute toxicity by the oral and dermal routes. Based on the provided information and in-house data on thymol, thyme oil is expected to be of low acute toxicity by the inhalation routes, corrosive to eyes and skin, and is a skin sensitizer. Inhalation of thymol vapor is likely to cause irritation of the respiratory tract.

From the available information on methyl salicylate, wintergreen oil is moderately acutely toxic by the oral route (LD_{50} in rats: 887 mg/kg bw) and has low toxicity by the dermal route. In a Fragrance Materials Monograph on Methyl salicylate, an inhalation study was reported in which rats were exposed for 20 days to a saturated atmosphere (120 ppm) for 7 hours per day without any reported effects. Wintergreen oil is not likely to be acutely toxic by the inhalation route, but it is likely to cause irritation of the respiratory tract. Wintergreen oil is likely to be severely irritating to eyes and moderately irritating to skin in animals. In a Fragrance Materials Monograph, a sensitization study was reported in which 8% methyl salicylate in petrolatum did not cause any effects in a maximization test on human subjects; therefore, wintergreen oil is not expected to be a sensitizer.

Short term and long-term toxicity

For thyme oil and wintergreen oil, the applicant requested data waivers for short-term and long-term studies on the basis that increased environmental/human exposure to the active ingredients from the uses of the end-use products will be minimal. Waiver requests were supported by the rationale: 1) Thyme oil is a designated generally recognized as safe substance (GRAS) by the United States Food and Drug Administration (USFDA) when used in food for human consumption, and thymol has major uses in food, fragrances, and cosmetics; 2) Wintergreen oil is present in food and flavourings which are regularly ingested, and it is also topically applied to human skin via fragrances and liniments at higher rates than contained in the proposed end-use products.

Since the end-use products are not intended for application to food or food crops, and the active ingredients have a long history of well-established uses, the uses of the end-use products are unlikely to result in short-term or long-term toxicity concerns from the active ingredients. Moreover, there is no conclusive evidence to suggest that thymol is carcinogenic, genotoxic, neurotoxic, or a developmental/reproductive toxicant. The data waiver requests were found to be justifiable, and accepted.

End-use products

TyraTech Drain Fly Killer

The toxicology data requirements to support the registration of TyraTech Drain Fly Killer were met by submitting studies conducted with a formulation identical in composition with that of the end-use product. Based on the submitted studies, TyraTech Drain Fly Killer is of low acute toxicity by the oral, dermal, and inhalation routes and is minimally irritating to eyes and skin. As thymol is a known dermal sensitizer, the end-use product is also considered to be a dermal sensitizer even though the applicant submitted a study that suggested it was not. The submitted study was considered inconclusive.

TyraTech TechDust

To meet the toxicology data requirements of TyraTech TechDust, the applicant provided surrogate data from toxicity studies conducted with a liquid formulation containing higher concentrations of both of the active ingredients.

Since the submitted studies were conducted with a formulation different in physical form and chemical composition, these studies were not utilized for this assessment. However, there is sufficient information available on the active ingredients and formulants to characterize the toxicity profile of TyraTech TechDust.

From the available information on thyme oil, wintergreen oil, and other formulants in the end-use product, TyraTech TechDust is likely to be of low toxicity by the oral, dermal, and inhalation routes, moderately irritating to eyes, mildly irritating to skin, irritating to respiratory tract, and is considered to be a potential skin sensitizer.

3.1.1 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. Information on the reporting of incidents can be found on the Health Canada website.

As wintergreen oil and thyme oil are new active ingredients for pesticidal use in Canada, there are no incidents reported.

3.2 Food Residues Exposure Assessment

Since the end-use products are not intended for food use and the labels have instructions not to contaminate food and water, dietary exposure to thyme oil and wintergreen oil from the uses of the end-use products is anticipated to be negligible to non-existent.

3.2.1 Drinking Water

Exposure to thyme oil and wintergreen oil from drinking water is not likely to occur from the uses of the end-use products because thyme oil and wintergreen oil are unlikely to persist in the environment to the extent that they could be consumed in drinking water.

3.2.2 Maximum Residue Limits

Maximum residue limits (MRLs) for thyme oil and wintergreen oil are not necessary because TyraTech Drain Fly Killer and TyraTech TechDust will not be applied directly to food; therefore, dietary exposures to thyme oil and wintergreen oil from the uses of the end-use products are considered to be negligible to non-existent.

Thyme oil is GRAS by the USFDA, and in the US, thyme oil is listed as an active ingredient that is exempted from federal registration under section 25(b) of Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Wintergreen oil is listed as an inert ingredient that is eligible for inclusion in pesticide products as a minimal risk inert ingredient in the US. There are no CODEX maximum residue levels established for thyme oil and wintergreen oil.

3.3 Occupational Exposure and Risk Assessment

3.3.1 Use Description

TyraTech Drain Fly Killer

TyraTech Drain Fly Killer is a ready-to-spray insecticide formulation for use indoors and outdoors around commercial, institutional and industrial structures including restaurants, kitchens, hospitals, schools, daycare facilities, hotels, nursing homes, commercial dining rooms, food processing plants, warehouses, lavatories, offices, multi-family housing, and veterinary clinics. The target pests include drain flies/moth flies, fruit flies, phorid flies, house flies, German cockroaches, house crickets, spiders, and springtails, and the maximum application rate of the end-use product is 1.7 L/m^2. The proposed use site category (USC) is Structural (20).

The end-use product must be sprayed directly on insects and in areas where insects feed or forage, such as: drains, sinks, urinals, waste areas, dumpsters, and any other areas where insects may be hiding or harboring. Reapplication is required as needed.

TyraTech TechDust

TyraTech TechDust is for use indoors and outdoors around commercial, institutional, and residential structures, such as hotels, hospitals, multi-family housing, schools, nursing homes, offices, restaurants, kitchens, laboratories, factories, slaughter-houses, production facilities, modes of transport (not to include airplane cockpits), garages, storage units and other areas of human habitation or activity.

The target pests include ants, bedbugs, cockroaches, crickets, fleas (including larvae), spiders, silverfish and wasps. The approved application rate is 10 to 140 g/m^2. The proposed USCs are Structural (20) and Human Habitat and Recreational Areas (25).

The product is to be applied with a hand or power duster. For best results, apply directly on insects. Reapplication is required as needed.

The indoor use-sites include cracks, crevices and wall voids, and other areas where insects are hiding or harboring, such as behind backsplashes, baseboards, under tack strips, edges of linoleum or carpet, under appliances, counters, window ledges, behind and under furniture, garages, attics, bathrooms, basements, and crawl spaces.

The use-sites in food areas and food handling areas include walls, floorboards, under and around appliances, waste disposal areas and any other area where insects may be hiding or harboring. Prior to product application food items must be covered or removed and direct contact with food or food preparation areas must be avoided.

The outdoor use-sites include edges of patios, cracks or expansion joints in or along foundations or pavement, driveways, porches, doorways (to include French and sliding glass doors), window

sills and weep holes, and in those areas where pests harbor around the structure including under doormats, under and around potted plants, under or in the cracks and crevices of columns, eaves and soffits.

3.3.2 Occupational exposure and risk assessment

3.3.2.1 Mixer/loader/applicator Exposure and Risk Assessment

TyraTech Drain Fly Killer

Since TyraTech Drain Fly Killer is a ready-to-use formulation, there is no loading or mixing required for the application. Moreover, the targeted application is likely to result in minimal occupational exposure to the applicators when the product is used according to label directions. Based on the toxicology information, the end-use product is likely to be of low acute toxicity by the oral, dermal, and inhalation routes, minimally irritating to skin and eyes, and is a potential skin sensitizer. The occupational exposure resulting from the end-use product application is not likely to result in a significant risk.

TyraTech TechDust

Being a dust formulation, TyraTech TechDust is to be applied with hand or dust blowers. The uses may result in exposure to the loader, applicator, and those responsible for clean-up and maintenance activities. Workers will be primarily exposed by both inhalation and dermal routes. Ocular exposure is also a possibility.

The toxicology profile of TyraTech TechDust indicates that it is of low acute toxicity irrespective of the routes of exposure, moderately irritating to eyes, mildly irritating to skin, and is a potential dermal sensitizer. Inhalation of the end-use product is likely to result in the irritation of the respiratory tract. The label instructs use of a NIOSH approved respirator for prolonged exposure to dust. Because of exposure concern and potential of the end-use product to irritate and sensitize, additional mitigation measures, such as personal protective equipment requirements (for example, a dust mask to prevent short-term exposure to workers) and precautionary statements are required on the label.

TyraTech TechDust label includes the following personal protective equipment requirements: When loading and applying the end-use product, and during clean-up/maintenance activities, workers must wear a long-sleeved shirt and pants, water-proof gloves, goggles, a dust mask, shoes, and socks. For prolonged exposure, a respirator is required.

3.3.3 Bystander Exposure and Risk

As the commercial applications of the end-use products involve only authorized personnel, bystander exposure is expected to be minimal when the end-use products are used according to the label directions.

Because of diverse use-locations, to ensure bystander protection, additional label statements are on the end-use product labels. The labels include a precautionary statement that the product must not be applied in a way that it will contact workers or other persons, either directly or through drift.

3.3.4 Post-application Worker Exposure

The post-application activity expected is the likely clean-up of excessive spray residues from non-target areas. Since there are application sites where sensitive populations are likely to be exposed, such as hospitals, schools, daycare facilities, multi-family housing, nursing homes and veterinary clinics, to minimize post-application exposure to children and pets, the labels of the end-use products must indicate that the products are not to be applied in areas accessible to children and pets.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The active ingredients, thyme oil and wintergreen oil, are naturally occurring constituents of the plants thyme and wintergreen, respectively, but are also found in many other plants, and used in food and personal care products. The use-pattern of TyraTech Drain Fly Killer and TyraTech TechDust are not expected to significantly increase the exposure of non-target organisms to thyme oil and wintergreen oil to levels which may already be present in the environment.

4.2 Effects on Non-Target Species and Environmental Risk Characterization

Indoor uses of TyraTech Drain Fly Killer and TyraTech TechDust are not expected to result in significant exposure of non-target organisms in the environment. For outdoor uses, the product is to be applied by hand as a ready-to-use commercial dust directly to the target insect pests, in and around the perimeter of structures where insect pests would enter buildings. As such, exposure to the environment from this use (in other words, of levels above pre-existing background levels) should not be significant. Therefore, health risks to non-target aquatic and terrestrial organisms from the use of TyraTech Thyme Oil Technical and Wintergreen Oil Technical are unlikely to occur.

5.0 Value

5.1 Effectiveness Against Pests

Twelve laboratory trials demonstrated that TyraTech Drain Fly Killer killed on contact the following pests: drain/moth flies, fruit flies, phorid flies, house flies, American cockroaches, German cockroaches, house crickets, spiders, and springtails.

Nine laboratory trials demonstrated that TyraTech TechDust killed on contact the following pests: kills ants, bed bugs, cockroaches, crickets, fleas (including larvae), spiders, silverfish and wasps.

5.1.1 Acceptable Efficacy Claims

TyraTech Drain Fly Killer is a ready-to-use product that kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact.

TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact.

5.1.2 Non-Safety Adverse Effects

The labels contain a precautionary statement advising the user to treat a small, inconspicuous area of the surface to be treated to determine if damage (for example, staining, discolouration) will occur prior to treating the entire area.

5.2 Sustainability

5.2.1 Survey of Alternatives

Pyrethrins and pyrethroids (for example, permethrin, d-phenothrin) (MOA 3A) constitute most of the active ingredients registered in commercial class products to kill pests listed on the labels of TyraTech Drain Fly Killer and TyraTech TechDust. Most registered pyrethroids and pyrethrins are currently under re-evaluation by the PMRA (REV2011-05, *Re-evaluation of Pyrethroids, Pyrethrins and Related Active Ingredients*).

Organophosphates (in other words, chlorpyrifos, dichlorvos and malathion; MOA 1B) are registered for use against many of the same pests on the labels of TyraTech Drain Fly Killer and TyraTech TechDust. Most of these restrict where the product can be used (for example, chlorpyrifos cannot be used in residential areas). Chlorfenapyr was recently registered to kill ants, crickets, house flies, silverfish and spiders but its use is limited to direct application on the exterior of buildings.

Boron (that is, boric acid, disodium octaborate tetrahydrate and/or borax (MOA 8D)) and propoxur (MOA 1A) are registered for use against most pests on the labels of TyraTech Drain Fly Killer and TyraTech TechDust. However, the proposed re-evaluation decisions for these active ingredients (PRVD2012-03, *Boric Acid and its Salts (Boron)* and PRVD2011-09, *Propoxur*) could result in a reduced number of products available (for example, removal of dust formulations; bait stations) or number of active ingredients available in the future. Cryonite (liquid carbon dioxide) is registered for use against bed bugs and cockroaches but it is no longer available for sale and its registration will expire in 2016.

Silicon dioxide and/or silica gel are also registered against all pests except for drain flies/moth flies and springtails. Baits registered against ants and/or cockroaches may contain abamectin (MOA 6), a neonicotinoid (in other words, thiamethoxam and/or imidacloprid; MOA 4) or hydramethynon (MOA 20). Insect growth regulators (in other words, pyriproxyfen, s-methoprene; MOA 7) are registered to kill developing fleas. A pheromone ((Z)-9-tricosene) and a microbial (*Beauveria bassiana* strain HF23) are registered against house flies. German cockroach extract is registered for use an attractant in a trap against German cockroaches. D-limonene is a non-conventional active ingredient registered for use against bed bugs, cockroaches, crickets, fleas and spiders.

No active ingredients are registered for use against drain flies/moth flies. TyraTech Drain Fly Killer would represent a new product listing this pest on the product label.

TyraTech TechDust represents a new dust formulation for the structural pest control industry. Several dust formulations were either recently phased out (bendiocarb) or are proposed for phase-out under the re-evaluation program (for example, boric acid). Dust formulations are useful in locations where application of a liquid is not possible (for example, around electric boxes).

5.2.2 Compatibility with Current Management Practices Including Integrated Pest Management

Both TyraTech Drain Fly Killer and TyraTech TechDust can be used with other pest control practices (for example, sanitation, structural repairs) against labelled pests.

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

Since thyme oil and wintergreen oil likely suffocate the pests, it is unlikely that resistance to these active ingredients will develop.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Indoor uses of TyraTech Drain Fly Killer and TyraTech TechDust are not expected to result in significant exposure of non-target organisms in the environment. For outdoor uses, the product is to be applied by hand as a ready-to-use commercial dust directly to the target insect pests, in and around the perimeter of structures where insect pests would enter buildings. As such, exposure to the environment from this use (in other words, of levels above pre-existing background levels) should not be significant. Therefore, health risks to non-target aquatic and terrestrial organisms from the use of TyraTech Thyme Oil Technical and TyraTech Wintergreen Oil Technical are unlikely to occur.

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 product are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[1]. The list is used as described in the PMRA Notice of Intent NOI2005-01[2] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[3] 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:

- The technical grade active ingredients TyraTech Thyme Oil Technical and TyraTech Wintergreen Oil Technical do not contain any contaminants of health or environmental concern as identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641-2643: *List of Pest Control Product Formulants of Health or Environmental Concern*.

- The end-use product, TyraTech Drain Fly Killer, contains the formulant soya lecithin which is identified in the *Canada Gazette,* Part II, Volume 139, Number 24, pages 2641-2643: *List of Pest Control Product Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions*. Therefore, the label for TyraTech Drain Fly Killer

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1 *Canada Gazette*, Part II, Volume 139, Number 24, SI/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 I 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.*

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

3 Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

will include the signal word and statement: “Warning, contains the allergen soy” on the principal display panel. The end-use product, TyraTech TechDust Dust does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The applicant submitted toxicology information collected from databases and published sources for thyme oil and wintergreen oil and toxicology studies for the end-use products. Thyme oil is likely to be corrosive to eyes and skin, and is a skin sensitizer. Wintergreen oil is likely to be severely irritating to eyes and moderately irritating to skin. TyraTech Drain Fly Killer is of low acute toxicity, minimally irritating, and is a potential dermal sensitizer. TyraTech TechDust is likely to be moderately irritating to eyes, mildly irritating to skin, and is a potential skin sensitizer.

The proposed use of TyraTech Drain Fly Killer is likely to result in minimal occupational exposure. Occupational exposure to TyraTech TechDust will be minimal if workers follow label directions, which include a number of exposure reduction measures (for example, personal protective equipment, clothing, precautionary and hygiene statement). Bystander exposure and post-application exposure are anticipated to be minimal, if label directions are followed.

The end-use products are not intended for food use; therefore, there is no dietary exposure to thyme oil or wintergreen oil.

7.2 Environmental Risk

The active ingredients, thyme oil and wintergreen oil, are naturally occurring substances found in common plant species, such as thyme (*Thymus vulgaris*) and wintergreen (*Gaultheria spp*.). The limited release of thyme oil and wintergreen oil in the environment following the proposed use of TyraTech Drain Fly Killer and TyraTech TechDust is unlikely to cause concern for non-target organisms. Exposure will be limited and their use should not increase the concentration of thyme oil and wintergreen oil above background levels that may already exist in the environment.

Exposure to the environment from this use should not be significant. Therefore, the risk to non-target organisms is considered to be negligible when these products are used according to label instructions.

7.3 Value

TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact. It is unlikely that pests will develop resistance to thyme oil and wintergreen oil. They could be used in conjunction with other pest control practices. Both products could be used in situations where alternatives to conventional pest control products are desired.

8.0 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 TyraTech Thyme Oil Technical and TyraTech Wintergreen Oil Technical and TyraTech Drain Fly Killer and TyraTech TechDust (end-use products), containing the technical grade active ingredients thyme oil and wintergreen oil. TyraTech Drain Fly Killer kills drain flies (moth flies), fruit flies, phorid flies, house flies, cockroaches, crickets, spiders and springtails on contact. TyraTech TechDust kills ants, bed bugs, cockroaches, crickets, fleas, spiders, silverfish and wasps on contact.

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

♂	male
♀	female
µm	micrometre
bw	body weight
CAS	Chemical Abstracts Service
DACO	Data Code
DNCB	1-chloro-2,4-dinitrobenzene
DU	dust
EC	emulsion
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
g	gram
GRAS	generally recognized as safe substance
HDPE	high-density polyethylene
hr(s)	hour(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
m	meter
mg	milligram
mL	millilitre
MAS	maximum average score
MIS	maximum irritation score
MOA	mode of action
MRL	maximum residue limit
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
nm	nanometre(s)
Pa	pascals
pH	potential of hydrogen
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
US	United States
USC	use site category
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration
UV	ultraviolet
w/w	weight per weight basis

Appendix I Tables

Table 1 Toxicity Profile of Thyme Oil

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Thyme Oil				
Oral Toxicity	Rats	2840 mg/kg bw	Low acute toxicity	2237511
Dermal Toxicity	Rabbits	> 5000 mg/kg bw	Low acute toxicity	2237511
Inhalation Toxicity	Domestic pets	> 5 mg/L Based on the information on thymol	Low acute toxicity	2237511, 2360208
Primary Eye Irritation	Rabbits	Corrosive to eyes Based on the information on thymol	DANGER - CORROSIVE TO EYES	2237511, 2360208
Dermal Irritation	Rabbits	Corrosive to skin Based on the information on thymol	DANGER - SKIN IRRITANT	2237511, 2360208
Dermal Sensitization	Based on the information on thymol		Dermal sensitizer	2237511, 2360208

Table 2 Toxicology Profile of Methyl Salicylate (For Wintergreen Oil)

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Methyl Salicylate				
Oral Toxicity	Rats	887 mg/kg bw	Moderately acutely toxic WARNING - POISON	2237532
Dermal Toxicity	Rabbits	> 5000 mg/kg bw	Low acute toxicity	2237532, 2360216
Primary Eye Irritation	Guinea pigs	Severely irritating	DANGER – EYE IRRITANT	2237532, 2360216
Dermal Irritation	Rabbits	Moderately irritating	WARNING – SKIN IRRITANT	2237532, 2360216

Table 3 Toxicology Profile of TyraTech Drain Fly Killer*

STUDY	SPECIES/STRAIN DOSES	RESULT	TARGET ORGAN/SIGNIFICANT EFFECTS/COMMENTS	REFERENCES
Oral (Up and Down method)	Sprague Dawley rats 3 ♀/dose by gavage 5000 mg/kg bw	LD_{50} ♀: > 5000 mg/kg bw	No mortality or treatment-related effects. **Low acute oral toxicity**	2360196
Dermal	Sprague Dawley rats 5/sex/dose 5050 mg/kg bw 24-hr exposure	LD_{50} ♂ & ♀: > 5050 mg/kg bw	No mortality or major treatment-related effects. **Low acute dermal toxicity**	2360197
Inhalation (Nose-only exposure)	Sprague Dawley rats 5/sex/dose Gravimetric chamber concentration of 2.32 mg/L, mass median aerodynamic diameter of 2.3 µm, and exposure period of 4 hrs	LC_{50} ♂ & ♀ > 2.3 mg/L	No mortality. Decreased activity and piloerection noticed up to 72 hrs post-treatment. Necropsy findings were normal. **Low acute inhalation toxicity**	2360200
Primary eye irritation (Draize method)	New Zealand white rabbits 2 ♂ and 1 ♀ Dosed with 0.1mL of the test substance and left unwashed up to 24 hrs Ocular irritation was scored at 1, 24, 48 and 72 hrs post-instillation	MAS [a] = 0.44/110 MIS [b] = 1.33/110 (24 hrs)	No corneal opacity or iritis. Slight conjunctival irritation observed in 2 animals at 24 hrs which was resolved by 48 hrs. **Minimally irritating to the eye** (Based on an MAS of 0.44/110)	2360201
Primary dermal irritation (Draize method)	New Zealand white rabbits 1 ♂ and 2 ♀ 0.5 mL of the test substance per site per animal for 4 hr exposure	MAS [a] = 0.55/8 MIS [b] = 1/8	Very slight erythema was observed from 24-72 hrs. There was no edema noticed at any observation period. **Minimally irritating to the skin**	2360203

STUDY	SPECIES/STRAIN DOSES	RESULT	TARGET ORGAN/SIGNIFICANT EFFECTS/COMMENTS	REFERENCES
Dermal Sensitization (Modified Buehler method) Scored at 24 and 48 hrs after the first induction, and scored at 24 hrs after the 2nd and the 3rd induction exposures Scored at 24, and 48 hrs after the challenge application	Hartley albino Guinea pigs 15/sex Naïve control: 5/sex Treatment group (Dosed with 0.4 mL of the undiluted test substance, once/week for a 3-week period): 10/sex All animals were challenged 2 weeks after the last induction exposure with a dose of 0.4 mL undiluted test substance Historical Positive control: Tested with 1-chloro-2,4-dinitrobenzene (DNCB), 97% w/w	Negative results Positive results in positive control testing	No treatment related effects were observed. Erythema was absent at induction and challenge phases. Historical positive control validation study validates the test system of this study. **Negative skin sensitizer; however, the results of the study were inconclusive**	2360204

*Study was conducted with TyraTech Naturals Crawling Insect Spray, which is identical to TyraTech Drain Fly Killer
[a] MAS = Maximum Average Score for 24, 48 and 72 hrs
[b] MIS = Maximum Irritation Score (average)

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA No.	Reference
2237512	2012, TyraTech Naturals Thyme Oil Insecticide Products Chemistry Requirements for TGAI, DACO: 2.1,2.10,2.11,2.12,2.13,2.14,2.14.14,2.2,2.3,2.5,2.6
2298345	2013, Lebermuth letter, DACO: 2.11 CBI (Third Party Data – Confidential)
2298346	2013, IR Spectra, DACO: 2.13.2 CBI
2237529	2012, TyraTech Naturals Wintergreen Oil Insecticide Products Chemistry Requirements for TGAI, DACO: 2.1,2.10,2.11,2.12,2.13,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2 ,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.2,2.3,2.4,2.5,2.6,2.7
2298355	2013, Lebermuth letter, DACO: 2.11 CBI (Third Party Data – Confidential)
2298356	2013, IR Spectra, DACO: 2.13.2 CBI
2210130	2012, Chemistry Requirements for TGAI, DACO: 2.0,2.1,2.10,2.11,2.11.1,2.12,2.13,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.1 4.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.2,2.3,2.4,2.5,2.6
2210131	2012, Chemistry Requirements for End Products, DACO: 3.0,3.1,3.1.1,3.1.2,3.2,3.4,3.4.1,3.4.2,3.5.1,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9, 3.7 CBI
2210145	2012, Analytical Method for TyraTech Products for EPA/PMRA T-9077 (F-4019), DACO: 3.4 CBI
2210178	2012, Chemistry Requirements for TGAI, DACO: 2.0,2.1,2.10,2.11,2.11.1,2.12,2.13,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.1 4.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.2,2.3,2.4,2.5,2.6
2210182	2012, Chemistry Requirements for End Products, DACO: 3.0,3.1,3.1.1,3.1.2,3.2,3.4,3.4.1,3.4.2,3.5.1,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9, 3.7 CBI
2210188	2012, Analytical Method for TyraTech Products for EPA/PMRA F-4072 (TTN-0817-4D-B), DACO: 3.4 CBI

2.0 Human and Animal Health

2210132	2012, Summary, DACO: 5.1,5.2,5.5,7.2,7.4,7.8,9.2.4
2210135	2012, Summary - Toxicology Profile, DACO: 4.1,4.2.1,4.2.2,4.6,4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6
2210183	2012, Summary, DACO: 5.1,5.2,5.5,7.2,7.4,7.8,9.2.4
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2360201 2007, Acute Eye Irritation Study in Rabbits, DACO: 4.6.4
2360203 2007, Acute Dermal Irritation Study in Rabbits, DACO: 4.6.5
2360204 2007, Skin Sensitization Study in Guinea Pigs, DACO: 4.6.6
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3.0 Environment

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4.0 Value

2210187 2010, Evaluation of TechDust Efficacy, Repellency, and Residual Activity against General Household Pests, DACO: 10.2
2237487 2012, TyraTech Naturals TechDust Insecticide Value Summary, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.2
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2210141 2007, Evaluation of TyraTech F-4001 15% When Applied as Direct Spray to House Flies, DACO: 10.2
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2210143 2007, Evaluation of TyraTech F-4001 15% When Applied as Direct Spray to Springtails, DACO: 10.2
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B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

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