Proposed Registration Decision PRD2017-09

Indaziflam

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

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

Canada

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Overview

Proposed Registration Decision for Indaziflam

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Indaziflam Technical Herbicide, Specticle SC and Specticle G, containing the technical grade active ingredient indaziflam, to control or suppress annual grasses and broadleaf weeds in field grown and container grown ornamentals.

Indaziflam Technical Herbicide (Registration Number 30219) is fully registered as a herbicide for use in several end-use products to control grassy and broadleaf weeds in terrestrial food crops (pome fruit, stone fruit, tree nuts and grape) as well as in non-agricultural areas. The detailed review for Indaziflam Technical Herbicide in terrestrial food crops can be found in the Proposed Registration Decision PRD2011-20, *Indaziflam* and Registration Decision RD2012-08, *Indaziflam*, while the detailed review for non-agricultural uses can be found in the Proposed Registration Decision PRD2014-04, *Indaziflam* and Registration Decision RD2014-18, *Indaziflam*.

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

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Indaziflam Technical Herbicide, Specticle SC and Specticle G.

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. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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

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

What Is Indaziflam?

Indaziflam is the active ingredient in the end-use products Specticle SC and Specticle G. They are systemic herbicides for the control or suppression of multiple species of broadleaf and grass weeds growing among ornamental plants. Indaziflam prevents germination and emergence of weeds by inhibiting cellulose biosynthesis.

Indaziflam is classified as a Group 29 herbicide by the Weed Science Society of America (WSSA) and as a Group L herbicide by the Herbicide Resistance Action Committee (HRAC).

Health Considerations

Can Approved Uses of Indaziflam Affect Human Health?

Specticle SC and Specticle G containing indaziflam are unlikely to affect your health when used according to label directions.

Potential exposure to indaziflam may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

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

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, indaziflam was of low acute oral, dermal and inhalation toxicity. Indaziflam was minimally irritating to the eyes and non-irritating to the skin, and did not cause an allergic skin reaction.

The end-use product, Specticle SC, was of low acute toxicity via the oral, dermal and inhalation routes of exposure and was non-irritating to the skin and eyes. It did not cause an allergic skin reaction. Consequently, no acute hazard labelling is required.

The end-use product, Specticle G, was considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was considered minimally irritating to the eye and non-irritating to the skin. It was not a dermal sensitizer. No acute hazard labelling is required.

Registrant-supplied short-term and long-term (lifetime) animal toxicity tests were assessed for the potential for indaziflam to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were effects on the nervous system. There was no indication that the young animal was more sensitive than the adult animal. The risk assessment is protective of the above-noted effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in test animals.

Residues in Water and Food

Occupational Risks from Handling Specticle SC and Specticle G

Occupational risks are not of concern when Specticle SC and Specticle G are used according to the proposed label directions, which include protective measures.

Growers, field workers and nursery workers who mix, load and apply Specticle SC or Specticle G to field or container grown ornamentals, respectively, as well as postapplication workers who re-enter freshly treated areas can come in direct contact with indaziflam residues on the skin.

Therefore, the label of Specticle SC specifies that all workers involved in activities such as mixing, loading, application by handheld equipment, clean-up and repair, must wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. During application by groundboom sprayer, workers must wear a long-sleeved shirt, long pants and shoes plus socks.

Similarly, the label of Specticle G specifies that all workers involved in activities such as use, loading, application by handheld or push-type spreaders, clean-up, repair and removal of granules from leaves to prevent localized damage, must wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. During application by tractor-pulled broadcast

spreader, drivers must wear a long-sleeved shirt, long pants and shoes plus socks. During all activities, workers handling Specticle G must also wear a NIOSH-approved N95 filtering facepiece respirator (dust mask) that is properly fit tested.

In addition, the label of Specticle SC requires that workers do not enter treated areas for 12 hours after application to allow the spray to dry, whereas the label of Specticle G requires that workers do not enter treated areas until granules are thoroughly watered-in and the treated soil has dried. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the occupational exposure risk to these individuals is not of concern.

For bystanders, exposure is expected to be negligible, and therefore, health risks to bystanders are also not of concern.

Environmental Considerations

What Happens When Indaziflam Is Introduced Into the Environment?

Indaziflam is not expected to pose risks of concern to the environment when used according to label directions.

Indaziflam enters the environment when it is used to control annual grass and broadleaf weeds in field- and container-grown ornamental plants. In water, indaziflam does not break down easily, and will move from the water to the sediment where it can persist. Indaziflam does not remain in the soil for long periods of time because soil bacteria break it down. Depending on the soil type, half of the applied indaziflam has been shown to break down within a time period ranging from less than one month up to approximately three months. Of the three breakdown products, two will not remain in the soil as they are readily broken down by microbes in the soil. The third breakdown product may persist, depending on the soil type. The movement of indaziflam and its breakdown products in the environment is expected to be minimal. Available information suggests that indaziflam is not expected to be found in air and not expected to move through the soil into groundwater. This was confirmed with water modelling which predicts low levels of indaziflam and its breakdown products in groundwater. Indaziflam will not accumulate in animals.

Indaziflam does not present a risk of concern to wild mammals, birds, bees, invertebrates, freshwater or marine invertebrates, fish and amphibians. However, exposure to indaziflam can affect non-target plants on land and in the water. To protect non-target plants from spray drift, spray buffer zones up to 15 meters are required. To protect aquatic plants from the potential effects of run-off, a label statement informing users how to reduce run-off will be required, as well as precautionary label statements to inform users of the toxicity of indaziflam to non-target plants.

Value Considerations

What Is the Value of Specticle SC and Specticle G?

Specticle SC and Specticle G are the first Group 29 herbicides that may be applied to field-grown or container-grown ornamental plants for control of broadleaf and grass weeds prior to weed emergence.

Specticle SC, which is in liquid form, may be applied once per year as a directed spray to established field-grown ornamental plants using ground application equipment.

Specticle G, which is in granular form, may be applied once per year to container-grown ornamental plants with an established root system.

The application of these herbicides alternately with herbicides of differing modes of action can be expected to help mitigate the development of resistance of broadleaf and grass weeds to other herbicide chemistries applied in ornamental plant production facilities.

Measures to Minimize Risk

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

The key risk-reduction measures being proposed on the label of Specticle SC and Specticle G to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

For both Specticle SC and Specticle G, because there is a concern with users coming into direct contact with indaziflam residues on the skin anyone involved in mixing, loading, application by handheld spraying or spreading equipment, clean-up or repair must wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. During application by groundboom sprayer or by tractor-pulled broadcast spreader, drivers must wear a long-sleeved shirt, long pants and shoes plus socks. For Specticle G, because there is an additional concern with the inhalation of dust particles, workers involved in all activities must also wear a NIOSH-approved N95 filtering facepiece respirator (dust mask) that is properly fit tested.

When re-entering freshly treated fields or nurseries to perform postapplication activities, workers are required to respect the restricted entry interval (REI) of 12 hours for Specticle SC, or until granules are thoroughly watered-in and the treated soil has dried, for Specticle G. Standard label statements to protect bystanders against drift during application are present on the two labels. In addition, a statement for not using the products in residential areas has been added to the two labels.

Environment

The end-use product containing indaziflam and formulated as a suspension, Specticle SC, is proposed for field-grown ornamental plants and will require spray buffer zones of 1 meter and 15 meters to protect aquatic plants and non-target terrestrial plants, respectively. To protect aquatic plants from the potential effects of run-off, a label statement informing users how to reduce run-off will be required. The end-use product containing indaziflam and applied as granules, Specticle G, is proposed for container-grown ornamental plants only and will not require spray buffer zones. Run-off from containers is likely to be minimal; therefore, run-off statements are not required for this product. Both Specticle SC and Specticle G will require precautionary label statements to inform users of the toxicity to aquatic plants and non-target terrestrial plants.

Next Steps

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

Other Information

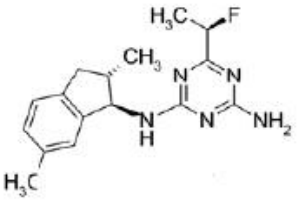
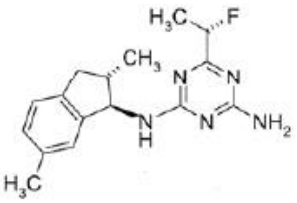
When the PMRA makes its registration decision, it will publish a Registration Decision on indaziflam (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's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

Science Evaluation

Indaziflam

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance:	Indaziflam
Function:	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	N^2-[(1R,2S)-2,6-dimethyl-2,3-dihydro-1*H*-inden-1-yl]-6-[(1Ξ)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine
2. Chemical Abstracts Service (CAS)	N-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine
CAS number	950782-86-2
Molecular formula	$C_{16}H_{20}FN_5$
Molecular weight	301.36
Structural formula	 
	730979-19-8 (isomer A) 730979-32-5 (isomer B)
Purity of the active ingredient	96.9%

1.2 Physical and Chemical Properties of the End-Use Products

End-Use Product–Specticle SC

Property	Result
Colour	Off white
Odour	Chalky odour
Physical state	Liquid

Property	Result
Formulation type	Suspension
Guarantee	75g/L
Container material and description	Plastic (0.5-20L)
Density	1.009
pH of 1% dispersion in water	5.7
Oxidizing or reducing action	The product does not contain any ingredient which is considered to be oxidizing or reducing agent.
Storage stability	The product is stable when stored for 12 months at the warehouse temperature in HDPE containers.
Corrosion characteristics	The product is non-corrosive to the commercial packaging material when stored for 12 months at the warehouse temperature in HDPE containers.
Explodability	No impact explosive characteristic is expected on the basis of the chemical nature of the formulation ingredients.

End-Use Product- Specticle G

Property	Result
Colour	Brown
Odour	Weak musty odor
Physical state	Solid
Formulation type	Granule
Guarantee	0.0224%
Container material and description	Plastic (1-25 kg)
Density	0.6728-0.7368 g/cm^3
pH of 1% dispersion in water	7.9 at 20°C
Oxidizing or reducing action	The product does not contain any ingredient which is considered to be oxidizing or reducing agent.
Storage stability	The product is stable when stored for 12 months at the warehouse temperature in commercial containers.
Corrosion characteristics	The product is non-corrosive when stored for 12 months at the warehouse temperature in commercial packaging material.
Explodability	No impact explosive characteristic is expected on the basis of the chemical nature of the formulation ingredients.

1.3 Directions for Use

Specticle SC is intended for application at 1.0 L/ha (equivalent to 75 g a.i./ha) prior to emergence of broadleaf and grass weeds. It is applied in a minimum of 93 L water/ha as a directed spray to the soil surface and in a manner that avoids contact with field-grown ornamental plants. Specticle G is intended for application at 336 kg/ha (equivalent to 75 g a.i./ha) prior to emergence of broadleaf and grass weeds in container-grown ornamental plants with an established root system. The treated area should receive sufficient irrigation within several days after application to move the herbicide into the soil. Specticle SC and Specticle G are only intended for application to established ornamental plants and not to newly rooted cuttings or seedling beds in production nurseries.

1.4 Mode of Action

Indaziflam, belonging to the alkylazine chemical class, inhibits cellulose biosynthesis. The lack of cellulose prevents cell wall formation thereby affecting cell division and elongation. This results in the inhibition of germination and very early seedling growth when applied to the soil prior to weed emergence.

Indaziflam is classified as a Group 29 herbicide by the Weed Science Society of America and as a Group L herbicide by the Herbicide Resistance Action Committee.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Please see PRD2011-20, *Indaziflam*

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredient in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicology database for indaziflam was conducted previously and is summarized in the Proposed Registration Decision, PRD2011-20, *Indaziflam*. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with the currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to indaziflam.

Specticle SC is of low acute oral, dermal and inhalation toxicity in rats. It is non-irritating to the eyes and skin of rabbits and did not cause dermal sensitization in guinea pigs.

A waiver was submitted and accepted for the Specticle G acute toxicity studies based on the reduced toxicity of granular pesticides. Based on the acute toxicity of the technical grade active ingredient (TGAI), Specticle G is considered of low acute oral, dermal and inhalation toxicity. It is considered minimally irritating to the eyes and non-irritating to the skin. It is not considered a dermal sensitizer.

A summary of the toxicology endpoints for indaziflam TGAI is available in PRD2011-20, *Indaziflam* and Appendix I, Table 2 of this document.

Human and Animal Health Incident Reports

As of 1 December 2016, three domestic animal incidents involving indaziflam were reported to the PMRA. None of these incidents had a causal relationship with indaziflam.

These incident reports were considered and did not affect the risk assessment.

3.2 Determination of Acute Reference Dose

Please refer to PRD2011-20, *Indaziflam*.

3.3 Determination of Acceptable Daily Intake

Please refer to PRD2011-20, *Indaziflam*.

Cancer Assessment

Please refer to PRD2011-20, *Indaziflam*.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Short- and Intermediate-term Dermal and Inhalation

Occupational exposure to Specticle SC and Specticle G is characterized as short- to intermediate-term, and is predominantly by the dermal and inhalation routes.

3.4.1.1 Dermal Absorption

A dermal absorption factor (DAF) of 25% was previously determined for indaziflam based on two studies conducted with a suspension concentrate formulation containing 500 g a.i./L of indaziflam and a weight-of-evidence approach. Please refer to the PRD2011-20, *Indaziflam* for further details.

Given that the PMRA generally assumes that liquid formulations (e.g., solutions, suspensions, emulsifiable concentrates) have greater dermal absorption potential than dry formulations (e.g., granules, pellets, dust), dermal absorption values determined from liquid formulations can be used in risk assessments of dry formulations. Therefore, the DAF of 25% is acceptable for use in the risk assessments conducted for both new end-use products, including Specticle SC, which is formulated as a suspension, and Specticle G, which is formulated as ready-to-use granules.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to Specticle SC and Specticle G during mixing, loading and application. Dermal and inhalation exposure estimates for workers mixing, loading and applying the two end-use products were generated from the Pesticide Handler Exposure Database (PHED) version 1.1. In addition, for workers applying Specticle G with a push-type rotary spreader, dermal and inhalation exposure estimates were derived from exposure studies owned by the Outdoor Residential Exposure Task Force (ORETF), of which Bayer CropScience Inc. is a member, and therefore, has full access to these proprietary data.

Exposure to workers mixing, loading or applying Specticle SC or Specticle G, is expected to be short- to intermediate-term in duration and to occur primarily by the dermal and inhalation routes.

Specticle SC Risk Assessment

For Specticle SC, exposure estimates were derived for mixers, loaders and applicators applying the product to field grown ornamentals using groundboom sprayers or manually-pressurized handheld equipment such as backpack or hand wand. The exposure estimates are based on mixers, loaders and applicators using manually-pressurized handheld equipment, all wearing a single layer of clothing (long-sleeved shirt and long pants, shoes plus socks) and chemical-resistant gloves. For application using a groundboom sprayer, the exposure estimates are based on the driver wearing a single layer of clothing; gloves are not required on the tractor.

Chemical-specific data for assessing human exposure during pesticide handling activities were not submitted for Specticle SC.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the DAF of 25%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption.

For groundboom application equipment, the amount handled per day was calculated using the application rate and the default area treated per day for field grown ornamental plants of 26 ha/day. For manually-pressurized handheld application equipment, the amount handled per day was calculated using the application rate, the minimum volume of 93 L/ha and the spray volume of 150 L/day. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints to obtain the margin of exposure (MOE); the target MOE is 100 for both dermal and inhalation exposure. Since the dermal and inhalation NOAEL are based on the same toxicological endpoint (7.5 mg/kg bw/day), the combined MOE was calculated.

Table 3.4.2.1.1 Unit Exposure Estimates[1] for Workers Handling Specticle SC

Scenario (Equipment & Personal Protective Equipment)		Dermal Exposure (µg/kg a.i. handled)	Absorbed Dermal Exposure (µg/kg a.i. handled)[2]	Inhalation Exposure (µg/kg a.i. handled)[3]	Total Combined Exposure (µg/kg a.i. handled)[4]
A	**PHED Estimates (3a): Liquid/Open Mixing & Loading**				
	Single layer plus CR[5] gloves	51.14	12.785	1.60	14.385
B	**PHED Estimates (11): Groundboom Application/Open Cab**				
	Single layer, no gloves	32.98	8.245	0.96	9.205
A+B	**PHED Estimates (3a +11): Liquid/Open Mixing & Loading/Groundboom/Open Cab**				
	Single layer plus CR gloves, no gloves for application	84.12	21.03	2.56	23.59
C	**PHED Estimates (23a): Liquid/Open Mixing & Loading/Backpack (M/L/A)[6]**				
	Single layer plus CR gloves	5 445.85	1 361.46	62.10	1 423.56
D	**PHED Estimates (21a): Liquid/Open Mixing & Loading/Manually Pressurized Hand Wand (M/L/A)[6]**				
	Single layer plus CR gloves	943.37	235.84	45.20	281.04

[1] Unit exposure values are from the PHED Tables (Version 1.1, February 2002).
[2] The dermal absorption factor of 25% has been applied to the dermal exposure estimates.
[3] Light inhalation rate is required for all scenarios except for backpack application, which requires moderate inhalation rate.
[4] The dermal and inhalation exposure estimates can be combined since the dermal and inhalation endpoints of concern are the same value and based on the same study.
[5] CR: chemical-resistant
[6] For scenarios C and D, there are no data for a single layer of clothing without CR gloves, and therefore, data include gloves for all workers.

Table 3.4.2.1.2 Occupational Exposure Risk Assessment for Workers Handling Specticle SC

Scenario (Equipment & Personal Protective Equipment)		Total Combined Exposure[1] (µg/kg a.i. handled)	Application Rate (kg a.i./ha)	ATPD[2] (ha/day)	Amount Handled per day[3] (kg a.i. handled)	Daily Exposure[4] (µg/kg bw/day)	MOE[5]
Worker wearing a single layer of clothing plus chemical-resistant gloves during mixing, loading & application (exception: no gloves required when applying with a groundboom sprayer)							
A+B	Liquid/open M/L + groundboom/open cab	23.59	0.075	26	1.95	5.750×10^{-4}	13 043
C	Liquid/open M/L + backpack	1 423.56		1.61	0.12075	2.149×10^{-3}	3 490
D	Liquid/open M/L + manually-pressurized hand wand	281.04				4.242×10^{-4}	17 680

[1] Total combined unit exposure estimates are from Table 3.4.2.1.1.

[2] The ATPD for groundboom application is the default value for ornamentals, while the ATPD for backpack and manually-pressurized hand wand application is based on 150 L/day of spray solution (PMRA Summary of ATPD Defaults for Commercial Scenarios, 2015-04-29) and a spray volume of 93 L/ha (label).

[3] Amount handled per day = Application rate × ATPD

[4] Daily exposure = (Total unit exposure × ATPD x Rate) / (80 kg bw × 1000 µg/mg)

[5] Based on the short- to intermediate-term NOAEL of 7.5 mg/kg bw/day and the target MOE of 100.

Acceptable margins of exposure (combined dermal and inhalation) were obtained for workers who mix, load and apply Specticle SC in field grown ornamentals using either groundboom equipment or manually-pressurized handheld equipment, such as backpack or hand wand.

The personal protective equipment (PPE) on the label of Specticle SC was amended to specify that during activities such as mixing, loading, application by handheld equipment, clean-up and repair, workers must wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. During application by groundboom sprayers, workers must wear a long-sleeved shirt, long pants and shoes plus socks. Based on the low acute toxicity of Specticle SC, this PPE is adequate to protect workers against any acute hazards.

Specticle G Risk Assessment

For Specticle G, exposure estimates were derived for loaders and applicators applying the product to container grown ornamentals using handheld spreaders (such as belly grinders), push-type spreaders (such as rotary spreaders) or tractor-pulled broadcast spreaders. In addition, the "granular bait dispersed by hand" scenario from PHED was considered as a 'worst case' in order to represent chemical handlers who may use hand shaker equipment or other equipment that could result in significant direct dermal contact with the end-use product. The exposure estimates are based on loaders and applicators using any type of handheld or push-type equipment, all wearing a single layer of clothing (long-sleeved shirt and long pants, shoes plus socks) and chemical-resistant gloves. For application using a tractor-pulled broadcast spreader, the exposure estimates are based on the driver wearing a single layer of clothing; gloves are not required on the tractor.

Chemical-specific data for assessing human exposure during pesticide handling activities were not submitted for Specticle G.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the DAF of 25%. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption.

For all types of application equipment, except belly grinders, the amount handled per day was calculated using the application rate and the default area treated per day of 2 ha/day. For belly grinders, the default area treated per day was 0.4 ha/day. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints to obtain the margin of exposure (MOE); the target MOE is 100 for both dermal and inhalation exposure. Since the dermal and inhalation NOAEL are based on the same toxicological endpoint (7.5 mg/kg bw/day), the combined MOE was calculated.

Table 3.4.2.1.3 Unit Exposure Estimates[1] for Workers Handling Specticle G

Scenario (Equipment & Personal Protective Equipment)		Dermal Exposure (µg/kg a.i. handled)	Absorbed Dermal Exposure (µg/kg a.i. handled)[2]	Inhalation Exposure (µg/kg a.i. handled)[3]	Total Combined Exposure (µg/kg a.i. handled)[4]
A	**PHED Estimates (2a or b): Granular/Open Mixing & Loading**				
	Single layer plus CR[5] gloves	13.04	3.26	2.20	5.46
B	**PHED Estimates (13): Solid Broadcast (Granular) Spreader, Open Cab**				
	Single layer, no gloves	21.94	5.485	1.60	7.085
C	**PHED Estimates (15a): Granular Bait Dispersed by Hand[6]**				
	Single layer plus CR gloves	157 418.22	39 354.56	605	39 959.56
D	**PHED Estimates (20a + 15a hand data): Granule/Open Pour/Belly Grinder (M/L/A)[6,7]**				
	Single layer plus CR gloves	25 464.15	6 366.038	79.9	6 445.94
E	**ORETF Estimates for Push Rotary Spreader for Professional Lawn Care Workers[6]**				
	Single layer plus CR gloves	474	118.5	16.5	135
A+B	**PHED Estimates for Granular/Open Mixing & Loading + Solid Broadcast (Granular) Spreader/Open Cab**				
	Single layer plus CR gloves (removed during application)	34.98	8.745	3.80	12.545

[1] Unit exposure values are from the PHED Tables (Version 1.1, Feb. 2002) for scenarios A to D, and from ORETF data (study no. OMA001, Merricks et al, 1999) for scenario E.
[2] The dermal absorption factor of 25% has been applied to the dermal exposure estimates.
[3] Light inhalation rate.
[4] The dermal and inhalation exposure estimates can be combined because the dermal and inhalation endpoints of concern are the same value and based on the same study.
[5] CR: chemical-resistant
[6] For scenarios C, D and E, there are no data for a single layer of clothing without CR gloves or it is impossible to separate the mixers/loaders from the applicators, and therefore, data include gloves for all workers.
[7] Due to the absence of hand data for the belly grinder scenario (PHED, 20a), hand data for this scenario are derived from the granular bait dispersed by hand scenario (PHED, 15a): 17 486.15 + 7978.00 = 25 464.15 µg/kg a.i. handled.

Table 3.4.2.1.4 Occupational Exposure Risk Assessment for Workers Handling Specticle G

Scenario (Equipment & Personal Protective Equipment)		Total Combined Exposure[1] (µg/kg a.i. handled)	Application Rate (kg a.i./ha)	ATPD[2] (ha/day)	Amount Handled per day[3] (kg a.i. handled)	Daily Exposure[4] (µg/kg bw/day)	MOE[5]
Worker wearing a single layer plus chemical-resistant gloves during mixing/loading & application (exception: no gloves required when applying with a tractor-pulled broadcast spreader)							
A+B	Granular/open M/L + broadcast spreader	12.545	0.075	2	0.15	2.352×10^{-5}	318 878
C	Granular bait dispersed by hand	39 959.56		2	0.15	7.492×10^{-2}	100
D	Granule/open-pour/belly grinder	6 445.94		0.4	0.03	2.417×10^{-3}	3 103
E	Push rotary spreader	135		2	0.15	2.531×10^{-4}	29 633

[1] Total combined unit exposure estimates are from Table 3.4.2.1.1.
[2] The ATPDs are based on the PMRA Summary of ATPD Defaults for Commercial Scenarios (2015-04-29).
[3] Amount handled per day = Application rate × ATPD
[4] Daily exposure = (Total unit exposure × ATPD × Rate) / (80 kg bw × 1000 µg/mg)
[5] Based on the short- to intermediate-term NOAEL of 7.5 mg/kg bw/day and the target MOE of 100.

Acceptable margins of exposure (combined dermal and inhalation) were obtained for workers who load and apply Specticle G in container grown ornamentals using any type of assessed application equipment, including hand shaker, handheld, push-type or tractor-pulled spreader equipment.

The PPE on the label of Specticle G was amended to specify that during activities such as use, loading, application by handheld or push-type spreaders, clean-up, repair and removal of granules from leaves to prevent localized damage, workers must wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. During application by tractor-pulled broadcast spreaders, workers must wear a long-sleeved shirt, long pants and shoes plus socks. Based on the low acute toxicity of Specticle G, this PPE is adequate to protect workers against any acute hazards. However, to address the inhalation concern due to the presence of crystalline silica in this granular product, a NIOSH-approved N95 filtering facepiece respirator (dust mask) that is properly fit tested was added to the PPE.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

Specticle SC is applied as a directed spray to the soil surface around field grown ornamentals, whereas granules of Specticle G are spread on the soil surface of container grown ornamentals. In addition, both labels indicate that contact with foliage should be avoided to prevent crop damage. Therefore, residues of indaziflam from these two products are not anticipated to occur on the foliage, and consequently, postapplication exposure is not expected to be of concern since contact with indaziflam treated soil is expected to be negligible. A postapplication risk assessment is not required for either of the two products. Nonetheless, the restricted entry interval (REI) of 12 hours must remain on the label of Specticle SC to allow the spray to dry and protect workers performing postapplication activities in previously treated areas. For Specticle G, the REI must indicate that workers cannot re-enter treated areas until granules are thoroughly watered-in and the treated soil has dried.

3.4.3 Residential Exposure and Risk Assessment

There are no residential uses for Specticle SC or Specticle G, and as such, a residential risk assessment was not required for either of the two products. Furthermore, given that Specticle SC and Specticle G are applied to the soil surface around field and container grown ornamentals, respectively, foliar residues are expected to be minimal and residential exposure to consumers buying and/or handling treated plants will be negligible.

3.4.3.1 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings. In addition, standard label statements to protect against drift during application are present on the two labels.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The fate and behaviour of indaziflam in the environment have been thoroughly reviewed and characterized previously. Please refer to the PRD2011-20, *Indaziflam*.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and

environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (such as protection at the community, population, or individual level).

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

4.2.1 Risks to Terrestrial Organisms

A risk assessment for terrestrial non-target organisms was previously conducted for foliar spray application of indaziflam (see PRD2011-20, *Indaziflam* for further details). Spray application of indaziflam (75 g a.i./ha) does not present risks of concern to wild mammals, birds, bees, or terrestrial invertebrates. Indaziflam is toxic to non-target terrestrial plants; therefore, spray buffer zones of 15 m for terrestrial habitats will be required for ground (spray) application.

A granular formulation is also proposed for application to container-grown ornamentals at the rate of 75 g a.i./ha. Risks of concern to bees and terrestrial invertebrates were not identified for this use as the potential for exposure is reduced when compared to other forms of application (for example, broadcast spraying). A risk assessment was conducted for birds and wild mammals as they may be exposed to indaziflam through direct ingestion of the granular formulated end-use product.

Birds and mammals

The proposed granular formulation containing indaziflam is composed of an inorganic carrier impregnated with the active ingredient. If granules are made using an organic carrier (such as corn cob) and/or they have nutritional value, then they may be intentionally consumed by birds or mammals as food. If the granules are not attractive as a food item, then they may only be ingested incidentally when birds and mammals are foraging for food, or they may be

intentionally ingested by birds as a source of grit. To assess the risk of indaziflam-impregnated granules, it was assumed that they would be consumed by birds and mammals incidentally or as grit, as they do not have nutritional value.

The risk assessment method considers a range of bird sizes (i.e., 0.02 kg, 0.1 kg and 1kg) and mammal sizes 0.015 kg, 0.035 kg and 1 kg) and the acute toxicity endpoint is adjusted by an uncertainty factor of 10 to account for potential differences in species sensitivity as well as varying protection levels (for example,, community, population, individual). The LD_{50} (acute oral end-point) and NOEL (reproduction end-point) values of indaziflam to birds and mammals have previously been established (PRD2011-20, *Indaziflam*, Appendix I, Table 11) and was used for calculations of risk quotients (RQs). As an initial worse-case scenario, in the screening level risk assessment, exposure is estimated based on the food ingestion rate typical of each size class. Following this approach, calculated risk quotients did not exceed the level of concern (LOC) for birds and mammals (Appendix I, Table 3). Thus, the proposed application of indaziflam-impregnated granules for the control of annual grass and broadleaf weeds in container-grown ornamental plants is not expected to pose risks of concern to birds and mammals when label directions are followed. Further to this, indaziflam residues on granules will decrease with time due to wash-off; thus the likelihood for long-term exposure to indaziflam through the uptake of granules as grit is expected to be reduced for birds and mammals. No mitigation measures are required for birds and mammals.

4.2.2 Risks to Aquatic Organisms

A risk assessment for aquatic non-target organisms was previously conducted for foliar spray application of indaziflam (see the PRD2011-20, *Indaziflam* for further details). The previous assessment is relevant for the proposed expanded use pattern for spray application around field-grown ornamental plants [i.e. same application rate and method/type of application (ground application only)]. Spray application of indaziflam (75 g a.i./ha) does not present a risk to freshwater or marine invertebrates and fish, and amphibians. Indaziflam is toxic to non-target aquatic plants and may pose a risk to these organisms through spray drift and run-off. Therefore, spray buffer zones of 1 m for aquatic habitats will be required for ground (spray) application. To protect aquatic plants from the potential effects of run-off, a label statement to inform users how to minimize run-off will be required, as well as precautionary label statements to inform users of toxicity to non-target terrestrial plants and aquatic plants.

Although the application rate for the granule is the same (3.36 kg/100 m^2, equivalent to 75 g a.i./ha), the potential for exposure to aquatic environments through application of indaziflam-impregnated granules to container-grown ornamental plants is considered to be reduced when compared to other forms/sites of application (such as broadcast spraying). Specticle G is to be applied using a drop, rotary, hand-shaker or other spreader equipment. Thus, exposure of aquatic habitats due to drift is negligible. Potential risk due to run-off has been covered by the assessment for the spray application. Precautionary label statements to inform users of toxicity to non-target terrestrial plants and aquatic plants will be required.

4.3 Environmental Incident Reports / Additional Considerations

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the United States Environmental Protection Agency (USEPA) Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting system regulations that came into force 26 April 26 under the *Pest Control Products Act* can be found at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

As of 12 December 2016, there were no environment incident reports located in the PMRA database.

The USEPA's EIIS was also queried for environment incidents (as of 12 December 2016). There were 16 incidents reports available in the EIIS database. Fifteen incidents were considered related to the reported pesticide. In nine incidents, the product was used on turf (at commercial sites or golf courses) and in six incidents, the listed use site was either pecans or in an agricultural area. Exposure in plants occurred via direct treatment. In all cases, unspecified plant damage was reported.

Overall, the assessment of incident reports involving indaziflam did not identify any significant environmental effects.

5.0 Value

5.1 Consideration of Benefits

Weed management in ornamental crop production often involves a multi-faceted approach that may consist of one or more of soil cultivation for field-grown plants, use of sterilized soil for container-grown plants, hand weeding and application of herbicides. While several herbicides are registered for application in ornamental plant production, the spectrum of weeds controlled is narrow for most of these products and many do not provide longer term (residual) control or control of grass weeds.

Specticle SC and Specticle G will serve as additional and alternate weed control options in ornamental plant production operations. Additionally, these herbicides can be expected to provide residual control or suppression of a broad spectrum of weeds thereby minimizing the total number of herbicide applications that may be required.

Currently, herbicides belonging to WSSA mode-of-action groups 1, 3, 5, 9, 14, 15, 20 and 21 are registered for pre-emergent or post-emergent application in commercial ornamental plant production. As Group 29 herbicides, Specticle SC and Specticle G can be expected to control populations of susceptible labelled weeds that may have developed resistance to herbicides of other mode-of-action groups. The application of Specticle SC or Specticle G with a post-emergent herbicide that is registered for use in established ornamental plants will provide control of emerged weeds. Application of a post-emergence herbicide could be made sequentially with

either Specticle SC or Specticle G, or in a tank mixture with Specticle SC. The application of either of these products with a post-emergence herbicide may reduce the potential for the development of resistance to both indaziflam as well as to the post-emergence herbicide for those weeds that are susceptible to both.

5.2 Effectiveness Against Pests

Specticle SC applied at 1.0 L/ha or Specticle G applied at 336 kg/ha will provide residual control or suppression of weed species listed in Appendix I, Table 4.

Efficacy claims were supported with data submitted from small-scale trials and data that were previously submitted for other indaziflam products. In several of the small-scale trials, the level of weed control in treatments of Specticle SC and/or Specticle G applied at up to 75 g a.i./ha was similar to that achieved in treatments of other indaziflam formulations, including a registered formulation when applied at the same or similar rates on an active ingredient basis. Therefore, data generated with any one of these formulations were considered in support of labelled claims.

The collective consideration of efficacy data that were generated in small-scale trials as well as data that were previously submitted for other indaziflam products support the claims summarized in Appendix I, Table 4 for both Specticle SC and Specticle G.

5.3 Non-Safety Adverse Effects

The tolerance of ornamental plant species to application of Specticle SC at 80 to 200 g a.i./ha or Specticle G applied at rates of 100 to 200 g a.i./ha was evaluated in small-scale field trials. Injury to multiple deciduous and conifer tree species and deciduous and conifer shrub species was usually low or not visually detectable at these exaggerated rates. The data from these trials along with data generated in the U.S. IR-4 program collectively demonstrate that the ornamental plant species listed in Appendix I, Table 4 can be expected to exhibit acceptable tolerance to an application of Specticle SC or Specticle G at the labelled rate of 75 g a.i./ha.

5.4 Supported Uses

The available value information supports claims of residual control or suppression, with the particular claim being specific to weed species, for Specticle SC applied at 1.0 L/ha or Specticle G applied at 336 kg/ha. Refer to Appendix I, Table 4 for details of the supported uses.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment),

bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the original review, indaziflam and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria (PRD2011-20, *Indaziflam*). The TSMP conclusions reached at that time apply to the current submission:

- Indaziflam Technical does not meet all Track 1 criteria, nor does it form any transformation products that meet all Track 1 criteria, and therefore is not considered a Track 1 substance.

6.2 Formulants and Contaminants of Health or Environmental Concern

Contaminants in the technical (Indaziflam Technical Herbicide) and formulants and contaminants in the end-use products (Specticle SC and Specticle G) were compared against the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern maintained in the Canada Gazette. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade indaziflam and the end-use products Specticle SC and Specticle G do not contain any formulants or contaminants of health or environmental concern identified in the Canada Gazette.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02. Refer to PRD2011-20, *Indaziflam* for more information on the Toxic Substances Management Policy Considerations (TSMP) considerations.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for indaziflam is adequate to define the majority of toxic effects that may result from exposure. There was no evidence of carcinogenicity in rats or mice after long-term dosing. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies. The primary effect was neurotoxicity. Other targets in short-term and chronic studies in laboratory animals were effects on reproductive potential, body weights, liver, kidneys and thyroid glands. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Provided that label amendments are made, that the appropriate PPE is worn, and that all label restrictions are followed, mixers, loaders and applicators handling Specticle SC or Specticle G, as well as workers re-entering treated areas of field or container grown ornamentals, respectively, are not expected to be exposed to levels of indaziflam that will result in health risks of concern. Bystander exposure and residential exposure to individuals buying and/or handling treated ornamentals are expected to be negligible.

7.2 Environmental Risk

Indaziflam is not expected to present risks of concern to birds, wild mammals, bees, invertebrates, freshwater or marine invertebrates and fish, and amphibians. However, exposure to indaziflam can affect non-target terrestrial plants and aquatic plants. Therefore, to protect non-target terrestrial plants and aquatic plants from spray drift, buffer zones of 15 metres and 1 metre are required for non-target terrestrial plants and aquatic habitats, respectively, for field-grown ornamentals. To protect aquatic plants from the potential effects of run-off, a label statement to minimize run-off will be required, as well as hazard label statements for toxicity to aquatic and terrestrial plants.

7.3 Value

The value information submitted to register Specticle SC and Specticle G for control or suppression of broadleaved and grass weeds is adequate to demonstrate value, including efficacy for use in field-grown and container-grown ornamental plants.

There are currently other herbicides belonging to WSSA groups 3, 5, 9, 14, 15, 20 and 21 that are registered for application in field-grown and container-grown ornamental plants. Specticle SC and Specticle G are the only Group 29 herbicides available for management of both broadleaved and grass weeds in ornamental plants. The application of these herbicides in combination with herbicides of differing modes of action can be expected to mitigate the potential for resistance development in susceptible weed populations.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Indaziflam Technical Herbicide, Specticle SC and Specticle G, containing the technical grade active ingredient indaziflam, to control or suppress annual grasses and broadleaf weeds in field grown and container grown ornamentals.

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

List of Abbreviations

%	percent
µg	micrograms
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
ATPD	Area treated per day
bw	body weight
°C	degrees Celsius
CAF	composite assessment factors
CAS	Chemical Abstracts Service
cm^3	centimetre(s) cubed
CR	Chemical-resistant
DACO	data code
DAF	Dermal absorption factor
EEC	exposure concentration
EDE	estimated daily exposure
FIR	food ingestion rate
g	gram
ha	hectare(s)
HDPE	high density polyethylene
HRAC	Herbicide Resistance Action Committee.
IR-4	Inter-Regional Research Project Number 4
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
MAS	maximum average score
mg	milligram
mL	millilitre
M/L	mixing/loading
M/L/A	mixer/loader/applicator
mg	milligram
MIS	mean irritation score
mm	milliliter
MOE	margin of exposure
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no observed adverse effect level
NOEL	no observed effect level
NZW	New Zealand white
ORETF	Outdoor Residential Exposure Task Force
pH	measure of the acidity or basicity of an aqueous solution

PHED	Pesticide handler exposure database
PMRA	Pest Management Regulatory Agency
PPE	Personal protective equipment
PRD	Proposed Registration Document
RD	Registration Decision
REI	Restricted entry interval
RQ	risk quotient
sp.	species
TGAI	Technical Grade Active Ingredient
TSMP	Toxic Substances Management Policy
U.S.	United States
USEPA	United States Environmental Protection Agency
WSSA	Weed Science Society of America

Appendix I Tables and Figures

Table 1 Toxicity Profile of Specticle SC

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Wistar rats PMRA #2513066	LD_{50} > 5000 mg/kg bw Low toxicity
Acute dermal toxicity Sprague-Dawley rats PMRA #2513067	LD_{50} > 5000 mg/kg bw Low toxicity
Acute inhalation toxicity (nose-only) Wistar rats PMRA #2513068	LC_{50} > 2.09 mg/L Low toxicity
Eye irritation NZW rabbits PMRA #2513069	At 1 hour, slight conjunctival redness and swelling was observed. Eyes were normal at 24 hours. MAS = 0/110, MIS = 3.33/110 Non-irritating
Dermal irritation NZW rabbits PMRA #2513070	MAS = 0/8, MIS = 0.67/8 Non-irritating
Dermal sensitization (Buehler test) Hartley guinea pigs PMRA #2513071	Non-sensitizer

Toxicity Profile of Specticle G

A waiver request was submitted (PMRA #2546455) and accepted for the Specticle G acute toxicity studies based on the acute toxicity of the TGAI and the criteria set out for the reduced toxicity of granular pesticides in the Guidance for Waiving or Bridging of Mammalian Acute Toxicity Test for Pesticides (December 2013).

Table 2 Toxicology Endpoints for Use in Health Risk Assessment for Indaziflam

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary general population	Acute neurotoxicity study	NOAEL = 50 mg/kg bw Reduced motor activity	100
	ARfD = 0.5 mg/kg bw		
Repeated dietary	12-month dog study	NOAEL = 2 mg/kg bw/day Axonal degeneration	100
	ADI = 0.02 mg/kg bw/day		
Short and Intermediate -term dermal[2]	90-day dog study	NOAEL = 7.5 mg/kg bw/day Axonal degeneration	100
Short and Intermediate -term inhalation[3]	90-day dog study	NOAEL = 7.5 mg/kg bw/day Axonal degeneration	100
Non-dietary oral ingestion (short-term)	N/A		
Aggregate	N/A		
Cancer	N/A		

[1] CAF (composite assessment factor) refers to a total of uncertainty and *Pest Control Products Act* factors for dietary assessments; MOE refers to a target MOE for occupational assessments
[2] Since an oral NOAEL was selected, a dermal absorption factor 25% was determined based on a weight-of-evidence approach
[3] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 3 Screening level risk assessment for Specticle G (assuming that 100% of granules are available on the soil surface)[1,2]

	Toxicity[2] (mg a.i./kg bw/day)	EDE[3] (mg a.i./kg bw)	RQ[4]	LOC[5] exceeded?
Small bird (0.02 kg)				
Acute	200.00	56.882	0.284	No
Reproduction	111.00	56.882	0.512	No

	Toxicity[2] (mg a.i./kg bw/day)	EDE[3] (mg a.i./kg bw)	RQ[4]	LOC[5] exceeded?
Medium sized bird (0.10 kg)				
Acute	200.00	44.682	0.223	No
Reproduction	111.00	44.682	0.402	No
Large sized bird (1.00 kg)				
Acute	200.00	13.026	0.065	No
Reproduction	111.00	13.026	0.117	No
Small mammal (0.015 kg)				
Acute	500.00	32.507	0.065	No
Reproduction	68.90	32.507	0.472	No
Medium sized mammal (0.035 kg)				
Acute	500.00	27.956	0.056	No
Reproduction	68.90	27.956	0.406	No
Large sized mammal (1.00 kg)				
Acute	500.00	15.393	0.031	No
Reproduction	68.90	15.393	0.223	No

[1] The proposed application rate for Specticle G is 336 kg granules/ha (75 g a.i./ha) with no soil incorporation. As some information specific to the granules or bird behavior is not currently available, some assumptions were made. It was assumed that there was no preference or avoidance of the granules (P_{ratio} = 1) for this assessment and that the granules did not disappear over time (F_{disap} = 0). Although in reality, the granules are expected to disappear over time, the disappearance rate is unknown.

[2] Toxicity endpoints (LD_{50} and NOEL) were taken from PRD2011-20 – *Indaziflam*– Appendix I Table 11.

[3] EDE (Estimated daily exposure; expressed as the number of granules consumed per day) = FIR × number of granules/g of product; where: FIR (Food ingestion rate; in g dry weight per day) is based on equations from Nagy (1987).
For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used.
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = $0.398(\text{bw in g})^{0.850}$
For generic birds with body weight greater than 200 g, the "all birds" equation was used.
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(\text{bw in g})^{0.651}$
For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(\text{bw in g})^{0.822}$

[4] RQ (Risk quotient) = EDE/Toxicity

[5] Level of concern (LOC) = 1 (for birds and mammals)

Table 4 List of Supported Uses for Specticle SC and Specticle G

List of Supported Uses for Specticle SC

Application Directions:

- Application of a maximum of once per year of 1 L/ha (75 g a.i./ha) in a minimum spray volume of 93 L water/ha
- Application as a directed broadcast or banded application to the soil surface around ornamental trees and shrubs
- Application prior to weed emergence
- Application followed by irrigation with a minimum of 6 mm of water within several days after application

Weeds Controlled or *Suppressed

Broadleaved weeds
Bittercress, (including Hairy)
Black medic
Carpetweed
Chickweed, Mouse-ear
Clover, White*
Corn speedwell
Cudweed
Curly dock
Dog fennel
Field bindweed
Fleabane, Hairy
Groundsel, Common
Hawksbeard, Smooth
Henbit
Kochia*
Lambsquarters, Common
Little mallow
London rocket*
Morning Glory
Mustard, Black
Mustard, Wild
Nightshade, American black
Nightshade, Hairy
Pigweed, Prostrate
Pigweed, Redroot*
Prostrate knotweed
Plantain, Buckthorn
Prickly lettuce*
Purslane, Common
Spurge, Spotted
Shepherd's-purse
Sowthistle, Annual
St-John wort
Starthistle, Yellow
Stork’s bill
Sunflower, Common
Vetch, Purple
Woodsorrel, Yellow

Grass and sedge weeds
Annual bluegrass / 'Poa'
Barnyardgrass, Common
Bluestem, Broomsedge
Cheatgrass
Crabgrass (Large, smooth and hairy)
Foxtail, Giant
Foxtail, Green
Foxtail, Yellow
Goosegrass
Grasses, Brome (Downy, ripgut and cheat)
Italian ryegrass
Medusa head
Ryegrass, Annual
Ryegrass, Perennial
Sedge, Globe
Stinkgrass
Tufted lovegrass
Volunteer common rye
Wild barley
Wild oats
Wild proso millet

Host Ornamental Trees and Shrub Plants

Common Name	Scientific Name	Cultivar/strain
Abelia	*Abelia grandiflora*	
Almond	*Prunus sp.*	
Apple	*Malus sp.*	(non-bearing)
Apple	*Malus domestica*	Haralred (non-bearing)
Apricot	*Prunus sp.*	
Arborvitae	*Thuja occidentalis*	Nigra Techny Green Giant
Asparagus Fern	*Asparagus plumosus*	
Aspen, Quaking	*Populus tremuloides*	
Azalea	*Rhododendron sp.*	Girard's Rose Fashion VF 14 Golden Torch
Azalea, Encore	*Rhododendron sp.*	Autumn Debutante
Bald Cypress	*Taxodium distichum*	
Bamboo, Golden	*Phyllostachys aurea*	
Barberry	*Berberis sp.*	
Beech	*Fagus sp.*	

Common Name	Scientific Name	Cultivar/strain
Birch	*Carpinus sp.* *Corylus sp.*	
Birch, Gray	*Betula populifolia*	Whitespire
Birch, Black	*Betula lenta*	
Birch, River	*Betula nigra*	Heritage
Black Tupelo	*Nyssa sylvatica*	Wild Fire
Bluebird	*Caryopteris x clandonensis*	Dark Knight
Boxwood	*Buxus microphylla*	Chicagoland Green Baby Gem Wintergreen
Butterfly Bush	*Buddleia sp.*	Nanho Blue
Camellia, Japanese	*Camellia japonica*	Margaret Heathcliff Pink
Camellia, Little leaf	*Camellia sasanqua*	Cleopatra Pink
Catalpa, Southern	*Catalpa bignoniaceae*	
Cedar, Atlantic white	*Chamaecyparis sp.*	
Cedar, Eastern Red	*Juniperus virginiana*	
Cedar, Japanese	*Cryptomeria japonica*	Black Dragon Burkii Yoshino
Cherry	*Prunus sp.*	(non-bearing)
Cherry, Laurel	*Prunus caroliniana*	
Cherry, American Plum	*Prunus americana*	
Cherry, Okame	*Prunus x incamp*	
Cherry, Japanese	*Prunus serrulata*	Kwanzan
Cherry, Purple Leaf Sand	*Prunus cistena*	
Cherry, Sargent	*Prunus sargentii*	Spring Wonder
Cherry, Yoshino	*Prunus x yedoensis*	Yoshino
Chestnut	*Castanea sp.*	
Chokeberry	*Aronia sp.*	
Cotoneaster	*Cotoneaster sp.*	
Cotoneaster	*Cotoneaster dammeri*	Coral Beauty
Cottonwood	*Populus deltoides*	Sioux
Crabapple	*Malus x 'Harvest Gold'*	
Crabapple	*Malus x 'Snowdrift'*	
Crabapple	*Malus coronaria*	
Crape Myrtle	*Lagerstroemia indica x fauriei*	Muskogee
Crape Myrtle	*Lagerstroemia x 'Miami'*	
Crape Myrtle	*Lagerstroemia indica*	Tuscarora
Cypress, False	*Chamaecyparis sp.*	Gold Mops
Cypress, Mediterranean	*Cupressus sempervirens*	
Cypress, Leyland	*Cupressus x leylandii*	
Daphne	*Daphne caucasica*	Summer Ice
Dawn Redwood	*Metasequoia glyptostroboides*	
Daylily (before unfurling)	*Hemerocallis sp.*	Green Flutter

Common Name	Scientific Name	Cultivar/strain
		Stella d'Oro
Dogwood, Flowering	*Cornus florida*	
Dogwood, Kousa	*Cornus kousa*	Kousa
Elm	*Celtis sp.*	Common Hackberry
Elm, American	*Ulmus americana*	
Elm, Bosque	*Ulmus parvifolia*	
Eucalyptus, Silver Dollar Gum	*Eucalyptus polyanthemos*	
Euonymus	*Euonymus alatus*	Compacta
Fir, Fraser	*Abies fraseri*	
Florida Pipestem	*Leucothoe populifolia*	
Forsythia	*Forsythia sp.*	Lynwood Golden Bell
Fragrant Tea Olive	*Osmanthus fragrans*	
Gardenia	*Gardenia radicans*	Radicans
Gardenia	*Gardenia jasminoides*	Mystery Frostproof
Gaura	*Gaura lindheimeri*	Pink Fountain
Ginkgo	*Ginkgo biloba*	
Gold-Dust Plant	*Aucuba japonica*	Gold Dust
Green Ash	*Fraxinus pennsylvanica*	
Green Ash	*Fraxinus pennsylvanica*	Georgia Gem
Hardy Kiwi	*Actinidia arguta*	Anna
Hawthorn, Single Seed	*Crategus monogyna*	
Hawthorn, Thornless	*Crataegus crus-galli*	Inermis
Hibiscus, Chinese	*Hibiscus rosa-sinensis*	San Diego Red
Hickory	*Carya sp.*	Hickory nut
Holly, Common	*Ilex aquifolium*	
Holly, Chinese	*Ilex cornuta*	Needlepoint
Holly, Foster	*Ilex x attenuata*	Fosteri
Holly, Gallberry	*Ilex glabra*	Densa
Holly, Meservae	*Ilex meservae*	Blue Princess
Holly, Nellie R. Stevens	*Ilex x 'Nellie R. Stevens'*	Nellie R. Stevens
Holly, American	*Ilex opaca*	
Holly, (Winterberry)	*Ilex verticillata*	Jim Dandy Red Sprite
Holly, Japanese	*Ilex crenata*	Sky Pencil
Honeylocust	*Gleditsia tricanthos*	Sunburst Skyline
Horsechestnut	*Aesculus sp.*	
Indian Hawthorn	*Raphiolepsis indica*	Pink Lady
Japanese Cleyera	*Ternstromia gymnanthera*	
Japanese Mock-orange	*Pittosporum tobira*	Variegata

Common Name	Scientific Name	Cultivar/strain
Japanese Plum	*Prunus mume*	
Japanese Plum (Loquat)	*Eriobotrya japonica*	
Jasmine, Asiatic/Yellow Star	*Trachelospermum asiaticum*	
Jasmine, Winter	*Jasminum nudiflorum*	
Juniper, Bar Harbour	*Juniperus horizontalis*	Bar Harbour
Juniper, Blue Pacific	*Juniperus conferta*	Blue Pacific
Juniper, Blue Rug	*Juniperus horizontalis*	Blue Rug
Juniper, Blue Star	*Juniperus squamata*	Blue Star
Juniper, Brodie	*Juniperus virginiana*	
Juniper, Japanese Garden	*Juniperus procumbens*	
Juniper, Spartan	*Juniperus chinensis*	Spartan
Lantana	*Lantana camara*	Landmark Sunrise Rose
Lilac	*Syringa x 'Penda'*	Bloomerang
London Plane Tree	*Plantanus acerifolia*	
Loropetalum	*Loropetalum chinensis*	Burgundy Ruby
Magnolia	*Magnolia grandiflora*	Bracken's Brown Beauty Little Gem
Magnolia, Jane	*Magnolia liliflora 'Nigra' x M. stellata*	Rosea
Maple, Autumn Blaze	*Acer freemanii*	Jeffersred
Maple, Red	*Acer rubrum*	Red Sunset October Glory
Maple, Silver	*Acer saccharinum*	
Maple, Sugar	*Acer saccharum*	Commemoration
Metasequoia	*Metasequoia sp.*	
Nandina	*Nandina domestica*	Firepower
Nectarine	*Prunus sp.*	(non-bearing)
Ninebark, Eastern	*Physocarpus opulifolius*	Summer Wine
Oak	*Quercus sp.*	
Oak, Pin	*Quercus palustris*	
Oak, Southern Live	*Quercus virginiana*	
Oak, Cathedral Live	*Quercus virginiana*	SDLN
Oak, Northern Red	*Quercus rubra*	
Oak, Nuttal	*Quercus nuttallii*	
Oak, Shumard	*Quercus shumardii*	
Oak, White	*Quercus alba*	
Ohio Buckeye	*Aesculus glabra*	
Palm, Areca	*Dypsis lutescens*	
Palm, Manila	*Adonidia merrillii*	
Palm, Alexander	*Archontophoenix alexandrae*	
Palm, Florida Thatch	*Thrinax radiata*	
Palm, Spindle	*Hyophorbe verschaffeltii*	

Common Name	Scientific Name	Cultivar/strain
Pear	*Pyrus sp.*	(non-bearing)
Pear, Callery	*Pyrus calleryana*	Chanticleer Bradford
Peach	*Prunus sp.*	(non-bearing)
Pieris	*Pieris japonica*	Shojo
Pine, Canary Island	*Pinus canariensis*	
Pine, Eastern White	*Pinus strobus*	
Pine, Scotch	*Pinus sylvestris*	
Pistache, Texas	*Pistacia texana*	
Plum	*Prunus sp.*	(non-bearing)
Plum, Crimson Pointe	*Prunus x cerasifera*	Cipriozam
Podocarpus	*Podocarpus macrophyllus*	
Privet, California	*Ligustrum ovalifolium*	
Redbud, Eastern	*Cercis canadensis*	MN Strain
Redbud	*Cercis reniformis*	Oklahoma
Rhododendron	*Rhododendron x crete*	
Rose	*Rosa wichurana*	Dr. Huey
Rose	*Rosa sp.*	Pink Knock Out® Knock Out®
Rose, Virginia	*Rosa virginiana*	
Rose Mallow	*Hibiscus moscheutos*	
Rose of Sharon	*Hibiscus syriacus*	Shrubbery althaea Pink Heart Boule de Feu
Russian Sage	*Perovskia atriplicifolia*	
Skip Laurel	*Prunus laurocerasis*	
Snowberry, Common	*Symphoricarpos albus*	
Spicebush	*Lindera benzoin*	
Spirea	*Spirea sp.*	
Spruce, Blackhills	*Picea glauca*	
Spruce, Norway	*Picea abies*	
Tamarisk	*Tamarix ramosissima*	Pink Cascade
Yew, Japanese	*Taxus cuspidata*	Capitada
Thin-fruit Sedge	*Carex flaccosperma*	
Viburnum, Burkwood	*Viburnum x burkwoodii*	
Virbunum (Wayfaring Tree)	*Virbunum lantana*	Mohican
Viburnum, Popcorn	*Viburnum plicatum*	Popcorn
Walnut	*Juglans sp.*	
Wax myrtle, Southern	*Myrica cerifera*	
Weigela, Variegated	*Weigela florida 'Variegata'*	
Willow, Weeping	*Salix babylonica*	

List of Supported Uses for Specticle G

Application Directions:

- Application of a maximum of once per year of 336 kg/ha (75 g a.i./ha)
- Application over the top of container-grown ornamental plants
- Application prior to weed emergence
- Application followed by irrigation with a minimum of 6 mm of water within one hour after application

Weeds controlled or *suppressed

Broadleaved weeds
Bittercress, (including Hairy)
Black medic
Carpetweed
Chickweed, Mouse-ear
Clover, White*
Corn speedwell
Cudweed
Curly dock
Dog fennel
Field bindweed
Fleabane, Hairy
Groundsel, Common
Hawksbeard, Smooth
Henbit
Kochia*
Lambsquarters, Common
Little mallow
London rocket*
Morning Glory
Mustard, Black
Mustard, Wild
Nightshade, American black
Nightshade, Hairy
Pigweed, Prostrate
Pigweed, Redroot*
Prostrate knotweed
Plantain, Buckthorn
Prickly lettuce*
Purslane, Common
Spurge, Spotted
Shepherd's-purse
Sowthistle, Annual
St-John wort

Starthistle, Yellow
Stork's bill
Sunflower, Common
Vetch, Purple
Woodsorrel, Yellow

Grass and sedge weeds
Annual bluegrass / 'Poa'
Barnyardgrass, Common
Bluestem, Broomsedge
Cheatgrass
Crabgrass (Large, smooth and hairy)
Foxtail, Giant
Foxtail, Green
Foxtail, Yellow
Goosegrass
Grasses, Brome (Downy, ripgut and cheat)
Italian ryegrass
Medusa head
Ryegrass, Annual
Ryegrass, Perennial
Sedge, Globe
Stinkgrass
Tufted lovegrass
Volunteer common rye
Wild barley
Wild oats
Wild proso millet

Host Ornamental Trees and Shrub Plants

Common Name	Scientific Name	Cultivar/strain
Abelia	*Abelia grandiflora*	
Almond	*Prunus sp.*	
Apple	*Malus sp.*	(non-bearing)
Apple	*Malus domestica*	Haralred (non-bearing)
Apricot	*Prunus sp.*	(non-bearing)
Arborvitae	*Thuja occidentalis*	Nigra Techny Green Giant
Asparagus Fern	*Asparagus plumosus*	
Aspen, Quaking	*Populus tremuloides*	
Azalea	*Rhododendron sp.*	Girard's Rose Fashion VF 14 Golden Torch

Common Name	Scientific Name	Cultivar/strain
Azalea, Encore	*Rhododendron sp.*	Autumn Debutante
Bald Cypress	*Taxodium distichum*	
Bamboo, Golden	*Phyllostachys aurea*	
Barberry	*Berberis sp.*	
Beech	*Fagus sp.*	
Beauty Bush	*Kolkwitzia amabilis*	
Birch	*Carpinus sp.* *Corylus sp.*	
Birch, Gray	*Betula populifolia*	Whitespire
Birch, Black	*Betula lenta*	
Birch, River	*Betula nigra*	Heritage
Black Hawthorn	*Crataegus douglasii*	
Black Tupelo	*Nyssa sylvatica*	Wild Fire
Bleeding Heart Vine	*Clerodendrum thomsoniae*	Bleeding Heart
Bluebird	*Caryopteris x clandonensis*	Dark Knight
Bottlebrush, Crimson	*Callestemon citrinus*	
Bottlebrush, Lemon	*Callestemon sp.*	
Bougainvillea	*Bougainvillea sp.*	Barbara Karst Double Red
Boxwood	*Buxus microphylla*	Green Beauty Chicagoland Green Baby Gem Wintergreen
Butterfly Bush	*Buddleia sp.*	Nanho Blue
Camellia, Japanese	*Camellia japonica*	Margaret Heathcliff Pink
Camellia, Little leaf	*Camellia sasanqua*	Cleopatra Pink
Catalpa, Southern	*Catalpa bignoniaceae*	
Cedar, Atlantic white	*Chamaecyparis thyoides*	
Cedar, Eastern Red	*Juniperus virginiana*	Idyllwild
Cedar, Japanese	*Cryptomeria japonica*	Black Dragon Burkii Yoshino
Cedar, Mediterranean	*Cedrus libani*	
Chaste Tree	*Vitex agnus-castus*	Abbeville Blue
Cherry	*Prunus sp.*	(non-bearing)
Cherry, American Plum	*Prunus americana*	
Cherry, Okame	*Prunus x incamp*	
Cherry, Japanese	*Prunus serrulata*	Kwanzan
Cherry, Purple Leaf Sand	*Prunus cistena*	
Cherry, Sargent	*Prunus sargentii*	Spring Wonder
Cherry, Yoshino	*Prunus x yedoensis*	Yoshino
Chestnut	*Castanea sp.*	

Common Name	Scientific Name	Cultivar/strain
Chokeberry	*Aronia sp.*	
Cotoneaster	*Cotoneaster dammeri*	Coral Beauty
Cottonwood	*Populus deltoides*	Sioux
Crabapple	*Malus x 'Harvest Gold'*	
Crabapple	*Malus x 'Snowdrift'*	
Crabapple	*Malus coronaria*	
Crape Myrtle	*Lagerstroemia indica x fauriei* *Lagerstroemia x 'Miami'* *Lagerstroemia indica*	Muskogee Natchez Tuscarora Sarah's Favourite Pocomoke Pink Burgundy Cotton Rose Red Siren Red
Cypress, False	*Chamaecyparis sp.*	Gold Mops Gold Thread
Cypress, Mediterranean	*Cupressus sempervirens*	
Cypress, Leyland	*Cupressus x leylandii*	
Daphne	*Daphne caucasica*	Summer Ice
Dawn Redwood	*Metasequoia glyptostroboides*	
Daylily (before unfurling)	*Hemerocallis sp.*	Green Flutter Stella d'Oro
Dogwood, Flowering	*Cornus florida*	
Dogwood, Kousa	*Cornus kousa*	Kousa
Deutzia	*Deutzia gracilis*	Nikko
Elm (Common hackberry)	*Celtis sp.*	
Elm, American	*Ulmus americana*	
Elm, Bosque	*Ulmus parvifolia*	
Eucalyptus, Silver Dollar Gum	*Eucalyptus polyanthemos*	
Euonymus	*Euonymus alatus*	Compacta
Fir, Fraser	*Abies fraseri*	
Florida Pipestem	*Leucothoe populifolia*	
Forsythia	*Forsythia sp.*	Golden Bell Lynwood Gold
Gardenia	*Gardenia radicans*	Radicans
Gardenia	*Gardenia jasminoides*	Mystery Frostproof
Gaura	*Gaura lindheimeri*	Pink Fountain
Ginkgo	*Ginkgo biloba*	
Gold-Dust Plant	*Aucuba japonica*	Gold Dust
Green Ash	*Fraxinus pennsylvanica*	Georgia Gem
Hardy Kiwi	*Actinidia arguta*	Anna
Hawthorn, Black	*Crataegus douglasii*	

Common Name	Scientific Name	Cultivar/strain
Hawthorn, Thornless	*Crataegus crus-galli*	Inermis
Hibiscus	*Hibiscus paramutabilis x syriacus*	Lohengrin
Hibiscus, Chinese	*Hibiscus rosa-sinensis*	San Diego Red President Red
Hickory	*Carya sp.*	Hickory nut
Holly	*Ilex sp.*	
Holly, Dragon Lady	*Ilex x aquipernyl*	
Holly, Chinese (Dwarf Burford)	*Ilex cornuta*	Needlepoint Burdordii Nana
Holly, Foster	*Ilex x attenuata*	East Palatka Fosteri
Holly, Gallberry (Inkberry)	*Ilex glabra*	Densa Compacta
Holly, Meservae	*Ilex meservae*	Blue Princess
Holly, Nellie R. Stevens	*Ilex x 'Nellie R. Stevens'*	Nellie R. Stevens
Holly, American	*Ilex opaca*	
Holly (Winterberry)	*Ilex verticillata*	Jim Dandy Red Sprite
Holly, Japanese	*Ilex crenata*	Sky Pencil
Honeylocust	*Gleditsia tricanthos*	Sunburst Skyline
Honeysuckle, European	*Lonicera periclymenum*	Harlequin
Horsechestnut	*Aesculus sp.*	
Hosta (before emergence)	*Hosta sp.*	
Indian Hawthorn	*Raphiolepsis indica*	Pink Lady
Japanese Cleyera	*Ternstromia gymnanthera*	
Japanese Mock-orange	*Pittosporum tobira*	Variegata
Japanese Plum Yew	*Cephalotaxus harringtonia*	Fastigiata
Japanese Yew	*Taxus x media*	Densiformis
Japanese Yew	*Taxus cuspidata*	
Jasmine, Asiatic/Yellow Star	*Trachelospermum asiaticum*	Minima
Jasmine, Winter	*Jasminum nudiflorum*	
Juniper, Bar Harbour	*Juniperus horizontalis*	Bar Harbour
Juniper, Blue Pacific	*Juniperus conferta*	Blue Pacific
Juniper, Blue Rug	*Juniperus horizontalis*	Blue Rug
Juniper, Blue Star	*Juniperus squamata*	Blue Star
Juniper, Brodie	*Juniperus virginiana*	
Juniper	*Juniperus chinensis*	Spartan Sea Green
Juniper, Japanese Garden	*Juniperus procumbens*	

Common Name	Scientific Name	Cultivar/strain
Lantana	*Lantana camara*	Landmark Sunrise Rose
Lilac	*Syringa x 'Penda'*	Bloomerang
Lilac, Manchurian	*Syringa 'pubescens' subsp. Patula*	Miss Kim
Lilac, Wild	*Ceanothos sp.*	
Lily of the Valley Shrub	*Pieris japonica var. yak* *Pieris japonica*	Cavatine Mountain Fire
London Plane Tree	*Plantanus acerifolia*	
Loropetalum	*Loropetalum chinensis*	Burgundy Ruby Plum Purple Rubra
Magnolia	*Magnolia grandiflora*	Bracken's Brown Beauty Little Gem
Magnolia, Jane	*Magnolia liliflora 'Nigra' x M. stellata*	Rosea
Magnolia, Loebner	*Magnolia x loebneria*	Leonard Messel
Magnolia, Star	*Magnolia stellata*	Waterlily
Maple, Autumn Blaze	*Acer freemanii*	Jeffersred
Maple, Japanese	*Acer palmatum*	Bloodgood
Maple, Red	*Acer rubrum*	
Maple, Red	*Acer rubrum*	Red Sunset October Glory Frank's Red
Maple, Silver	*Acer saccharinum*	
Maple, Sugar	*Acer saccharum*	Commemoration
Nandina	*Nandina domestica*	Firepower
Nectarine	*Prunus sp.*	(non-bearing)
Ninebark, Eastern	*Physocarpus opulifolius*	Summer Wine Coppertina Darts Gold
Oak	*Quercus sp.*	
Oak, Cathedral Live	*Quercus virginiana*	SDLN
Oak, Northern Red	*Quercus rubra*	
Oak, Nuttal	*Quercus nuttallii*	
Oak, Shumard	*Quercus shumardii*	
Ohio Buckeye	*Aesculus glabra*	
Oleander	*Nerium oleander*	Cardinal Red
Palm, Areca	*Dypsis lutescens*	
Palm, Manila	*Adonidia merrillii*	
Palm, Alexander	*Archontophoenix alexandrae*	
Palm, Florida Thatch	*Thrinax radiata*	
Palm, Spindle	*Hyophorbe verschaffeltii*	
Passionvine	*Passiflora caerulea*	Blue

Common Name	Scientific Name	Cultivar/strain
Peach	*Prunus sp.*	(non-bearing)
Pear	*Pyrus sp.*	(non-bearing)
Pear, Callery	*Pyrus calleryana*	Chanticleer Bradford
Periwinkle	*Vinca minor*	
Periwinkle, Madagascar	*Catharanthus roseus*	Titan Lilac
Photinia	*Photinia x fraseri*	Red Tip
Pieris	*Pieris japonica*	Shojo
Pine, Canary Island	*Pinus canariensis*	
Pine, Eastern White	*Pinus strobus*	
Pine, Loblolly	*Pinus taeda*	
Pine, Mondell	*Pinus eldarica*	
Pine, Scotch	*Pinus sylvestris*	
Pistache, Texas	*Pistacia texana*	
Plum	*Prunus sp.*	(non-bearing)
Plum, Japanese	*Prunus mume*	
Plum, Japanese (Loquat)	*Eriobotrya japonica*	
Plum, Crimson Pointe	*Prunus x cerasifera*	Cipriozam
Podocarpus	*Podocarpus macrophyllus*	
Potentilla, Shrubbery Cinquefoil	*Potentilla fruticosa*	Goldfinger
Privet, Vicary Golden	*Ligustrum x vicaryi*	Vicary Golden
Pyracantha/Firethorn	*Pyrancantha coccinea*	Red Cushion
Quince, Common Flowering	*Chaenomeles speciosa*	
Redbud, Eastern	*Cercis canadensis*	MN Strain
Redbud	*Cercis reniformis*	Oklahoma
Rhododendron	*Rhododendron x crete*	
Rose	*Rosa wichurana*	Dr. Huey
Rose	*Rosa sp.*	Pink Knock Out® Knock Out® Louis Philippe
Rose, Virginia	*Rosa virginiana*	
Rose Mallow	*Hibiscus moscheutos*	
Rose of Sharon	*Hibiscus syriacus*	Pink Heart Boule de Feu
Russian Olive	*Elaeagnus angustifolia*	
Russian Sage	*Perovskia atriplicifolia*	
Scotchbroom	*Cytisus scoparius*	Burkwoodii
Serviceberry	*Amelanchier canadensis*	
Skip Laurel	*Prunus laurocerasis*	
Smoketree	*Cotinus coggygria*	Royal Purple
Snowberry, Common	*Symphoricarpos albus*	
Spicebush	*Lindera benzoin*	

Common Name	Scientific Name	Cultivar/strain
Spruce, Blackhills	*Picea glauca*	
Spruce, Norway	*Picea abies*	
Sweet olive, fragrant tea olive	*Osmanthus fragrans*	
Switchgrass	*Panicum virgatum*	Shenandoah
Tamarisk	*Tamarix ramosissima*	Pink Cascade
Taxus (Yew)	*Taxus cuspidata*	Capitada
Thin-fruit Sedge	*Carex flaccosperma*	
Verbena	*Verbena canadensis*	Homestead Purple
Viburnum, Burkwood	*Viburnum x burkwoodii*	
Virbunum	*Virbunum sp.*	Jeddi St. Veverne Arrowwood
Viburnum, Popcorn	*Viburnum plicatum*	Popcorn
Virginia Sweetspire	*Itea virginica*	
Walnut	*Juglans sp.*	
Wax myrtle, Southern	*Myrica cerifera*	
Weigela, Variegated	*Weigela florida 'Variegata'*	
Witchalder, Dwarf	*Fothergilla gardenii*	
Yellow Anise	*Illicium parviflorum*	
Yew	*Taxus sp.*	

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	References
	1.0 Chemistry
2545507	2015, Marengo 7.4SC- Information to Address PMRA DACO Elements 3.1.1, 3.1.2, 3.1.3 and 3.1.4, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2545508	2010, Product Chemistry of Specticle Flo, DACO: 3.2.1, 3.2.2, 3.3.1, 3.4.1, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2545509	2012, Packaging Storage Stability and Corrosion Characteristics of Specticle 74 SC, DACO: 3.5.10, 3.5.14, 3.5.5 CBI
2546449	2015, Marengo G-Information to Address PMRA DACO Elements 3.1.1, 3.1.2, 3.1.3 and 3.1.4, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2546450	2011, Product Chemistry of Indaziflam G, DACO: 3.2.1, 3.2.2, 3.3.1, 3.4.1, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2546451	2012, Packaging Storage Stability and Corrosion Characteristics of Specticle G., DACO: 3.5.10, 3.5.14, 3.5.5 CBI
2546453	2011, Physical and Chemical Properties of Specticle G, DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.7 CBI
2595564	2015, Manufacturing Directions for Specticle G, DACO: 3.2.2 CBI
	2.0 Human and Animal Health
2513066	2010, Acute Oral Toxicity Up And Down Procedure In Rats, DACO: 4.6.1
2513067	2010, Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2513068	2010, Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
2513069	2010, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2513070	2010, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2513071	2010, Primary Skin Irritation Study in Rabbits, DACO: 4.6.6
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3.0 Environment

4.0 Value

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B. Additional Information Considered

i) Published Information

1.0 Environment

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