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Proposed Registration Document

PRD2014-04

# Indaziflam

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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 (Registration Number 30219) and Esplanade SC Herbicide, containing the technical grade active ingredient indaziflam, to control or suppress annual grasses and broadleaf weeds in non-residential non-crop areas such as: railroad and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, military bases, and municipal and government sites.

Indaziflam Technical Herbicide is fully registered in Canada to control both grassy and broadleaf weeds in pome fruit, stone fruit, tree nuts and grapes. The detailed review for Indaziflam Technical Herbicide can be found in the Proposed Regulatory Decision PRD2011-20, *Indaziflam* and the Registration Decision RD2012-08, *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 Section provides detailed technical information on the human health, environmental and value assessments of Indaziflam Technical Herbicide and Esplanade SC Herbicide.

## 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<sup>1</sup> 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<sup>2</sup> 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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<sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>2</sup> "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](http://healthcanada.gc.ca/pmra).

Before making a final registration decision on indaziflam, the PMRA will consider all comments received from the public in response to this consultation document.<sup>3</sup> The PMRA will then publish a Registration Decision<sup>4</sup> 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 Section of this consultation document.

## **What Is Indaziflam?**

Indaziflam belongs to the chemical class of alkylazines and acts in susceptible plants by inhibiting the synthesis of cellulose and cell wall biosynthesis. Indaziflam acts only where cellulose synthesis is occurring such as in actively growing meristematic tissues, dividing cells, expanding cells, and growing roots. Indaziflam has little to no impact on fully developed leaves, tissues, and plant organs since cell wall formation has already been completed.

Indaziflam is classified as a Group 29 Herbicide by the Weed Science Society of America and as a Group L Herbicide (inhibition of cellulose synthesis) by the Herbicide Resistance Action Committee.

Indaziflam is the active ingredient of Esplanade SC Herbicide, which is intended for residual control or suppression of grasses and broadleaf weeds in non-residential, non-crop areas. Esplanade SC Herbicide is determined to be agronomically similar to Indaziflam 200 SC Herbicide (Registration Number 30221), which is registered for pre-emergent residual control or suppression of grasses and broadleaf weeds in pome fruits, stone fruits, grapes, and tree nuts in Eastern Canada and British Columbia.

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

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

## Health Considerations

### Can Approved Uses of Indaziflam Affect Human Health?

**Indaziflam is 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.

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.

Esplanade SC Herbicide was considered to have a similar toxicity profile to Indaziflam 500 SC Herbicide. The acute toxicity of the end-use product Indaziflam 500 SC Herbicide containing indaziflam was low via the oral, dermal and inhalation routes of exposure. It was non-irritating to the eyes and skin and did not cause an allergic skin reaction.

Indaziflam did not cause cancer in animals and did not damage genetic material. There was no indication that indaziflam caused damage to the immune system. Indaziflam did not cause birth defects in animals. Health effects in animals given repeated doses of indaziflam included effects on body weight, and the liver, kidney, thyroid, nervous and reproductive systems with neurotoxicity being the primary effect.

When indaziflam was given to pregnant or nursing animals, there were effects on the developing fetus and juvenile animal. In rat reproductive toxicity studies, effects consisted of decreased body weights, decreased spleen, uterine and brain weights, decreased litter sizes, delayed sexual maturation, neurological effects, and diarrhea. In the rabbit developmental toxicity study, effects consisted of decreased body weights and increased skeletal variations. The effects were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to indaziflam than the adult animal.

The risk assessment protects against the effects of indaziflam by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

## **Occupational Risks From Handling Esplanade SC Herbicide**

**Occupational risks are not of concern when Esplanade SC Herbicide is used according to the proposed label directions, which include protective measures.**

Workers and custom applicators who mix, load or apply Esplanade SC Herbicide as well as field workers entering freshly treated areas can come in direct contact with Esplanade SC Herbicide residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Esplanade SC Herbicide must wear a long-sleeved shirt, long pants and chemical-resistant gloves. The label also requires that workers do not enter treated fields after application until residues have dried. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the occupational risk to these individuals is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

## **Environmental Considerations**

### **What Happens When Indaziflam Is Introduced Into the Environment?**

**Indaziflam enters the environment when it is used to control weeds in non-residential non-crop areas.**

**Indaziflam may pose a risk to terrestrial and aquatic plants.**

In water, indaziflam does not readily break down, and will move from the water to the sediment where it is persistent. Indaziflam does not remain in soil for long periods of time because soil bacteria break it down. Depending on the soil type, 50% 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. This breakdown of indaziflam results in the formation of three breakdown products. Two of these products will not remain in the soil as they are readily broken down by microbes in the soil. The third product may persist for extended periods of time; however, this is highly dependent 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 modelling which resulted in low predicted levels of indaziflam and its breakdown products in groundwater.



Indaziflam does not present a risk to wild mammals, birds, bees, invertebrates, freshwater or marine invertebrates and fish, or amphibians. Exposure to indaziflam can affect terrestrial and aquatic plants. To protect terrestrial and aquatic plants from spray drift, spray buffer zones of 15 metres and 1 metre are required for terrestrial and aquatic habitats<sup>5</sup>, respectively. To protect aquatic plants from the potential effects of runoff, a label statement to minimize runoff will be required, as well as hazard based label statements for toxicity to terrestrial and aquatic plants.

## **Value Considerations**

### **What Is the Value of Esplanade SC Herbicide**

#### **Esplanade SC Herbicide, as a pre-emergent treatment in non-residential non-crop areas, provides residual control or suppression of grasses and broadleaf weeds**

A single application of Esplanade SC Herbicide at the rate of 75 g a.i./ha provides effective residual control or suppression of grasses, including barnyard grass, giant foxtail, green foxtail, Italian ryegrass, large crabgrass, wild proso millet, yellow foxtail, wild barley, wild oats, brome grasses, medusa head, bluestem broomsedge, and volunteer common rye, and broadleaf weeds, including annual sow-thistle, black mustard, common groundsel, field bindweed, lamb's-quarters, prickly lettuce, redroot pigweed, shepherd's purse, spotted spurge, stork's-bill, white sweet clover, wild mustard, yellow starthistle, kochia, St. John's wort, cudweed, dog fennel, smooth hawk's-beard, and morning glory in non-residential non-crop areas such as: railroads and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, military bases, municipal and government sites.

Esplanade SC Herbicide provides an additional option for herbicide mode of action rotation for residual control or suppression of both grassy and broadleaf weeds in non-residential non-crop areas. Esplanade SC Herbicide may also be applied in tank mixes with other herbicides for additional residual weed control and/or burndown control of emerged weeds. The application of Esplanade SC Herbicide does not restrict the sequential use of other chemicals of alternate modes of action.

### **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 Esplanade SC Herbicide to address the potential risks identified in this assessment are as follows.

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<sup>5</sup> Some areas do not require buffer zones for terrestrial plants (railways, rights-of-ways, etc.)

## **Key Risk-Reduction Measures**

### **Human Health**

Because there is a concern with users coming into direct contact with indaziflam on the skin or through inhalation of spray mists, anyone mixing, loading and applying Esplanade SC Herbicide must wear a long-sleeved shirt, long pants and chemical-resistant gloves while mixing/loading, applying and during clean-up and repair. In addition, standard label statements to protect against drift during application are present on the label. Entry into treated areas is not permitted until sprays have dried to protect workers following application.

### **Environment**

Spray buffer zones of 1 and 15 meters are required to protect aquatic and terrestrial plants, respectively.

Hazard based label statements for toxicity will be required for terrestrial plants and aquatic plants.

Run-off statements will be required on the label.

### **Next Steps**

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

### **Other Information**

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

# Science Evaluation

## Indaziflam

### 1.0 The Active Ingredient, Its Properties and Uses

#### 1.1 Identity of the Active Ingredient

Please refer to the Proposed Regulatory Decision PRD2011-20, *Indaziflam*.

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

Please refer to the Proposed Regulatory Decision PRD2011-20.

#### 1.3 Directions for Use

Esplanade SC Herbicide is a selective pre-emergent herbicide for residual control or suppression of grasses and broadleaf weeds in non-residential non-crop areas such as: railroads and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, military bases, municipal and government sites (Table 1.3.1). Esplanade SC Herbicide may be applied once per year at a rate of 75 g a.i./ha (equivalent to 375 mL/ha) with ground application equipment only. Since Esplanade SC Herbicide does not control weeds that are already emerged at the time of application, it should be applied in the spring before emergence of the target weed species.

**Table 1.3.1 Weed claims for Esplanade SC Herbicide at the Rate of 75 g a.i./ha**

<b>Grasses</b>	<b>Broadleaf Weeds</b>
Control of barnyard grass, giant foxtail, green foxtail, Italian ryegrass, large crabgrass, wild proso millet, and yellow foxtail, brome grasses, wild barley, wild oats, medusa head, bluestem broomsedge, and volunteer common rye.	Control or suppression of annual sow-thistle, black mustard, common groundsel, field bindweed, lamb's-quarters, prickly lettuce, redroot pigweed, shepherd's-purse, spotted spurge, stork's-bill, white sweet clover, wild mustard, yellow starthistle, kochia, St. John's wort, cudweed, dog fennel, smooth hawk's-beard, and morning glory.

Esplanade SC Herbicide may be applied in tank mixtures with glyphosate herbicides that are registered for industrial vegetation management for burndown control of emerged weeds or with other labelled herbicides to control a broader spectrum of weeds (Table 1.3.2).

**Table 1.3.2 Application Rates and Weed Claims for Esplanade SC Herbicide in Tank Mixtures**

<b>Products</b>	<b>Rates</b>	<b>Weed Claims</b>
Esplanade SC Herbicide + Roundup WeatherMax Vision Max Roundup Ultra Roundup Ultra2 Roundup Transorb HC IPCO Factor 540 R/T 540 Liquid	375 mL/ha + 1.5-8.0 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus burndown control of emerged weeds labeled for listed glyphosate formulations.
Esplanade SC Herbicide + Milestone + Glyphosate herbicides listed above	375 mL/ha + 0.25-0.5 L/ha + 1.5-8.0 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus Milestone alone plus residual control of prickly lettuce plus burndown control of emerged weeds labeled for listed glyphosate formulations.
Esplanade SC Herbicide + Payload + Glyphosate herbicides listed above	375 mL/ha + 280-420 g/ha + 1.5-8.0 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus Payload alone plus residual control of kochia, redroot pigweed, and hairy willow herb plus burndown control of emerged weeds labeled for listed glyphosate formulations.
Esplanade SC Herbicide + Milestone	375 mL/ha + 0.25-0.5 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus Milestone alone plus residual control of prickly lettuce.

#### **1.4 Mode of Action**

Indaziflam belongs to the chemical class of alkylazines. Indaziflam acts in susceptible plants by inhibiting the synthesis of cellulose, and thus, cell wall biosynthesis. Specifically, indaziflam inhibits crystalline cellulose deposition in the plant cell wall, severely affecting cell wall formation, cell division as well as cell elongation. Indaziflam acts only in plant cells and tissues where cellulose synthesis is actively taking place (germinating weed seeds and developing seedlings), for example, in actively growing meristematic tissues, dividing cells, expanding cells, as well as growing roots. Indaziflam has little to no impact on fully developed leaves, tissues, and plant organs since cell wall formation has already been completed.

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**

Please refer to the PRD2011-20.

## **3.0 Impact on Human and Animal Health**

### **3.1 Toxicology Summary**

Please refer to the PRD2011-20.

Acute toxicity studies were performed with Indaziflam 500 SC Herbicide which is toxicologically equivalent to Esplanade SC Herbicide. Indaziflam 500 SC Herbicide was of low acute oral, dermal and inhalation toxicity in rats. It was non-irritating to the eyes and skin of rabbits and not a dermal sensitizer in guinea pigs.

### **3.2 Health Related Incident Reports**

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website. There were no health-related incidents reports submitted to the PMRA for end-use products containing indaziflam as of 31 October 2013.

### **3.3 Occupational and Residential Risk Assessment**

#### **3.3.1 Toxicological Endpoints**

Occupational exposure to indaziflam is characterized as short- to intermediate-term in duration and is predominantly by the dermal and inhalation routes.

#### **3.3.2 Occupational Exposure and Risk**

##### **3.3.2.1 Mixer/loader/applicator Exposure and Risk Assessment**

Workers who mix, load and apply Esplanade SC Herbicide have the potential for exposure to indaziflam by the dermal and inhalation routes.

Potential exposure to workers mixing, loading and applying Esplanade SC Herbicide is expected to be short- to intermediate-term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixers/loaders/applicators applying Esplanade SC Herbicide to non-crop and industrial areas using groundboom, backpack or right-of-way sprayers. The exposure estimates are based on mixers/loaders/applicators wearing long-sleeved shirts, long pants and gloves. No indaziflam specific mixer/loader/applicator exposure data were submitted by the applicant. Therefore, the daily exposure were quantified using a Tier 1 risk assessment approach by coupling the dermal inhalation generic unit exposure data from the

Pesticide Handlers Exposure Database Version 1.1, with the amount of product handled per day and 25% dermal and 100% inhalation absorption values. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight. The estimated daily exposures were compared to the toxicological endpoints to obtain a margin of exposure (MOE). The MOEs for all mixer/loader/applicator scenarios of indaziflam were above the target of 100 and no occupational risks of concern were identified.

**Table 3.3.2.1.1 Risk Assessment for Mixing/Loading/Applying Indaziflam to Non-crop Areas**

Exposure scenario	PHED unit exposure <sup>a</sup> (µg/kg a.i. handled)	ATPD (ha/day) <sup>b</sup>	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day) <sup>c</sup>	MOE <sup>d</sup>
<b>PPE: Single layer and gloves</b>					
Open pour mixing/loading, application using groundboom sprayer	23.59	360	0.075	0.00796	940
Open pour mixing/loading, application using right-of- way sprayer	237.52	40.4	0.075	0.00900	830
Open pour mixing/loading, application using backpack sprayer	1423.56	1.6	0.075	0.00214	3,500

<sup>a</sup> Combined dermal (absorbed) and inhalation unit exposures; PHED = Pesticide Handler Exposure Database Combined

<sup>b</sup> Default Area Treated Per Day tables (2010); minimum water volume is considered to be 94 L/ha

<sup>c</sup> Daily exposure = (PHED unit exposure × ATPD × Rate) / (80 kg bw × 1000 µg/mg)

<sup>d</sup> Based on NOAEL = 7.5 mg/kg bw/day, dermal absorption value of 25%, target MOE = 100

### 3.3.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for dermal exposure to workers entering industrial and non-crop land areas treated with Esplanade SC Herbicide during scouting activities. Given the nature of activities performed, dermal contact with treated surfaces should be short- to intermediate-term in duration. Based on the very low vapour pressure of indaziflam, the potential for inhalation exposure is expected to be negligible. Therefore, further assessment of the postapplication inhalation exposure was not conducted. No indaziflam specific dislodgeable foliar residue (DFR) dissipation study was submitted. Therefore, the exposure of a postapplication worker to indaziflam treated plants/trees was generated by a Tier 1 approach for foliage treatment by coupling default DFR values with the activity specific transfer coefficients for scouting and an 8 hour duration for a work day. The estimated exposure was compared to the toxicological endpoint to obtain the MOE. The postapplication exposure and risk estimates on the day of application are presented in Table 3.3.2.2.1.

The MOEs for scouting exposure scenarios of indaziflam were above the target of 100 and no occupational risks of concern were identified. No risk-based restricted-entry interval is required.

However, a default restricted-entry interval of ‘until residues have dried’ was recommended for workers before entering a treated field.

**TABLE 3.3.2.2.1 Postapplication Exposure and Risk Estimate for Indaziflam on Day 0 After the Last Application**

Re-entry activity	Peak DFR ( $\mu\text{g}/\text{cm}^2$ ) <sup>a</sup>	Transfer coefficient ( $\text{cm}^2/\text{hr}$ ) <sup>b</sup>	Dermal exposure ( $\text{mg}/\text{kg bw}/\text{day}$ ) <sup>c</sup>	MOE <sup>d</sup>
Scouting, min. foliage	0.1875	580	0.00272	2,760

<sup>a</sup> Calculated using the default 25% dislodgeable on the day of application and 10% dissipation per day.

<sup>b</sup> Transfer coefficients (TC) obtained from ARTF Transfer Coefficients Table 2012 (based on values for scouting in orchard crops and Christmas trees, as per the Proposed Acceptability for Continuing Registration, PACR2007-06 *Re-evaluation of the Agricultural, Forestry, Aquatic and Industrial Site Uses of (2,4-dichlorophenoxy)acetic Acid [2,4-D]*); although 4 hours was considered adequate in the re-evaluation of 2,4-D, an exposure duration of 8 hours was selected for government and military sites, where full-day exposure may take place.

<sup>c</sup> Exposure = (Peak DFR [ $\mu\text{g}/\text{cm}^2$ ]  $\times$  TC [ $\text{cm}^2/\text{hr}$ ]  $\times$  8 hours  $\times$  25% dermal absorption) / (80 kg bw  $\times$  1000  $\mu\text{g}/\text{mg}$ )

<sup>d</sup> Based on a NOAEL of 7.5 mg/kg bw/day, target MOE = 100

### 3.3.3 Residential Exposure and Risk Assessment

No residential uses were requested for registration.

#### 3.3.3.1 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to non-crop and industrial areas 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.

## 4.0 Impact on the Environment

### 4.1 Fate and Behaviour in the Environment

Please refer to the PRD2011-20.

## **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. A risk assessment was previously conducted which covers off the proposed expanded use of indaziflam (for application to non-residential non-crop areas)(see PRD2011-20, for further details). The proposed expanded use pattern falls within the currently registered use pattern for indaziflam (in other words, the same rate and type of application (ground application only)). As such, the identified risks and required mitigation measures outlined in PRD2011-20 would also apply to for the uses currently being proposed.

### **4.2.1 Risks to Terrestrial Organisms**

Please refer to the PRD2011-20.

### **4.2.2 Risks to Aquatic Organisms**

Please refer to the PRD2011-20.

## **4.3 Environmental Incident Reports**

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 Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 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 September 2013, no environmental incident reports were found for indaziflam.

## **5.0 Value**

### **5.1 Effectiveness Against Pests**

Value information submitted for review included scientific rationales and efficacy data from a total of 18 field trials conducted over three years in California, North Carolina, Washington State, Kansas, Pennsylvania, Oregon, and Florida. The trials were conducted on non-crop areas including railway, roadside, bare ground, and fence rows. Efficacy of Esplanade SC Herbicide applied in tank mix with glyphosate, Milestone (containing 240 g/L aminopyralid), Milestone plus glyphosate, or Payload (containing 51.1% flumioxazin) plus glyphosate was evaluated. The herbicide treatments were applied post-emergence to weeds in 17 trials and pre-emergence to weeds in one trial. Visual weed control was evaluated on 2-3 occasions at up to 392 days after treatment.



### 5.1.1 Acceptable Efficacy Claims for Esplanade SC Herbicide as an Alone Treatment

Since (1) Esplanade SC Herbicide is agronomically similar to Indaziflam 200 SC Herbicide and (2) Indaziflam 200 SC Herbicide is registered for weed control in non-competitive environments similar to that for which Esplanade SC Herbicide is intended, efficacy claims labelled for Indaziflam 200 SC Herbicide are supported to appear on the Esplanade SC Herbicide label at the equivalent use rate of 75 g a.i./ha (Table 5.1.1.1).

**Table 5.1.1.1 Weed Claims for Esplanade SC Herbicide at the Rate of 75 g a.i./ha**

<b>Grasses</b>	<b>Broadleaf Weeds</b>
Control of barnyard grass, giant foxtail, green foxtail, Italian ryegrass, large crabgrass, wild proso millet, and yellow foxtail.	Control or suppression of annual sow-thistle, black mustard, common groundsel, field bindweed, lamb's-quarters, prickly lettuce, redroot pigweed, shepherd's-purse, spotted spurge, stork's-bill, white sweet clover, and wild mustard.

Efficacy of Esplanade SC Herbicide in tank mix with glyphosate herbicide was evaluated for additional residual weed control claims. Since it is well known that glyphosate herbicide has no soil residual activity and only controls emerged weeds, efficacy data for late flush weed control provided by Esplanade SC Herbicide in tank mix with glyphosate herbicide can be used to support residual weed control claims for Esplanade SC Herbicide alone.

Adequate information was provided to support additional efficacy claims for Esplanade SC Herbicide applied alone at the rate of 75 g a.i./ha (Table 5.1.1.2).

**Table 5.1.1.2 Additional Weed Claims for Esplanade SC Herbicide at the Rate of 75 g a.i./ha**

<b>Grasses</b>	<b>Broadleaf Weeds</b>
Control of brome grasses, wild barley, wild oats, medusa head, bluestem broomsedge, and volunteer common rye.	Control or suppression of yellow starthistle, kochia, St. John's wort, cudweed, dog fennel, smooth hawk's-beard, and morning glory.

### 5.1.2 Acceptable Efficacy Claims for Esplanade SC Herbicide Applied in Tank Mixtures

Adequate information was also provided to support efficacy claims for tank mixtures of Esplanade SC Herbicide with glyphosate, Milestone, Milestone + glyphosate, or Payload + glyphosate (Table 5.1.2.1).

**Table 5.1.2.1 Application Rates and Efficacy Claims for Esplanade SC Herbicide in Tank Mixtures with Glyphosate, Milestone, Milestone + Glyphosate, or Payload + Glyphosate**

<b>Products</b>	<b>Rates</b>	<b>Weed Claims</b>
Esplanade SC Herbicide + Roundup WeatherMax Vision Max Roundup Ultra Roundup Ultra2 Roundup Transorb HC IPCO Factor 540 R/T 540 Liquid	375 mL/ha + 1.5-8.0 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus burndown control of emerged weeds labeled for listed glyphosate formulations.
Esplanade SC Herbicide + Milestone + Glyphosate herbicides listed above	375 mL/ha + 0.25-0.5 L/ha + 1.5-8.0 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus Milestone alone plus residual control of prickly lettuce plus burndown control of emerged weeds labeled for listed glyphosate formulations.
Esplanade SC Herbicide + Payload + Glyphosate herbicides listed above	375 mL/ha + 280-420 g/ha + 1.5-8.0 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus Payload alone plus residual control of kochia, redroot pigweed, and hairy willow herb plus burndown control of emerged weeds labeled for listed glyphosate formulations.
Esplanade SC Herbicide + Milestone	375 mL/ha + 0.25-0.5 L/ha	All weeds controlled by Esplanade SC Herbicide alone plus Milestone alone plus residual control of prickly lettuce.

## 5.2 Sustainability

### 5.2.1 Survey of Alternatives

Several active ingredients that may be used alone or in various tankmix combinations are available for weed control in non-residential non-crop areas. Such products include 2,4-D, acetic acid, aminopyralid, bromacil, chlorsulfuron, clopyralid, flumioxazin, fluroxypyr, glyphosate, imazapyr, metsulfuron, picloram, triclopyr, etc. Both pre-emergence residual and post-emergence products are available.

## **5.2.2 Compatibility with Current Management Practices Including Integrated Pest Management**

Esplanade SC Herbicide provides an additional option for herbicide mode of action rotation for controlling grassy and broadleaf weeds in non-residential non-crop areas. The use of Esplanade SC Herbicide does not restrict the sequential use of other chemicals of alternate modes of action.

## **5.2.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance**

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of selecting naturally resistant biotypes. Therefore, Esplanade SC Herbicide should be used in rotation with herbicides having different modes of action.

Esplanade SC Herbicide is an alternative herbicide to those presently registered for industrial vegetation management. Herbicide-resistant populations from 15 weed species have been discovered and are variously resistant to Groups 2, 4, 5, 7, 9, and 22. When applied at the labelled use-rate, Esplanade SC Herbicide is expected to control or suppress biotypes of labelled weeds that are resistant to other groups of chemistries. Consequently, indaziflam has the potential to delay the onset of herbicide resistance and to manage certain forms of resistance once present.

The Esplanade SC Herbicide label includes the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

## **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: in other words, persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act* (Appendix I, Table 10)].

During the review of indaziflam and Esplanade SC Herbicide, the PMRA has taken into account the federal Toxic Substances Management Policy and has followed its Regulatory Directive DIR99-03. It has been determined that this product does not meet TSMP Track-1 criteria. Please refer to PRD2011-20 for information on the 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 the 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.

Mixers, loaders and applicators handling Esplanade SC Herbicide and workers entering treated areas to perform scouting activities are not expected to be exposed to levels of indaziflam that will result in an unacceptable risk when the Esplanade SC Herbicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers mixing, loading, applying Esplanade SC Herbicide and performing scouting activities.

### **7.2 Environmental Risk**

Indaziflam does not present a risk to wild mammals, birds, bees, invertebrates, freshwater or marine invertebrates and fish, or amphibians. Exposure to indaziflam can affect terrestrial and aquatic plants. To protect terrestrial and aquatic plants from spray drift, spray buffer zones of 15 metres and 1 metre are required for terrestrial and aquatic habitats<sup>6</sup>, respectively. To protect aquatic plants from the potential effects of runoff, a label statement to minimize runoff will be required, as well as hazard based label statements for toxicity to terrestrial and aquatic plants.

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<sup>6</sup> Some areas do not require buffer zones for terrestrial plants (railways, rights-of-ways, etc.).

### 7.3 Value

The value information submitted to support the registration of Esplanade SC Herbicide is adequate to describe the efficacy claims in non-residential non-crop areas such as: railroads and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, military bases, municipal and government sites. A single pre-emergent application of Esplanade SC Herbicide at 75 g a.i./ha can be expected to result in the control or suppression of barnyard grass, giant foxtail, green foxtail, Italian ryegrass, large crabgrass, wild proso millet, yellow foxtail, wild barley, wild oats, brome grasses, medusa head, bluestem broomsedge, volunteer common rye, annual sow-thistle, black mustard, common groundsel, field bindweed, lamb's-quarters, prickly lettuce, redroot pigweed, shepherd's purse, spotted spurge, stork's-bill, white sweet clover, wild mustard, yellow starthistle, kochia, St. John's wort, cudweed, dog fennel, smooth hawk's-beard, and morning glory. Information also demonstrated that Esplanade SC Herbicide may be applied in combination with glyphosate, Milestone, Milestone plus glyphosate, or Payload plus glyphosate for burndown control of emerged weeds and/or residual control of a broader weed spectrum.

Indaziflam belongs to chemistry group Group 29 (akylazines) that inhibits the synthesis of cellulose (cell wall synthesis), and represents a mode of action that is different from those of registered herbicides for use in non-residential non-crop areas and for which weed resistance has been reported (Groups 2, 4, 5, 7, 9 and 22). Indaziflam, therefore, has the potential to delay the onset of resistance of weeds to currently used herbicides of other chemistries and to manage resistance that may already be present to currently used herbicides.

### 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 and Esplanade SC Herbicide, containing the technical grade active ingredient indaziflam, to control or suppress annual grasses and broadleaf weeds in non-residential non-crop areas such as: railroad and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, military bases, and municipal and government sites.

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**

µg	micrograms
a.i.	active ingredient
ARTF	Agricultural Reentry Task Force
ATPD	area treated per day
bw	body weight
cm	centimetres
DFR	dislodgeable foliar residue
EIIS	USEPA ecological incident information system
g	gram
hr	hours
ha	hectare(s)
kg	kilogram
L	litre
mg	milligram
mL	millilitre
MOE	margin of exposure
NOAEL	no observed adverse effect level
PHED	Pesticide Handler Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
TC	transfer coefficient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency





## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Environment

##### PMRA

##### Document

Number	Reference
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1769230	2008, BCS DER for [triazine-2,4-14C] and [indane-3-13/14C]AE 1170437: Hydrolytic degradation, DACO: 8.2.3.2
1769231	2008, [Triazine-2,4-14C] and [indane-3-13C/14C]AE 1170437: Phototransformation on soil, DACO: 8.2.3.3.1
1769232	2008, BCS DER for [triazine-2,4-14C] and [indane-3-13C/14C]AE 1170437: Phototransformation on soil, DACO: 8.2.3.3.1
1769233	2007, [Indane-3-13C/14C] AE 1170437 and [triazine-2,4-14C] AE 1170437: Phototransformation in water, DACO: 8.2.3.3.2
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1769237	2008, [Triazine-2,4-14C]AE 1956114 (diaminotriazine): Aerobic soil metabolism in three EU soils, DACO: 8.2.3.4.2
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1769242	2008, BCS DER for [triazine-2,4-14C]AE 1170437: Aerobic soil metabolism in two US soils, DACO: 8.2.3.4.2
1769243	2008, BCS DER for [triazine-2,4-14C]AE 1170437: Aerobic soil metabolism in four EU soils, DACO: 8.2.3.4.2
1769244	2008, BCS DER for [indane-3-13/14C] AE 1170437: Aerobic soil metabolism in four EU soils, DACO: 8.2.3.4.2
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- 1769248 2008, BCS DER for [triazine-2,4-14C] and [indane-3-13C/14C]AE 1170437: Anaerobic soil metabolism, DACO: 8.2.3.4.4
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- 1769259 2008, BCS DER for [triazine-2,4-14C] AE 1170437: Adsorption/desorption on five soils, DACO: 8.2.4.2
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## 2.0 Value

### PMRA

#### Document

Number	Reference
2201728	2012, Esplanade SC Herbicide a pre-emergence residual herbicide for control of annual broadleaf and grass weeds on railroad beds, roadsides and industrial sites DACO 10.