Evaluation Report ERC2011-09

Phoma macrostoma strain 94-44B

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Overview

Registration Decision for *Phoma macrostoma* strain 94-44B

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide, Scotts EcoSense Weed-B-Gon Manufacturing Use Concentrate, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial, containing the technical grade active ingredient *Phoma macrostoma* strain 94-44B, to control a broad spectrum of broadleaf weeds in established turfgrass and new seeding of grasses and in field grown nursery and ornamental plants and trees and container grown ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, these products have value and do not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the registrant must submit additional scientific information as a condition of registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide, Scotts EcoSense Weed-B-Gon Manufacturing Use Concentrate, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial.

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.

What Is *Phoma macrostoma* strain 94-44B?

Phoma macrostoma strain 94-44B is a fungus which is used as a microbial pest control agent (MPCA) to control weed seeds and established broadleaf weeds on turf, in field grown nursery and landscape ornamentals and in container grown ornamentals. The fungus colonizes roots and produces bioherbicidal compounds (macrocidins) which cause photobleaching and root inhibition in susceptible plants, ultimately resulting in plant death. The 94-44B strain of *Phoma macrostoma* was originally isolated from Canada thistle. Dicotyledonous plants demonstrate various levels of susceptibility to *Phoma macrostoma* strain 94-44B whereas monocotyledonous plants show resistance.

The three new end-use products, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial contain *Phoma macrostoma* strain 94-44B as the active ingredient. Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide and Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control are for domestic-class biological control of weed seeds (pre-emergent) and established broadleaf weeds (post-emergent) on turf. Scotts Phoma P Commercial is for commercial-class biological control of weed seeds (pre-emergent) and established broadleaf weeds (post-emergent) on turf, in field grown nursery and landscape ornamentals, and in container grown ornamentals.

Health Considerations

Can Approved Uses of *Phoma mactostoma* strain 94-44B Affect Human Health?

***Phoma macrostoma* strain 94-44B is unlikely to affect your health when Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial are used according to the label directions**

People can be exposed to *Phoma macrostoma* strain 94-44B when handling and applying the products. When assessing health risks, several key factors are considered: the microorganism's biological properties (for example, production of toxic byproducts); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When *Phoma macrostoma* strain 94-44B was tested on laboratory animals, there were no signs that it caused any toxicity or disease. Furthermore *Phoma macrostoma* strain 94-44B showed minimal to no growth in the range of 35°C to 45°C and no adverse effects from *Phoma macrostoma* strain 94-44B were reported in the published scientific literature.

Residues in Water and Food

Dietary risks from food and water are not of concern

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

As there are no direct applications to food, there is no concern for risks posed by dietary exposure of the general population, including infants and children, or animals to *Phoma macrostoma* strain 94-44B.

Occupational Risks From Handling Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial

Occupational risks are not of concern when Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial are used according to label directions, which include protective measures

Workers using Scotts Phoma P Commercial can come into direct contact with *Phoma macrostoma* strain 94-44B on the skin, in the eyes, or by inhalation. For this reason, the label will specify that workers exposed to Scotts Phoma P Commercial must wear waterproof gloves, long-sleeved shirt, long pants, shoes plus socks, eye goggles when handling and a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter).

Users of the domestic-class end-use products, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide and Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control, are expected to have infrequent contact with *Phoma macrostoma* strain 94-44B on the skin, in the eyes or by inhalation. For this reason, the labels for the two domestic-class end-use products will instruct users to avoid contact with eyes, wash hands thoroughly with soap and water after handling; and to remove contaminated clothing and wash before wearing them again.

For the general population, exposure could occur during maintenance or recreational activities on treated turf, but it is not expected that bystander exposures will pose an undue risk on the basis of the low toxicity/pathogenicity profile for *Phoma macrostoma* strain 94-44B. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial Are Introduced Into the Environment?

Environmental risks are not of concern

Following application, *Phoma macrostoma* strain 94-44B is likely able to survive in the outdoor soil under suitable environmental conditions (i.e., temperature, moisture), but over time populations of *Phoma macrostoma* strain 94-44B are expected to return to natural background levels.

The effects of *Phoma macrostoma* strain 94-44B on beneficial and/or environmentally important insects were examined. The studies showed that *Phoma macrostoma* strain 94-44B was not toxic to beneficial insects (i.e. bees, ladybird beetles and parasitic wasps). The effects of *Phoma macrostoma* strain 94-44B on avian species were also examined. *Phoma macrostoma* strain 94-44B was shown to be non-toxic and non-pathogenic to birds.

Although wild mammal, earthworm and microorganism testing were not conducted, adequate information was available to determine that significant adverse effects to these non-target terrestrial organisms are not expected. The information included *Phoma macrostoma* strain 94 44B showing minimal to no growth in the range of 35°C–45°C, and no adverse effects on laboratory mammals from human health and safety studies. Also, there are no published reports of disease associated with *Phoma macrostoma* strain 94-44B in wild mammals, earthworms and microorganisms.

The potential hazard to non-target terrestrial plants was addressed in studies that examined the host range of the *Phoma macrostoma strain* 94-44B. Although *Phoma macrostoma* strain 94-44B is pathogenic to a number of plant species, there are significant differences in host susceptibility depending on the rate of application and plant species. In general, monocotyledonous plants are resistant whereas dicotyledonous plants demonstrate various levels of susceptibility. Therefore, a precautionary statement will warn users to avoid contact with desirable plants, fruits and vegetables.

The effects of *Phoma macrostoma* strain 94-44B on aquatic non-target organisms were examined. The studies showed that *Phoma macrostoma* strain 94-44B was not toxic or pathogenic to fish. Also, *Phoma macrostoma* strain 94-44B was shown to have low toxicity to aquatic invertebrates and was pathogenic to aquatic plants. Minimal exposure to aquatic organisms is anticipated from the use pattern of the end-use products. Furthermore, label statements will be added to the label requiring handlers to not contaminate irrigation or drinking water or aquatic habitats by cleaning of equipment or disposal of wastes

Value Considerations

What Is the Value of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial?

End-use products containing *Phoma macrostoma* strain 94-44B, a pre-emergence as well as a post-emergence bioherbicide, control a broad spectrum of broadleaf weeds in established turfgrass, new seeding of grasses, in field grown nursery and ornamental plants and trees, and container grown ornamentals.

A single pre-emergence application of *Phoma macrostoma* strain 94-44B provides effective control of numerous broadleaf weeds including dandelion, scentless chamomile and English daisy and provides suppression of white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard.

Two to three post-emergence applications of *Phoma macrostoma* strain 94-44B provide effective control of white clover and black medic and provide suppression of dandelion, Canada thistle and broadleaf plantain.

A single pre-emergence spot application or two to three post-emergence spot applications of *Phoma macrostoma* strain 94-44B provide effective pre-emergence or post-emergence control and/or suppression of all the weeds listed above.

Phoma macrostoma strain 94-44B is a reduced-risk / non-conventional herbicide and as such, would not be included in the list of pesticides prohibited for sale by many provincial and municipal legislations; and therefore this active ingredient represents a viable alternative in the control of broadleaf weeds in lawns.

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 labels of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

As with all microbial pest control products, there are concerns with users developing allergic reactions through repeated high exposures to *Phoma macrostoma* strain 94-44B. Therefore, anyone handling, mixing/loading, or involved in clean-up/repair activities of Scotts Phoma P Commercial must wear waterproof gloves, long-sleeved shirt, long pants, shoes plus socks, and a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter).

For the domestic-class end-use products, users must wash hands thoroughly with soap and water after handling; and to remove contaminated clothing and wash before wearing them again.

Environment

As a general precaution, the label for the commercial class end-use product prohibits the direct application of the product to aquatic habitats (such as lakes, streams and ponds). The labels on the end-use products prohibit contamination of irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes. The labels further advise users to avoid contact of the end-use products with desirable plants, fruits and vegetables.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the registrant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation section of this Evaluation Report or in the section 12 Notice associated with these conditional registrations. The registrant must submit the following information within the time frames indicated.

Product Characterization and Analysis

To confirm the manufacturing methods and quality assurance for final commercial production, the registrant is required to provide confirmation of production methods, a five batch analysis for microbial contaminants and confirmation of product guarantee from production lots of Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide and its associated end-use products from the manufacturing sites.

Value

Data are required from additional field trials in which the efficacy of *Phoma macrostoma* strain 94-44B, applied pre-emergence at 16 g a.i./ha, is evaluated to confirm its efficacy for season-long control of the following weeds: chickweed, broadleaf plantain, common ragweed, wild mustard and English daisy.The outstanding product characterization and value information must be submitted to the PMRA by September 1, 2014.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted,[3] the PMRA will publish a consultation document when there is a proposed decision on the applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca)

[3] As per subsection 28(1) of the *Pest Control Products Act*.

Science Evaluation.

Phoma *macrostoma*

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active microorganism	*Phoma macrostoma* strain 94-44B
Function	control weed seeds (pre-emergent) and established broadleaf weeds (post-emergent) on turf, in field grown nursery and landscape ornamentals, and in containerized ornamentals
Binomial name	*Phoma macrostoma* strain 94-44B
Taxonomic designation	
Kingdom	Eumycota
Phylum	Deuteromycotina
Class	Coelomycetes
Order	Sphaeropsidales
Genus	*Phoma*
Species	*macrostoma*
Strain	94-44B
Patent Status information	Although applications have been submitted, no patents are currently held by the applicant in Canada.
Minimum purity of active	1.0×10^3 colony forming units (CFU)/g
Identity of relevant impurities of toxicological, environmental and/or significance.	The technical grade active ingredient does not contain any impurities or micro-contaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances. The product must meet microbiological contaminants release standards. Macrocidins, secondary metabolites of *Phoma macrostoma* strain 94-44B have been identified in the technical and end-use products. Each lot of the production lots will be monitored to ensure that macrocidins are at acceptable levels to ensure efficacy of the final technical grade active ingredient and/or end-use products.

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

Technical Product—Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide

Property	Result
Physical state	Powder
Colour	Brownish-grey
Odour	Earthy
Guarantee	1.0×10^3 CFU/g
Density	0.4 g/mL
Storage Stability	In progress
Corrosion Characteristics	In progress
pH	5.53
Flammability	N/A
Explodability	N/A

N/A= not applicable

Manufacturing Concentrate–Scotts EcoSense Weed-B-Gon Manufacturing Use Concentrate

The manufacturing concentrate and all end-use products have the same formulation. As such, refer to the table below for physical and chemical properties of the manufacturing concentrate.

End-Use Product—Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial

Property	Result
Physical state	Granule
Colour	Dark Brown
Odour	Earthy
Guarantee	1.0×10^3 CFU/g
Density	0.7 g/mL
Storage Stability	In progress
Corrosion Characteristics	In progress
pH	5.28
Flammability	N/A
Explodability	N/A

N/A= not applicable

1.3 Directions for Use

Phoma macrostoma strain 94-44B is a living fungus and the efficacy of all the end-use products is maximized when applied on moist soil, the daytime temperature is between 15 and 30ºC and where rainfall or irrigation occurs within 24 to 72 hours after application.

1.3.1 Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide

Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, containing *Phoma macrostoma* strain 94-44B, is a selective bioherbicide for use as a pre-emergent treatment (pre-emergence to weeds and pre- or post-emergence to turfgrass) or as a post-emergent treatment (post-emergence to weeds and pre- or post-emergence to turfgrass) in bentgrass, bermudagrass (not at the time of seeding for bermudagrass), fine fescue, tall fescue, Kentucky bluegrass, perennial ryegrass, annual ryegrass and mixture of these grasses for the control and suppression of many broadleaf weeds in Canada. This is a domestic class product that is applied once per growing season for pre-emergence control of weeds at a rate of 16 g product/m^2 and two to three times for post-emergence control of weeds at a rate of 32 g product/m^2 (Table 1.1) as a broadcast treatment with ground application equipment only.

Table 1.1 Rates of Application for Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence control in turfgrass (single application)	16 g product/m^2	dandelion, scentless chamomile, and English daisy	white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard
Post-emergence control in turfgrass (2 to 3 applications)	32 g product/m^2 per application	white clover and black medic	dandelion, Canada thistle, and broadleaf plantain

1.3.2 Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control

Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control, containing *Phoma macrostoma* strain 94-44B, is a selective bioherbicide for use as a pre-emergent spot treatment (pre-emergence to weeds and pre- or post-emergence to turfgrass) or as a post-emergent spot treatment (post-emergence to weeds and pre- or post-emergence to turfgrass) in bentgrass, bermudagrass (not at the time of seeding for bermudagrass), fine fescue, tall fescue, Kentucky bluegrass, perennial ryegrass, annual ryegrass and mixture of these grasses for the control and suppression of many broadleaf weeds in Canada. This is a domestic class product that is applied once per growing season for pre-emergence control of weeds and two to three times for post-emergence control of weeds. The container equiped EZ Dose Tip and Pour applicator applies 2 g of product per dose over a 20 centimetre diameter area (approximately 64 g product/m^2) (Table 1.2)

Table 1.2 Rates of Application for Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence spot control in turfgrass (single application)	2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2	dandelion, scentless chamomile, and English daisy	white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard
Post-emergence spot control in turfgrass (2 to 3 applications)	2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2 per application	dandelion, white clover, Canada thistle, and black medic	broadleaf plantain

1.3.3 Scotts Phoma P Commercial

Scotts Phoma P Commercial, containing *Phoma macrostoma* strain 94-44B, is a selective bioherbicide for use as a pre-emergent treatment or as a post-emergent treatment in turfgrass, field grown nursery and ornamental plants, and trees and container grown ornamentals consisting of bentgrass, bermudagrass (not at the time of seeding for bermudagrass), fine fescue, tall fescue, Kentucky bluegrass, perennial ryegrass, annual ryegrass and mixture of these grasses, creeping red fescue (*Festuca rubra*), smooth brome grass (*Bromus inermis*), meadow brome grass (*Bromus biebersteinii*), timothy grass (*Phleum pretense*), pot marigold (*Calendula officinalis*), salvia 'Vista Red' (*Salvia splendens*), Carolina geranium (*Geranium carolinianum*), snapdragon 'Rocket rose' (*Antirrhinum majus*), pansy 'Delta Pure Rose' (*Viola tricolour*), coral bells (*Heuchera* sp.) 'Purple palace', yarrow (*Achillea*), hydrangea (*Hydrangea arborescence*) 'Annabelle', blazing-star (*Liatris spicata*), Rhododendron x. PJM, Forsythia x. intermedia 'Golden Times', Boxwood (*Buxus sempervirens*) 'Elegantissma', Holly (*Ilex x. meserveae*) 'Blue Boy', Arborvitae (*Thuja x.*) 'Green Giant', Cotoneaster sal. Rep. 'Scarlet Leader', Petunia (*Petunia x hybrida*), marigold (*Tagetes patula*), alyssum (*Lobularia maritima*), crimson sage (*Salvia coccinea*), periwinkle (*Catharanthus roseus*), *Populus* spp. (hybrid poplar), *Picea mariana* (black spruce), and *Pinus* spp. (pine) for the control and suppression of many broadleaf weeds in Canada. This is a commercial class product that is applied once per growing season for pre-emergence control of weeds at a rate of 16 g product/m^2 or 2 g of product per dose over a 20 centimetre diameter area, and two to three times for post-emergence control of weeds at the rate of 32 g product/m^2 or with two to three spot applications of 2 g of product per dose over a 20 centimetre diameter area (approximately 64 g product/m^2) (Table 1.3).

Table 1.3 Rates of Application for Scotts Phoma P Commercial

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence control in turfgrass and field grown nursery and ornamental plants and trees and container grown ornamentals (single application)	16 g product/m^2 or 2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2	dandelion, scentless chamomile, and English daisy	white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard
Post-emergence control in turfgrass and field grown nursery and ornamental plants and trees and container grown ornamentals (2 to 3 applications)	32 g product/m^2 or 2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2 per application	dandelion, white clover, Canada thistle, and black medic	broadleaf plantain

1.4 Mode of Action

When *Phoma macrostoma* strain 94-44B is applied to the soil, susceptible plants turn yellow to white and then die or seedlings fail to emerge. Root growth is also inhibited. The fungus colonizes roots of both susceptible and resistant hosts but symptoms are only expressed in susceptible hosts. The symptoms are the result of phloem mobile metabolites produced by the growing fungus. The metabolites were found to be novel compounds and named as "macrocidins", the first representatives of a new family of cyclic tetramic acids. It was determined that macrocidins inhibit root growth and cause foliar bleaching. In general, monocotyledonous plants are resistant whereas dicotyledonous plants demonstrate various levels of susceptibility depending on plant age and method of application.

2.0 Methods of Analysis

2.1 Methods for Identification of the Microorganism

Phoma macrostoma strain 94-44B can be identified to the species level through microscopic examination of standard morphological features, such as pycnidia and conidia production as provided by Boerema *et al*., (2004). Further identification of biocontrol isolates was carried out by Polymerase Chain Reactions (PCR) using DNA probes specific to *Phoma macrostoma* isolates with herbicidal activity.

2.2 Methods for Establishment of Purity of Seed Stock

The strain known as *Phoma macrostoma* 94-44B was deposited with the International Depositary Authority of Canada (IDAC), National Microbiology Laboratory, Public Health Agency of Canada, 1015 Arlington Street, Winnipeg, Manitoba, Canada R3E 3R2. The accession number assigned by IDAC on February 23, 2001, is IDAC-230201-3.

Practices for ensuring the purity of the seed stock were adequately described in the method of manufacture and quality assurance program.

2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products

The potency (CFU/g) of the technical grade active ingredient and the end-use products will be determined by plate counts on standard media with antibiotics to which the microbial pest control agent (MPCA) is resistant.

2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites

Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial are not intended for use on food or feed crops. As there are no direct applications to food, no methods to determine and quantify the MPCA and relevant metabolites are required.

In the event it becomes required to analyze for residues of *Phoma macrostoma* strain 94-44B in plants, the PCR method developed to identify the MPCA in section 2.1 could be used to analyze for the MPCA and standardized high performance liquid chromatography methods for detection of the secondary metabolites, macrocidins.

2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

The manufacturing process described was for small pre-production batches in a research facility. The proposed manufacturing process for larger commercial-scale production was also described and is comparable to that described for pre-production.

The quality assurance procedures that will be used to limit contaminating microorganisms during manufacture of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial are acceptable.

During manufacturing, several approaches will be used to limit microbial contamination in the technical grade active ingredient and associated end-use products. These approaches will include frequent purity checks on agar media, sterilization of all equipment and media, and sanitization of recovery equipment.

The absence of human pathogens and below-threshold levels of contaminants were shown in the manufacture of pre-production batches using pathogen-specific growth media. Microbe-specific screening methods for enteric bacteria/total coliforms, yeasts/moulds, *Salmonella* spp., *Shigella* spp., *Staphylococcus* spp., and *Pseudomonas aeruginosa* are adequate for detecting and enumerating microbial contaminants of concern. Release standards for microbial contaminants in the pre-production batches comply with those permitted by the PMRA and are adequate to ensure that the end-use products do not contain unacceptable levels of human and animal disease-causing microorganisms. However, as analyses have only been done on pre-production batches, five batch analysis data will be required from commercial production lots to assure safety.

2.6 Methods to Determine Storage Stability and Shelf-life of the Microorganism

Results from storage stability testing from pre-production batches of three lots of the technical grade active ingredient and three lots of the end-use product showed that the end-use product is stable at 23°C or below for up to one year. These results support a similar storage stability claim for future lots from the proposed commercial production.

3.0 Impact on Human and Animal Health

3.1 Toxicity and Infectivity Summary

The PMRA conducted a detailed review of the toxicological database for *Phoma macrostoma* strain 94-44B. The database is complete, consisting of laboratory animal (*in vivo*) toxicity and/or infectivity studies (acute oral toxicity and infectivity, acute oral toxicity, acute pulmonary toxicity/pathogenicity, acute intraperitoneal infectivity, acute dermal toxicity), as well as irritation studies (dermal irritation and eye irritation) required for health hazard assessment purposes which were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered sufficient to characterize the toxicity and infectivity of this pest control agent and products.

The toxicology studies were conducted with various test substances. The acute oral toxicity and infectivity study was conducted using a mixture containing the spores of the MPCA and the technical grade active ingredient which contains mycelial propagules of the MPCA. The acute oral toxicity study was conducted with only the end-use product containing mycelial propagules of the MPCA. Only spores of the MPCA were tested in acute pulmonary and intraperitoneal studies. The end-use product was tested in the acute dermal toxicity, dermal irritation and eye irritation studies.

In an acute oral infectivity/toxicity study, no significant toxicity was observed in CD rats following oral gavage with 1×10^8 CFU of *Phoma macrostoma* strain 94-44B (as a mixture of spores and mycelial propagules). The test substance was initially detected in the lungs, spleen, liver, kidneys and stomach (and small intestine). Also, the test substance was detected initially in the feces of one female dosed rat. Test substance was cleared from all organs and tissues by Day 7. Based on the results of this study *Phoma macrostoma* strain 94-44B is of low toxicity and is non-infective in the rat when challenged via the oral route.

In an acute oral toxicity study, no mortalities and no signs of toxicity were observed in Sprague-Dawley rats following oral gavage with 5000 mg/kg bw of the end-use product of *Phoma macrostoma* strain 94-44B (4.5×10^4 CFU/g).

In a pulmonary toxicity/pathogenicity study, no significant toxicity was observed in CD rats following intratracheal treatment with spores of *Phoma macrostoma* strain 94-44B at a dose of 1.4×10^8 viable spores per animal. At necropsy, one male and two female rats sacrificed on Day 7 were reported to have enlarged lungs. Lungs (all lobes) were mottled with dark red colour for most study animals. The observation was reported to be due to animals being euthanized by carbon dioxide asphyxiation prior to necropsy. Although the MPCA was initially recovered from the lungs and spleen of one male and from the liver and kidneys of one female, clearance was achieved by Day 7. Based on the results of this study *Phoma macrostoma* strain 94-44B is of low toxicity and is non-infective in the rat when challenged via the pulmonary route.

In an intraperitoneal infectivity study, no mortalities and no significant clinical signs of toxicity were observed in CD rats following injection with a dose of 2.5×10^8 CFU/animal of *Phoma macrostoma* strain 94-44B spores in water. The MPCA was initially recovered in the lungs, spleen, liver, kidneys, mesenteric lymph nodes, cecum and lavage fluid (from peritoneal cavity). Clearance was achieved by Day 7. Based on the results, there was no evidence of pathogenicity or infectivity observed in rats following intraperitoneal injection with *Phoma macrostoma* isolate 94-44B at 2.5×10^8 CFU per test animal.

In an acute dermal toxicity study, no mortalities and no signs of toxicity were observed in rabbits treated with the end-use product of *Phoma macrostoma* strain 94-44B at a dose of 5000 mg/kg bw over 240 cm^2 of body surface.

In a dermal irritation study, no mortalities were observed in rabbits treated with the end-use product of *Phoma macrostoma* isolate 94-44B at a dose of 4.5×10^4 CFU/g over 240 cm^2 of body surface. There was slight erythema observed at 30–60 minutes post-exposure, however, no signs of irritation remained by 24 hours.

In an eye irritation study, irritation of the conjunctivae and iris was observed one hour after 0.1 g of the ground end-use product of *Phoma macrostoma* isolate 94-44B was instilled into the conjunctival sac of the right eye of New Zealand white rabbits. Irritation was completely resolved by Day 3 of the treatment period. The end-use product of *Phoma macrostoma* isolate 94-44B is mildly irritating to the eye based on the maximum irritation score (MIS) of 20.7 (at one hour). Consequently the eye irritation signal words "CAUTION EYE IRRITANT" are required on the principal display panels of all product labels, as well as label precautions requiring personal protective equipment and judicious handling to minimize exposure to handlers.

A statement summarizing the number of people who were potentially exposed to *Phoma macrostoma* isolate 94-44B during production indicated that no incidence of hypersensitivity occurred. Although a hypersensitivity study is not required, any incidents of hypersensitivity in workers or bystanders must be reported to the PMRA as a condition of registration according to Section 13 of the *Pest Control Products Act*.

A survey of published scientific literature revealed no cases of clinical infection by *Phoma macrostoma*. However, other species of *Phoma* have been associated with infections in humans. Reports of *Phoma* sp. skin infections include a subcutaneous abscess in an immunocompromised person, a subcutaneous infection by *Phoma minutella* in a person undergoing corticosteroid therapy, skin lesions by *Phoma minutispora* in two people with impaired immune systems and in skin lesions caused by a co-infection with *Phoma* spp. and *Scopulatiopsis brevicaulis* in two brothers. *Phoma* spp. were noted at low levels in skin lesions of dogs. In all these instances, the association of *Phoma* spp. is not sufficient to be regarded as the causative agent.

Phoma spp. are reported to produce pharmaceutical and other beneficial metabolites, including squalestatins with cholesterol lowering and antifungal activity. Furthermore, *Phoma exigua* var. *heteromorpha* and *Phoma herbarum* are reported to produce cytochalasins. *In vitro* cytotoxicity from cytochalasin and epoxycytochalasin was reported from *Phoma* sp. SNF-1778. Among the many reported metabolites produced by *Phoma* spp., some metabolites have reported mammalian cytotoxicity. There are no reports that the MPCA produces those metabolites with reported mammalian cytotoxicity.

An analysis of metabolites produced by *Phoma macrostoma* strain 94-44B only showed the production of macrocidins. Macrocidin A is the most abundant from extracts of mycelia and growth media, followed by deoxymacrocidin A, saturated deoxymacrocidin A, macrocidin B (13-hydroxymacrocidin A) at very low levels, and a macrocidin A derivative with an olefinic double bond replacing the epoxide group. Macrocidins are described as tetramic acid derivatives with a heterocyclic (2,4-pyrrolidinedione) moiety at epoxy group 16. Currently, macrocidins have only been associated with phytotoxicity through passive mobilization in plant roots and phloem, leading to root growth inhibition and foliar bleaching in susceptible plants.

Analyses of pre-production batches have identified the presence of macrocidins in the final product. The pre-production batches were made using methods similar to those used to make the test substances in the toxicity and infectivity studies. Although toxicity studies were not conducted directly on macrocidins, the technical grade active ingredient and end-use product test substances used in the toxicity and infectivity studies are expected to have also tested for any effects related to macrocidins. Therefore, the absence of toxic effects in the acute oral toxicity and infectivity study with the technical grade active ingredient and in the acute dermal toxicity study with the end-use product supports the absence of toxic effects related to the MPCA as well as any macrocidins present in the test substances.

Higher tier subchronic and chronic toxicity studies were not required because of the low acute toxicity of the MPCA, and no indications of infectivity, toxicity or pathogenicity in the test animals treated in the Tier I acute oral and pulmonary toxicity/infectivity tests.
Within the available scientific literature, there are no reports to suggest that *Phoma macrostoma* strain 94-44B has the potential to cause adverse effects on the endocrine system of animals. The submitted toxicity/infectivity studies in the rodent indicate that, following oral and pulmonary routes of exposure, the immune system is still intact and able to process and clear the MPCA. Based on the weight of evidence of available data, no adverse effects to the endocrine or immune systems are anticipated for *Phoma macrostoma* strain 94-44B.

3.2 Occupational / Bystander Exposure and Risk Assessment

3.2.1 Occupational

When handled according to the label instructions, the potential for dermal, inhalation and eye exposure for applicators, mixer/loaders, and handlers exist, with the primary source of exposure to workers being exposure to the skin or inhalation of dusts.

Since unbroken skin is a natural barrier to microbial invasion of the human body, dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. *Phoma macrostoma* has not been identified as a wound pathogen and there is no indication that it could penetrate intact skin of healthy individuals. Also, *Phoma macrostoma* strain 94-44B demonstrated low toxicity and minimal irritation in the dermal toxicity/irritation studies.

Workers loading the granular powder formulation for broadcast applications are at risk for inhalation of dusts and/or particulate matter. Inhalation exposure from spot treatment applications is expected to be minimal. Based on the toxicological profile for *Phoma macrostoma* strain 94-44B, exposure to a large single quantity of the MPCA via the pulmonary route is not of concern.

The PMRA assumes that all microorganisms contain substances that can elicit positive hypersensitivity reactions, regardless of the outcome of sensitization testing. Label statements (i.e. 'Potential Sensitizer') and risk mitigation measures such as the wearing of personal protective equipment, including waterproof gloves, long-sleeved shirt, long pants, shoes plus socks, and a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter) are required to minimize exposure and protect mixer/loaders, applicators and handlers who are most likely to be exposed repeatedly to the product.

Based on the results from the eye irritation study which showed the end-use product to be mildly irritating, label statements (i.e. 'Caution Eye Irritant') and risk mitigation measures such as the wearing of eye goggles when handling are required to minimize exposure to handlers who are most likely to be exposed repeatedly to the product.

3.2.2 Bystander

For the commercial end-use product, the product label allows application to turf and lawns, field grown ornamentals and container-grown ornamentals. For the domestic end-use products, the product labels allow application to residential lawns. The potential for non-occupational exposure to bystanders including adults, infants and children is therefore high, but the PMRA does not expect that this will pose an unacceptable risk to human health and safety on the basis of the low toxicity and pathogenicity profile for *Phoma macrostoma* strain 94-44B.

3.3 Incident Reports Related to Human and Animal Health

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Incidents from Canada and the United States were searched and reviewed for products containing *Phoma macrostoma*. As of June 6, 2011, there were no health-related incident reports submitted to the PMRA, nor summarized by the USEPA or the California Department of Pesticide Regulation, for end-use products containing *Phoma macrostoma*.

3.4 Dietary Exposure and Risk Assessment

3.4.1 Food

As there are no direct applications to food, there is no concern for risks posed by dietary exposure of the general population, including infants and children, or animals to *Phoma macrostoma* strain 94-44B and its associated metabolites, macrocidins.

3.4.2 Drinking Water

The end-use products are granular formulations which will be applied to turf, lawns, or field-grown and container-grown ornamentals by broadcast application or by spot treatments. Although *Phoma macrostoma* strain 94-44B could enter neighbouring aquatic environments via run-off, no risks are expected from exposure to this microorganism via drinking water because exposure will be minimal and there were no harmful effects observed in animals that were exposed orally in Tier I acute oral toxicity tests. The label on each of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control, and Scotts Phoma P Commercial instructs users not to contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes. Also, municipal treatment of drinking water will likely remove the transfer of residues to drinking water. Therefore, potential exposure to *Phoma macrostoma* strain 94-44B in surface and drinking water is negligible.

3.4.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Calculations of acute reference doses and acceptable daily intakes are not usually possible for predicting acute and long term effects of microbial agents in the general population or to potentially sensitive subpopulations, particularly infants and children. The single (maximum hazard) dose approach to testing MPCAs is sufficient for conducting a reasonable general assessment of risk if no significant adverse effects (i.e. no acute toxicity, infectivity or pathogenicity endpoints of concern) are noted in acute toxicity and infectivity tests. Based on all the available information and hazard data, the PMRA concludes that the MPCA is of low toxicity, is not pathogenic or infective to mammals, and that infants and children are likely to be no more sensitive to the MPCA than the general population. Thus there are no threshold effects of concern and, as a result, no need to require definitive (multiple dose) testing or apply uncertainty factors to account for intra- and interspecies variability. Further factoring of consumption patterns among infants and children; special susceptibility in these subpopulations to the effects of the MPCA, including neurological effects from pre- or post-natal exposures; and cumulative effects on infants and children of the MPCA and other registered microorganisms that have a common mechanism of toxicity, does not apply to this MPCA. As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of this MPCA to human health.

3.5 Maximum Residue Limits

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

As there are no direct applications to food crops the establishment of a MRL is not required for *Phoma macrostoma* strain 94-44B.

3.6 Aggregate Exposure

Based on the toxicity and infectivity test data submitted for the technical grade active ingredient and the end-use products and other relevant information in the PMRA's files, there is reasonable certainty that no harm will result from aggregate exposure of residues of *Phoma macrostoma* strain 94-44B to the general Canadian population, including infants and children, when the pest control product is used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information. Although uses of the domestic and commercial end-use products on public and residential lawns carry the potential for dermal and inhalation exposure to the general public, no increase in potential human health risks are expected as evidenced by the low toxicity findings in the dermal and pulmonary studies.

3.7 Cumulative Effects

The PMRA has considered the available information on the cumulative effects of residues and other substances that have a common mechanism of toxicity and action. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Besides naturally occurring strains of *Phoma macrostoma* in the environment, the PMRA is not aware of any other microorganisms, or other substances that share a common mechanism of toxicity or action with this microbial active ingredient. No cumulative effects are anticipated if the residues of the *Phoma macrostoma* strain 94-44B found in the domestic and commercial end-use products interact with related strains of this microbial species.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Environmental fate testing is intended to demonstrate whether a MPCA is capable of surviving or replicating in the environment to which it is applied. The testing could also provide an indication of which non-target organisms may be exposed to the MPCA as well as provide indications to the extent of exposure. Environmental fate data (Tier II/III) are not normally required at Tier I and are only triggered if significant toxicological effects in non-target organisms are noted in Tier I testing or are submitted by the applicant to support rationales to waive effects testing on non-target organisms. Since no significant toxicological effects are expected from the use of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial, no fate data are required to complete the environmental risk assessment of *Phoma macrostoma* strain 94-44B and its associated end-use products.

Phoma macrostoma strain 94-44B is a naturally occurring fungus that was isolated from Saskatchewan on infected thistle. The end-use products contain *Phoma macrostoma* strain 94-44B in the form of mainly mycelia with pycnidiospores and are applied in a dried form to the soil where plants are actively growing. Once activated the mycelia will grow in the soil, colonize plant roots and begin producing macrocidins which in susceptible plants will inhibit root growth and cause foliar bleaching. When susceptible hosts die, *Phoma macrostoma* returns to the soil with decomposition of the plant tissues. Studies have shown that fungal populations decline within four months of application and are undetectable after a year. Associated phytotoxic effects also decline over time. The application of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial is not expected to result in a sustained increase of populations of the MPCA beyond those of naturally occurring soil dwelling *Phoma* species.

4.2 Environmental Risk Characterization

4.2.1 Risks to Terrestrial Organisms

An avian oral toxicity study, four terrestrial arthropod toxicity studies, and a summary report of a terrestrial plant host range study were submitted to address the effects of *Phoma macrostoma* strain 94-44B on non-target organisms.

The potential for the MPCA to cause acute oral toxicity and pathogenicity in an avian species was assessed in a study on northern bobwhite quail (*Colinus virginianus*). Three groups of healthy 14-day-old birds were administered daily in the crop or proventriculus for five days with either *Phoma macrostoma* strain 94-44B (2.22×10^5 CFU/kg bw/day, nominal concentration), heat-inactivated *Phoma macrostoma* strain 94-44B (10 mL/kg bw/day) or deionized water (10 mL/kg bw/day; negative control). The birds were observed for 30 days. No mortalities, signs of toxicity or pathogenicity were noted throughout the study period. When compared to controls, there were no apparent effects on body weight. At necropsy, no significant observations were noted. Consequently, *Phoma macrostoma* strain 94-44B and inactivated *Phoma macrostoma* strain 94-44B are considered to be of low toxicity and not pathogenic to the northern bobwhite quail. Infectivity could not be assessed in the study as microbial enumeration was not conducted. However, *Phoma macrostoma* strain 94-44B does not grow above 35°C and therefore, would not be expected to grow in northern bobwhite quail whose standard body temperature is 41°C.

The potential for adverse effects of the MPCA on non-target terrestrial arthropods was assessed in a honeybee toxicity study, a lady beetle (*Hippodamia convergens*) toxicity study, a green lacewing (*Chrysoperla rufilabris*) toxicity study and a parasitic wasp (*Pediobius foveolatus*) toxicity study. The studies were conducted with *Phoma macrostoma* strain 94-44B (ground mycelia).

In the 5-day dietary toxicity study, honeybees (*Apis mellifera*) were exposed to *Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5 and 1×10^6 CFU/g. No significant effect on bee mortality was observed in the treatment groups (24–25%) compared to an untreated control group (27%). Although a few treated bees demonstrated lethargy and immobility, this observation was not statistically significant when compared to the number seen in the untreated control group. The 5-day LC_{50} is therefore estimated to be $> 1 \times 10^6$ CFU/mL. Although this study did not test for pathogencity, the current scientific literature does not indicate that *Phoma macrostoma* is a pathogen to honeybees.

In a 12-day dietary toxicity study, ladybird beetles (*Hippodamia convergens*) were exposed to *Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5 and 1×10^6 CFU/mL. No significant effect on lady beetle mortality was observed in the treatment groups (13–20%) compared to the untreated control group (24%). No signs of toxicity or pathogenicity were observed. Therefore, the 12-day LC_{50} is estimated to be $> 1 \times 10^6$ CFU/mL.

In a 15-day dietary toxicity study, green lacewing larvae (*Chrysoperla rufilabris*) were exposed to *Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5 and 1×10^6 CFU/mL. No significant effect on green lacewing larvae mortality was observed in the treatment groups (7–27%) compared to the untreated control group (21%). No signs of toxicity or pathogenicity were observed. Therefore, the 15-day LC_{50} is estimated to be $> 1 \times 10^6$ CFU/mL.

In a 16-day dietary toxicity study, parasitic hymenoptera (*Pediobius foveolatus*) were exposed to *Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5 and 1×10^6 CFU/mL. No significant effect on parasitic hymenoptera mortality was observed in the treatment groups (28–32%) compared to the untreated control group (21%). No signs of toxicity or pathogenicity were observed. Therefore, the 16-day LC_{50} is estimated to be $> 1 \times 10^6$ CFU/mL.

The potential hazard to non-target terrestrial plants was addressed in a summary of 10 studies that examined the host range of the MPCA. The studies involved pre- or post-emergent applications of either an MPCA culture or technical grade active ingredient or end-use product to soil. By planting in the treated soil, a total of 75 plant species in 22 plant families were tested for signs of susceptibility to the MPCA. Parameters monitored included: decrease seed emergence, decrease foliar biomass, chlorosis, and mortality. The following seven plant families were resistant: Salicaceae, Pinaceae, Iridaceae, Curcurbitaceae, Solanaceae (bell pepper, tomato), Linaceae, Graminae. The following sixteen plant families were susceptible: Convolvulaceae, Lythraceae, Polygonaceae, Rubiaceae, Euphorbiaceae, Caryophyllaceae, Brassicaceae, Amaranthaceae, Labiatae, Lamiaceae, Leguminosae/Fabaceae, Rosaceae, Plantaginaceae, Asteraceae, Balsminaceae, Solanaceae (petunia).

Germination was affected in some plant species including strawberry. Taxonomically strawberry is in the Rosaceae family, which is the main host family where *Phoma macrostoma* is often isolated. The largest number of susceptible plants to *Phoma macrostoma* strain 94-44B were found in Asteraceae, Leguminosae/ Fabaceae, and Brassicaceae. Although *Phoma macrostoma* strain 94-44B is pathogenic to a number of plant species, there are significant differences in host susceptibility depending on the rate of application and plant species. Therefore, a precautionary statement on the end-use product labels will advise users to avoid contact with desirable plants, fruit and vegetables.

A request to waive wild mammal toxicity testing was accepted based on sound scientific reasoning: i) *Phoma macrostoma* is ubiquitous in nature, occurring globally in a wide variety of habitats, such that use of the end-use products would not significantly increase the fungus in the environment; ii) the use of the end-use products is a direct application to soil and the MPCA has been shown to have limited mobility and persistence in soil which would limit exposure to wild mammals; iii) although ubiquitous in nature, there have been no reports of adverse effects to wild mammals and results from human health and safety studies conducted on laboratory mammals with *Phoma macrostoma* strain 94-44B indicated no toxicity or pathogenicity; and iv) *Phoma macrostoma* strain 94-44B exhibits minimal to no growth in the range of 35–45°C. Based on these arguments, the PMRA has concluded that no adverse effects are likely to occur following exposure of wild mammals to the MPCA, *Phoma macrostoma* strain 94-44B.

An extensive search of the published scientific literature did not reveal any suggestive evidence that *Phoma macrostoma* is associated with adverse effects in earthworms or other soil macroorganisms. *Phoma macrostoma* is considered a ubiquitous organism that occurs mostly on woody plants and incidentally on herbaceous host plants, as a weak plant pathogen. Although *Phoma macrostoma* has been found on nematode eggs and cysts, the MPCA is not considered a pathogen of non-arthropod invertebrates.

Based on all the available data and information on the effects of the *Phoma macrostoma* strain 94-44B to terrestrial organisms, there is reasonable certainty that no harm will be caused to birds, wild mammals, arthropods, non-arthropod invertebrates, and to other non-target microorganisms from the use of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide and Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control on residential lawns, and Scotts Phoma P Commercial on turf, and field and container grown ornamentals.

4.2.2 Risks to Aquatic Organisms

A freshwater fish study, aquatic arthropod toxicity study and an aquatic plant study were submitted to address the effects of *Phoma macrostoma* strain 94-44B on aquatic non-target organisms.

No treatment-related toxicity or pathogenicity was observed when groups of rainbow trout (*Oncorhynchus mykiss*) were exposed to *Phoma macrostoma* strain 94-44B in dilution water over a 32-day period. Under static-renewal conditions, rainbow trout were exposed to *Phoma macrostoma* strain 94-44B at concentrations of 1.56×10^4 CFU/mL, 3.13×10^4 CFU/mL, 6.25×10^4 CFU/mL, 1.25×10^5 CFU/mL or 2.5×10^5 CFU/mL. The same groups of fish were given the following dietary concentrations of 26 CFU/g, 53 CFU/g, 105 CFU/g, 210 CFU/g or 420 CFU/g, respectively. Based on this study, the 32-day LC_{50} is $> 2.5 \times 10^5$ CFU/mL, with a dietary concentration of 420 CFU/g. The study indicates that *Phoma macrostoma* strain 94-44B is neither toxic nor pathogenic to freshwater fish.

In a 21-day aquatic study, cladocerans (*Daphnia magna*) were exposed to *Phoma macrostoma* strain 94-44B at concentrations of 1.56×10^4 CFU/mL, 3.13×10^4 CFU/mL, 6.25×10^4 CFU/mL, 1.25×10^5 CFU/mL or 2.50×10^5 CFU/mL under static renewal conditions. The LC_{50} was estimated to be $> 1.56 \times 10^4$ CFU/mL. Based upon the 100% mortality observed in the attenuated (heat-inactivated) control group by Day 16, the reported mortality was related to toxicity rather than to infectivity or pathogenicity. Furthermore observations of the test daphnids being trapped in precipitated material in the aqueous test solutions likely contributed to mortalities. The study indicates that *Phoma macrostoma* strain 94-44B has low toxicity to cladocerans.

In a 7-day aquatic plant study, duckweed (*Lemna gibba*) was exposed to *Phoma macrostoma* strain 94-44B in concentrations of 1.56×10^3 CFU/mL, 3.13×10^4 CFU/mL, 6.25×10^4 CFU/mL, 1.25×10^4 CFU/mL or 2.5×10^5 CFU/mL. By the end of the 7-day study period, the test substance caused necrosis in some fronds and a statistically significant inhibition in frond number and biomass at the higher test concentrations. The NOEC was 6.25×10^4 CFU/mL and the LOEC was 1.25×10^5 CFU/mL. The study indicates that *Phoma macrostoma* strain 94-44B is a potential pathogen to duckweed. Therefore, *Phoma macrostoma* may cause adverse effects to aquatic plants.

A search of the published scientific literature also found no reports of adverse effects on aquatic non-target organisms. *Phoma macrostoma*, furthermore, is not considered to be an aquatic fungus and therefore is not expected to persist long in exposed aquatic habitats. Based on all the available data and information on the effects of *Phoma macrostoma* strain 94-44B to aquatic organisms, there is reasonable certainty that no harm will be caused to non-target aquatic organisms from the proposed use of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide and Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control on residential lawns, and Scotts Phoma P Commercial on turf, and in field and container grown ornamentals. As a general precaution, label statements will be added to the label requiring handlers to not contaminate irrigation or drinking water or aquatic habitats by cleaning of equipment or disposal of wastes.

4.3 Incident Reports Related to the Environment

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Only incidents in which the pesticide is determined to be linked to the effects (Canadian causality of highly probable, probable and possible; U.S. causality of highly probable, probable and possible) are considered in the reviews.

As of June 6, 2011, there were no environmental incident reports submitted to the PMRA for end-use products containing *Phoma macrostoma*. As *Phoma macrostoma* is not listed in the United States Environmental Protection Agency's (USEPA) Ecological Incident Information System (EIIS), the PMRA assumes that no environmental incidents were reported to the USEPA.

5.0 Value

5.1 Effectiveness Against Pests

Phoma macrostoma strain 94-44B is a living fungus and the efficacy of all the end-use products is maximized when applied on moist soil, the daytime temperature is between 15 and 30ºC and where rainfall or irrigation occurs within 24 to 72 hours after application.

5.1.1 Acceptable Efficacy Claims for Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide

Efficacy data were submitted from over 75 replicated field and greenhouse trials conducted from 2002 to 2008 at several locations in Alberta, Saskatchewan, New Brunswick, Ontario, Nova Scotia, Prince Edward Island, California and Ohio. Various rates of *Phoma macrostoma* strain 94-44B were assessed to determine the lowest effective rate. The herbicide treatments were applied using small plot application equipment in field trials or with a shaker in greenhouse trials.

The efficacy of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide was visually assessed as percent weed control and compared to an untreated check. Observations were made at various times throughout the growing season. The data support the weed control claims summarized in Table 5.1 when Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide is applied as a pre- or post-emergence treatment in established turfgrass or new seeding of grasses.

Table 5.1 Weed Control Claims for Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence control in turfgrass (single application)	16 g product/m^2	dandelion, scentless chamomile, and English daisy	white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard
Post-emergence control in turfgrass (2 to 3 applications)	32 g product/m^2 per application	white clover and black medic	dandelion, Canada thistle, and broadleaf plantain

5.1.2 Acceptable Efficacy Claims for Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control

Efficacy data were submitted from over 30 replicated field trials conducted from 2005 to 2008 at several locations in Alberta, Saskatchewan, British Columbia, New Brunswick, Ontario, Nova Scotia, Prince Edward Island, California and Ohio. Various rates of *Phoma macrostoma* strain 94-44B were assessed to determine the lowest effective rate. The herbicide treatments were applied by sprinkling a pre-measured amount of the bioherbicide from a shaker.

The efficacy of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control was visually assessed as percent weed control and compared to an untreated check. Observations were made at various times throughout the growing season. The data support the weed control claims summarized in Table 5.2 when Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control is applied as a pre or post-emergence treatment in established turfgrass or new seeding of grasses.

Table 5.2 Weed Control Claims for Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence spot control in turfgrass (single application)	2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2	dandelion, scentless chamomile, and English daisy	white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard
Post-emergence spot control in turfgrass (2 to 3 applications)	2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2 per application	dandelion, white clover, Canada thistle, and black medic	broadleaf plantain

5.1.3 Acceptable Efficacy Claims for Scotts Phoma P Commercial

Efficacy data were submitted from over 30 replicated field and greenhouse trials conducted from 2002 to 2008 at several locations in Alberta, Saskatchewan, New Brunswick, Ontario, Nova Scotia, Prince Edward Island, California and Ohio. Various rates of *Phoma macrostoma* strain 94-44B were assessed to determine the lowest effective rate. The herbicide treatments were applied by sprinkling a pre-measured amount of the bioherbicide from a shaker.

The efficacy of Scotts Phoma P Commercial was visually assessed as percent weed control and compared to an untreated check. Observations were made at various times throughout the growing season. The data support the weed control claims summarized in Table 5.3 when *Phoma macrostoma* strain 94-44B is applied as a pre or post-emergence treatment in established turfgrass or new seeding of grasses and field grown nursery and ornamental plants and trees and container grown ornamentals.

Table 5.3 Weed Control Claims for Scotts Phoma P Commercial

Timing	Herbicide Rate	Weeds Controlled	Weeds Suppressed
Pre-emergence control in turfgrass and field grown nursery and ornamental plants and trees and container grown ornamentals (single application)	16 g product/m^2 or 2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2	dandelion, scentless chamomile, and English daisy	white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard
Post-emergence control in turfgrass and field grown nursery and ornamental plants and trees and container grown ornamentals (2 to 3 applications)	32 g product/m^2 or 2 g of product over a 20 cm diameter area equivalent to 64 g product/m^2 per application	dandelion, white clover, Canada thistle, and black medic	broadleaf plantain

5.2 Phytotoxicity to Host Plants

5.2.1 Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide and Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control

Data from a combination of 69 dedicated tolerance trials and efficacy trials conducted from 2004 to 2008 at multiple locations in Alberta, Saskatchewan, New Brunswick, Ontario, Nova Scotia, Prince Edward Island and Ohio were submitted in support of new seeding of grasses or established turfgrass tolerance claims. Some trials included multiple species of grasses and some trials included treatments of *Phoma macrostoma* strain 94-44B applied at the 2X, 4X, and 8X maximum proposed rate.

Crop injury was visually assessed up to four times during the growing season. Crop injury to established turfgrass and new seeding of bentgrass, bermudagrass (not at the time of seeding for bermudagrass), fine fescue, tall fescue, Kentucky bluegrass, perennial ryegrass, annual ryegrass and mixture of these grasses was acceptable for up to three applications of *Phoma macrostoma* strain 94-44B at the maximum rate of application of 64 g product/m^2 per application.

5.2.2 Scotts Phoma P Commercial

Data from all trials submitted in support of seeding grasses and established turfgrass for Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide and Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control were used to confirm the tolerance claims to seeding grasses and established turfgrass treated with Phoma P Commercial. In addition, data from 2 dedicated tolerance trials conducted in 2009 in Ohio were submitted in support of various species of container ornamentals and garden transplants. Both trials included multiple species of ornamental plants and one trial included treatments of *Phoma macrostoma* strain 94-44B applied at the 2X and 4X maximum proposed rate.

Crop injury was visually assessed up to four times during the growing season. Crop injury to established turfgrass and new seeding of bentgrass, bermudagrass (not at the time of seeding for bermudagrass), fine fescue, tall fescue, Kentucky bluegrass, perennial ryegrass, annual ryegrass and mixture of these grasses was acceptable for up to three applications of *Phoma macrostoma* strain 94-44B at the maximum rate of application of 64 g product/m^2 per application. In addition, crop injury to field grown nursery and ornamental plants and trees and container grown ornamentals consisting of creeping red fescue (*Festuca rubra*), smooth brome grass (*Bromus inermis*), meadow brome grass (*Bromus biebersteinii*), timothy grass (*Phleum pretense*), pot marigold (*Calendula officinalis*), salvia 'Vista Red' (*Salvia splendens*), Carolina geranium (*Geranium carolinianum*), snapdragon 'Rocket rose' (*Antirrhinum majus*), pansy 'Delta Pure Rose' (*Viola tricolour*), coral bells (*Heuchera* sp.) 'Purple palace', yarrow (*Achillea*), hydrangea (*Hydrangea arborescence*) 'Annabelle', blazing-star (*Liatris spicata*), Rhododendron x. PJM, Forsythia x. intermedia 'Golden Times', Boxwood (*Buxus sempervirens*) 'Elegantissma', Holly (*Ilex x. meserveae*) 'Blue Boy', Arborvitae (*Thuja x.*) 'Green Giant', Cotoneaster sal. Rep. 'Scarlet Leader', Petunia (*Petunia x hybrida*), marigold (*Tagetes patula*), alyssum (*Lobularia maritima*), crimson sage (*Salvia coccinea*), periwinkle (*Catharanthus roseus*), *Populus* spp.

(hybrid poplar), *Picea mariana* (black spruce), and *Pinus* spp. (pine) was also acceptable for up to three applications of *Phoma macrostoma* strain 94-44B at the maximum rate of application of 64 g product/m^2 per application.

5.3 Economics

Broadleaf weeds found growing in residential turf have been an ongoing problem with Canadian homeowners and considerable time and money is spent in the control of weeds in lawns. Healthy lawns are a valuable resource and benefit to both the homeowner as well as the environment at large; it provides homeowners a safe place to play, free of irritants such thistle and stinging nettles. Healthy turf also provides protective cushioning and level surfaces to make for safe and enjoyable outdoor activities. Allergy sufferers as well as those with respiratory problems face severe discomfort from an open space riddled with weeds such as ragweed. Healthy lawns also provide homeowners curb appeal which leads to increased home value.

In Canada, some provincial and municipal legislation prohibit the sale and use of certain synthetic pesticides for cosmetic purposes on lawns, gardens, parks and school yards since such uses are considered to be for aesthetic purposes only. As a result of these legislations, the most commonly used tools to control weeds in lawn (i.e. Group 4 chemical herbicides) are no longer available to the majority of Canadians living in urban areas. However, these legislations do allow the use of certain lower-risk pesticides, such as *Phoma macrostoma* strain 94-44B for controlling weeds in lawns and gardens.

5.4 Sustainability

5.4.1 Survey of Alternatives

Since the late 1940's homeowners have had the ability to control unwanted weeds in their lawns with the use of selective post-emergence herbicides containing 2,4-D, mecoprop, and dicamba. However, the use of these products for cosmetic purposes in lawns is not permitted in a number of municipalities and provinces and homeowners have to rely on management practices such as multiple lawn feedings, overseeding, manual removing of weeds, and the use of certain non-conventional, reduced-risk, products containing corn gluten, iron (present as FeHEDTA) and *Sclerotinia minor* strain IMI 344141 to control unwanted weeds in their lawns.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

End-use products containing *Phoma macrostoma* strain 94-44B offer an alternative to the use of traditional chemical herbicides for the control of broadleaf weeds in turf and on ornamental plants. The availability of herbicides containing *Phoma macrostoma* strain 94-44B will allow homeowners and nursery owners the possibility to develop and implement sustainable turf management practices, especially in areas where the application of chemical herbicides is undesirable or prohibited by law.

The application of *Phoma macrostoma* strain 94-44B is compatible with all the integrated pest management practiced in turf including adequate fertilization of the lawn, irrigation, overseeding, and manual removing of weeds.

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

Based on the mode of action of *Phoma macrostoma* strain 94-44B, the development of resistance is unlikely.

5.4.4 Contribution to Risk Reduction and Sustainability

Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control, and Scotts Phoma P Commercial are non-conventional products that offer an alternative to the use of traditional chemical herbicides in turf, especially where the use of traditional herbicides is not desirable or prohibited by law. As such, these products may contribute to a reduction in the use of chemical herbicides in turf and in ornamental plants.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's *Toxic Substances Management Policy*, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

While reviewing *Phoma macrostoma* strain 94-44B, the PMRA took into account the federal Toxic Substances Management Policy and followed its Regulatory Directive DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy. Substances associated with its use were also considered, including microcontaminants in the technical product, Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide, and formulants in the manufacturing concentrate, Scotts EcoSense Weed-B-Gon Manufacturing Use Concentrate and in the end-use products, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial. The PMRA has reached the following conclusions:

Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide does not meet the Track 1 criteria because the active ingredient is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products. There are also no formulants, contaminants or impurities present in the manufacturing concentrate and end-use products that would meet the TSMP Track 1 criteria.

Therefore, the use of Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide, Scotts EcoSense Weed-B-Gon Manufacturing Concentrate, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial are not expected to result in the entry of Track 1 substances into the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

The technical grade active ingredient, Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide, does not contain any contaminants of health or environmental concern identified in Canada Gazette Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The manufacturing concentrate, Scotts EcoSense Weed-B-Gon Manufacturing Use Concentrate, does not contain any contaminants of health or environmental concern identified in Canada Gazette Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

The end-use products, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial do not contain any contaminants of health or environmental concern identified in Canada Gazette Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

7.0 Summary

7.1 Methods for Analysis of the Microorganism as Manufactured

The product characterization data for Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide, Scotts EcoSense Weed-B-Gon Manufacturing Concentrate, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial were adequate to assess their potential human health and environmental risks. The technical grade active ingredient was fully characterized and the specifications were supported by sufficient batch analysis data. However, microbial contamination and potency testing are required on the technical grade active ingredient and end-use products produced at the manufacturing site to ensure they meet the registrant's quality control standards. Furthermore, confirmatory batch analysis data for potency and microbial contamination from five full-scale production lots of the technical grade active ingredient and end-use products from the manufacturing site must be submitted to PMRA as a

condition of registration. Storage stability data were sufficient to support a shelf life of one year at or below 23°C.

7.2 Human Health and Safety

The acute toxicity and infectivity studies submitted in support of *Phoma macrostoma* strain 94-44B were determined to be sufficiently complete to permit a decision on registration. The technical grade active ingredient with spores of the MPCA was not toxic and not infective to the rat via the oral exposure route. The spores of the MPCA were of low toxicity and not infective to the rat via the pulmonary exposure route. The end-use product was not toxic to the rat via the oral exposure route and to the rabbit via the dermal exposure route. The end-use product was not irritating to the skin and was mildly irritating to the eyes of rabbits.

When handled according to the label instructions, the potential for dermal, inhalation and eye exposure for applicators, mixer/loaders, and handlers exist, with the primary source of exposure to workers being exposure to the skin or inhalation of dusts. Precautionary statements on the end-use product label and the wearing of personal protective equipment by workers will adequately mitigate the risks from exposure. Furthermore, precautionary labelling will alert users of the potential sensitization hazard of the product.

7.3 Environmental Risk

The non-target studies on beneficial arthropods and bees, birds, terrestrial and aquatic plants, aquatic invertebrates and fish, as well as scientific rationale and supporting published scientific literature submitted in support of *Phoma macrostoma* strain 94-44B were determined to be sufficiently complete to permit a decision on registration. The use of Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial containing *Phoma macrostoma* strain-94-44B is not expected to pose a risk to birds, mammals, aquatic invertebrates, fish, and other microorganisms, but may pose a risk to certain non-target plants present on treated turf or treated fields. These effects are expected to be limited to the treated areas and users will be warned to avoid contact with desirable plants, fruits, and vegetables.

No additional studies were required to address the environmental fate and behaviour of *Phoma macrostoma* strain 94-44B. Environmental fate data are higher tier requirements and are not normally required in the absence of significant toxicological effects in non-target organisms in Tier I testing. *Phoma macrostoma* is a naturally occurring organism in many countries, including Canada. Although *Phoma macrostoma* has a widespread distribution, the levels of natural occurrence in the environment are quite low. Under natural conditions, *Phoma macrostoma* is seen as a weak plant pathogen. Studies with *Phoma macrostoma* strain 94-44B have shown that fungal populations decline within four months in terrestrial environments and are undetectable after a year. Although *Phoma* spp. have been isolated from marine and aquatic environments, viability of *Phoma macrostoma* strain 94-44B mycelia in water was shown to decline over time. Furthermore, the MPCA has limited mobility once applied to soil environments. Therefore, environmental exposure to *Phoma macrstoma* strain 94-44B is expected to be minimal.

As a general precaution, the label for the commercial class end-use product prohibits the direct application of the product to aquatic habitats (such as lakes, streams and ponds). The labels on all end-use products prohibit contamination of irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes. The labels further advise users to avoid contact of the end-use products with desirable plants, fruits and vegetables.

7.4 Value

The data submitted to register Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide and Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control (both domestic class products), as well as Scotts Phoma P Commercial (commercial class product), are sufficient to support the following claims:

- A single pre-emergence application of *Phoma macrostoma* strain 94-44B provides effective control of numerous broadleaf weeds including dandelion, scentless chamomile and English daisy and provides suppression of white clover, Canada thistle, black medic, chickweed, broadleaf plantain, common ragweed and wild mustard.

- Two to three post-emergence applications of *Phoma macrostoma* strain 94-44B provide effective control of white clover and black medic and provide suppression of dandelion, Canada thistle and broadleaf plantain.

- A single pre-emergence spot application or two to three post-emergence spot applications of *Phoma macrostoma* strain 94-44B provide effective pre-emergence or post-emergence control and/or suppression of all the weeds listed above.

Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control, and Scotts Phoma P Commercial offer an alternative to the use of chemical herbicides for the control of broadleaf weeds in turf and on ornamental plants, especially where the use of traditional chemical herbicides is not desirable or prohibited by law.

7.5 Unsupported Uses

Certain uses originally proposed by the applicant were not supported by the PMRA because the value was not adequately demonstrated. These uses include:

- Pre-emergence control of buckhorn plantain, California burclover, spotted spurge and cudweed.

- Post-emergence control of chickweed, common ragweed, buckhorn plantain, scentless chamomile, wild mustard, English daisy, California burclover, spotted spurge and cudweed.

8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide, Scotts EcoSense Weed-B-Gon Manufacturing Use Concentrate. Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control Herbicide, Scotts EcoSense Weed-B-Gon Ready To Use Lawn Weed Control and Scotts Phoma P Commercial, containing the technical grade active ingredient *Phoma macrostoma* strain 94-44B, to control a broad spectrum of broadleaf weeds in established turfgrass and new seeding of grasses and in field grown nursery and ornamental plants and trees and container grown ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, these products have value and do not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk-reduction measures are followed, as a condition of these registrations, additional scientific information is being requested from the registrant. For more details, refer to the Section 12 Notice associated with these conditional registrations. The registrant will be required to submit this information within the time frames indicated below.

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

Product Characterization and Analysis

To confirm the manufacturing methods and quality assurance for final commercial production, the registrant is required to provide confirmation of production methods, a five batch analysis for microbial contaminants and confirmation of product guarantee from production lots of Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide and its associated end-use products from the manufacturing sites.

Value

Data are required from additional field trials in which the efficacy of *Phoma macrostoma* strain 94-44B applied pre-emergence at 16 g a.i./ha is evaluated to confirm its efficacy for season-long control of the following weeds: chickweed, broadleaf plantain, common ragweed, wild mustard and English daisy.

The outstanding product characterization and value information is to be submitted to the PMRA by September 1, 2014.

List of Abbreviations

a.i.	active ingredient
°C	degree(s) Celsius
bw	bodyweight
CFU	colony forming unit
cm	centimetre(s)
cm^2	centimetre(s) squared
DNA	deoxyribonucleic acid
g	gram(s)
ha	hectare(s)
HE	high efficiency
IDAC	International Depositary Authority of Canada
kg	kilogram(s)
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOEC	low observed effect concentration
m^2	metre(s) squared
MAS	maximum average score
mg	milligram(s)
MIS	maximum irritation score
mL	millilitre(s)
MPCA	microbial pest control agent
MRL	maximum residue limit
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
NOEC	no observed effect concentration
PCR	Polymerase Chain Reaction
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Tables and Figures

Table 1 Toxicity and Infectivity of *Phoma macrostoma* strain 94-44B and its associated end-use products

Study Type	Species, Strain, and Doses	Results	Significant Effects and Comments	Reference
Acute Toxicity/Infectivity of Scotts EcoSense Weed-B-Gon Technical Bio-Herbicide and spores of MPCA				
Oral Toxicity and Infectivity	Rat- CD, 12/sex, suspension in sterile distilled water 1×10^8 CFU/animal (9.6×10^7 CFU/2mL), interim sacrifices on Days 0, 7, and 21 (21-day study). Control group (KTG): 3/sex treated with autoclaved dose Untreated control (NC): 3/sex housed with KTG Untreated control (SC): 3/sex housed with test group	$LD_{50} > \sim 1.0 \times 10^8$ CFU/animal	No mortalities. No clinical signs of toxicity. The test substance was initially detected in the lungs, spleen, liver, kidneys and stomach (and small intestine). Also, test substance was detected initially in the feces of one female dosed rat. Test substance numbers were below detection limit from all tissues tested by Day 7 and 21. No gross findings observed at necropsy. **LOW TOXICITY** **NO INFECTIVITY** **NO PATHOGENICITY** **ACCEPTABLE**	1827582
Acute Toxicity/Infectivity of spores of *Phoma macrostoma* strain 94-44B				
Pulmonary Toxicity and Infectivity (Intratracheal)	Rat-CD 9/sex: suspension in sterile distilled water, 1.4×10^8 CFU/0.1mL per animal, interim sacrifices on Days 7 and 21 (21-day study). 3/sex treated with autoclaved spores (0.1 mL) 3/sex untreated control	$LD_{50} > \sim 1.4 \times 10^8$ CFU/animal	No mortalities. No clinical signs of toxicity. There were no significant differences in weekly body weights, body weight gain or total body weight gain between study groups. At necropsy, one male and two female rats sacrificed on Day 7 were reported to have enlarged lungs. Lungs (all lobes) were mottled with dark red colour for most study animals. The observation was reported to be due to animals being euthanized by carbon dioxide asphyxiation prior to necropsy. The MPCA was initially recovered from the lungs, spleen (one male only), liver and kidneys (one female only).	1827583

Study Type	Species, Strain, and Doses	Results	Significant Effects and Comments	Reference
			Clearance was achieved by Day 7. **LOW TOXICITY** **NO INFECTIVITY** **NO PATHOGENICITY** **ACCEPTABLE**	
Intra-peritoneal Infectivity	Rat-CD 12/sex: suspension in sterile water, 2.5×10^8 CFU/1.0 mL per animal, interim sacrifices at Days 0, 7 and 14 (in 28-day study). 3/sex treated with autoclaved MPCA, 1 mL per animal 3/sex untreated control	$LD_{50} > 2.5 \times 10^8$ CFU/animal	No mortalities. No effect on body-weight gain and no apparent signs of treatment-related toxicity or pathogenicity. No abnormalities on necropsy. Lungs (all lobes) were noted as mottled with dark read colour for all study animals, this observation was likely due to animals being euthanized by carbon dioxide asphyxiation prior to necropsy. Following injection, the MPCA was recovered in lungs, spleen, liver, kidneys, mesenteric lymph nodes, caecum and lavage fluid (from peritoneal cavity). Clearance was achieved by Day 7. **NO PATHOGENICITY** **NO INFECTIVITY** **ACCEPTABLE**	1827584
Acute Toxicity/Irritation of End-Use Product				
Acute Dermal Toxicity	Rabbit- New Zealand white, 5/sex, undiluted, 4.5×10^8 CFU/g per animal to an area of approximately 240 cm^2 mL/kg bw, exposed for 24 hours (14-day study) (5000 mg/kg bw)	$LD_{50} > 5000$ mg/kg bw	No mortalities and no signs of toxicity. **LOW TOXICITY** **ACCEPTABLE**	1827368
Dermal Irritation	Rabbit- New Zealand white, 3 females, undiluted, 4.5×10^4 CFU/g to an area of 240 cm^2, exposed for four hours, 3-day study	Not a dermal irritant	No mortalities. Slight erythema at 30–60 minutes post-exposure. No signs of irritation by 24 hours. **ACCEPTABLE**	1827367

Study Type	Species, Strain, and Doses	Results	Significant Effects and Comments	Reference
Reporting of Hypersen-sitivity Incidence	No incidence of hypersensitivity occurred among persons who were potentially exposed to *Phoma macrostoma* isolate 94-44B during production **ACCEPTABLE**			1827587
Acute Oral	Sprague-Dawley rats, 5/sex, 5000 mg/kg bw (4.5×10^4 CFU/g), single oral dose (14-day study)	LD_{50} > 5000 mg/kg bw	No mortalities. No signs of toxicity. No gross findings observed at necropsy **LOW TOXICITY** **ACCEPTABLE**	1827364
Eye Irritation	Rabbit-New Zealand white, 3 ♀, 0.1 g of the ground end-use product (equivalent to 4.5×10^3 CFU/animal), conjunctival sac of right eye, instilled for 24 hours, observed for three days.	MAS[1]=7.1/110 (24, 48 and 72 hours) MIS[2] = 20.7/110 (1 hour)	After one hour, conjunctivae redness and chemosis (grades 2–4) were noted; as well as irritation in the iris (grade 2). All Irritation cleared by Day 3. **MILDLY IRRITATING** **ACCEPTABLE**	1827365

[1] MAS = Maximum Average Score
[2] MIS = Maximum Irritation Score

Table 2 Toxicity to Non-Target Species

Organism	Exposure	Test Substance(s)	Significant Effects, Comments	Reference
Terrestrial Organisms				
Vertebrates				
Birds (Bobwhite Quail)	Acute Oral	*Phoma macrostoma* strain 94-44B, 30 birds Heat-inactivated form *Phoma macrostoma* strain 94-44B, 10 birds Deionized water, 10 birds	30-day $LD_{50} > 2.22 \times 10^5$ CFU/kg bw No signs of toxicity or pathogenicity. No mortalities. When compared to controls, there were no apparent effects on body weight. At necropsy, no significant observations in treated, and control groups. **LOW TOXICITY** INFECTIVITY NOT TESTED (but MPCA does not grow above 35°C) **ACCEPTABLE**	1827589
Wild Mammals (waiver)	In lieu of wild mammal toxicity/pathogenicity testing, the registrant submitted a waiver rationale. *Phoma macrostoma* is ubiquitous in nature, occurring globally in a wide variety of habitats, such that use of the end-use products would not significantly increase the fungus in the environment. The use of the end-use products is a direct application and the MPCA has been shown to have limited mobility and persistence in soil which would limit exposure to wild mammals. Although ubiquitous in nature, there have been no reports of adverse effects to wild mammals and results from human health and safety studies with *Phoma macrostoma* 94-44B on mammals indicated no toxicity or pathogenicity. Furthermore, *Phoma macrostoma* 94-44B exhibits minimal to no growth in the range of 35–45°C. Based on the available information, no adverse effects are likely to occur following exposure of wild mammals to the microbial pest control agent (MPCA), *Phoma macrostoma* strain 94-44B. Consequently the request to waive wild mammal testing is accepted. **WAIVER ACCEPTED**			1827590

Organism	Exposure	Test Substance(s)	Significant Effects, Comments	Reference
Invertebrates				
Terrestrial Arthropods	Honeybee-Dietary Toxicity	*Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5, 1×10^6 CFU/mL, 75 bees in each dose group Heat-inactivated form *Phoma macrostoma* strain 94-44B, 75 bees Negative control, 75 bees	5-day $LC_{50} > 1 \times 10^6$ CFU/mL (nominal) No significant treatment-related effect on bee mortality was observed over the 5-day monitoring period. **LOW TOXICITY** Length of exposure was considerably shorter than recommended 21–30 days to assess pathogenicity. **ACCEPTABLE**	1827593
	Lady beetle (*Hippodamia convergens*)-Dietary toxicity	*Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5, 1×10^6 CFU/mL, 25 beetles in each dose group Heat-inactivated form *Phoma macrostoma* strain 94-44B, 25 beetles Negative control, 25 beetles	12-day $LC_{50} > 1 \times 10^6$ CFU/mL (nominal) No significant effect on mortality. No signs of toxicity or pathogenicity. Infectivity was not assessed. **LOW TOXICITY** **ACCEPTABLE**	1827595
	Green lacewing (*Chrysoperla rufilabris*)-Dietary toxicity	*Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5, 1×10^6 CFU/mL, 30 larvae in each dose group Heat-inactivated form *Phoma macrostoma* strain 94-44B, 30 larvae Negative control, 30 larvae	15-day $LC_{50} > 1 \times 10^6$ CFU/mL (nominal) No significant effect on green lacewing larvae mortality was observed over the 15-day monitoring period. No signs of toxicity or pathogenicity. Infectivity was not assessed. **LOW TOXICITY** **ACCEPTABLE**	1827592

Organism	Exposure	Test Substance(s)	Significant Effects, Comments	Reference
	Parasitic Hymenop-tera (*Pediobius foveolatus)* Dietary toxicity	*Phoma macrostoma* strain 94-44B at 1×10^4, 1×10^5, 1×10^6 CFU/mL, 75 wasps in each dose group Heat-inactivated form *Phoma macrostoma* strain 94-44B, 75 wasps Negative control, 75 wasps larvae	16-day $LC_{50} > 1.66 \times 10^{10}$ CFU/mL (nominal) No significant effect on mortality. No signs of toxicity and pathogenicity. Infectivity was not assessed. **LOW TOXICITY** **ACCEPTABLE**	1827594
Plants				
Terrestrial Plants	A summary of 10 studies done to test the host range and determine the pathogenicity of *Phoma macrostoma* strain 94-44B on terrestrial plants. 75 plant species in 22 plant families studied 7 plant families were resistant from chlorosis and mortality: Salicaceae, Pinaceae, Iridaceae, Curcurbitaceae, Solanaceae (bell pepper, tomato), Linaceae, Graminae 16 plant families were susceptible: Convolvulaceae, Lythraceae, Polygonaceae, Rubiaceae, Euphorbiaceae, Caryophyllaceae, Brassicaceae, Amaranthaceae, Labiatae, Lamiaceae, Leguminosae/Fabaceae, Rosaceae, Plantaginaceae, Asteraceae, Balsminaceae, Solanaceae (petunia) Germination was affected in some plant species such as strawberry, but not in most. Taxonomically strawberry is Rosaceae, which is the main host family where *Phoma macrostoma* is often isolated (see M.2.7.2 for literature). The largest number of susceptible plants to *Phoma macrostoma* strain 94-44B were found in Asteraceae, Leguminosae/ Fabaceae, and Brassicaceae. Although *Phoma macrostoma* strain 94-44B is pathogenic to a number of plant species, there are significant differences in host susceptibility (i.e. a differential response) depending on the rate of application and plant species. Therefore, risk to non-target terrestrial plant species can be mitigated by application rate, with hosts that are resistant and in areas where susceptible species of economic and environmental importance do not occur. **ACCEPTABLE**		1827597

Organism	Exposure	Test Substance(s)	Significant Effects, Comments	Reference
Aquatic Organisms				
Vertebrates				
Freshwater Fish	Rainbow Trout (*Oncorhyn-chus mykiss)* Aqueous and Dietary Toxicity/Pa-thogenicity	*Phoma macrostoma,* strain 94-44B, 10 fish per dose group Aqueous (CFU/mL): i) 1.56×10^4; ii) 3.13×10^4; iii) 6.25×10^4; iv) 1.25×10^5; and v) 2.5×10^5. (dietary) i) 26 CFU/g ii) 53 CFU/g iii) 105 CFU/g) iv) 210 CFU/g; and v) 420 CFU/g Heat-inactivated form *Phoma macrostoma* strain 94-44B, 10 fish Negative control, 10 fish	32-day $LC_{50} > 2.5 \times 10^5$ CFU/mL No treatment-related effects were noted. No mortalities. **NOT TOXIC** **NOT PATHOGENIC** Infectivity was not assessed **ACCEPTABLE**	1827591
Invertebrates				
Aquatic Arthropods	Cladoceran (*Daphnia magna*)	*Phoma macrostoma,* strain 94-44B, 100 cladocerans Aqueous (CFU/mL): i) 1.56×10^4; ii) 3.13×10^4; iii) 6.25×10^4; iv) 1.25×10^5; and v) 2.5×10^5. 20 per dose group Heat-inactivated control, 20 Negative control, 20	21-day $LC_{50} > 1.56 \times 10^4$ CFU/mL Heat-inactivated control had 100% mortality by Day 16. Infectivity was not assessed **LOW TOXICITY** **NOT PATHOGENIC** **ACCEPTABLE**	1827596

Organism	Exposure	Test Substance(s)	Significant Effects, Comments	Reference
Plants				
Aquatic Plants	Duckweed (*Lemna gibba*)	*Phoma macrostoma*, strain 94-44B, 100 cladocerans Aqueous (CFU/mL): i) 1.56×10^4; ii) 3.13×10^4; iii) 6.25×10^4; iv) 1.25×10^5; and v) 2.5×10^5. Negative control (culture medium only)	NOEC: 6.25×10^4CFU/mL LOEC: 1.25×10^5 CFU/mL The test substance caused necrosis in some fronds and a significant inhibition in frond number and biomass at the higher tested concentrations as compared to that seen in the lower test concentrations Infectivity was not assessed **POTENTIAL PATHOGEN** **ACCEPTABLE**	1827598

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A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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