Product Review of Esplanade 200 SC Herbicide
For Addition to the Sensitive Area Materials List in Massachusetts

Product Information: Esplanade 200 SC, (EPA Reg. No. 432-1516)

The Herbicide Review Process for Sensitive Areas[1] provides procedures and criteria for review of new herbicide products for use within sensitive areas of Rights-of-Way (ROW). These review procedures and criteria address both the herbicide active ingredients as well as the "inert" or "other" ingredients, more specifically the surfactants.

Esplanade 200 SC Herbicide is a suspension concentrate containing the active ingredient indaziflam at a concentration of 19.05% by weight (Bayer Environmental Science).[2] The label and SDS document do not specify the nature of the other ingredients.

The product is labeled for use as a pre-emergent herbicide for control of annual grasses and broadleaf weeds in non-residential non-crop areas, railroad and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, municipal, and government sites, and for the release or restoration of desirable vegetation in parks and open space, wildlife management areas, recreational areas, fire rehabilitation areas, prairies and fire breaks.

The active ingredient indaziflam was reviewed for addition to the Sensitive Area Materials List. The review document (MDAR/MassDEP, 2022)[3] summarizes information on the human, mammalian and ecological toxicity of indaziflam as well as its environmental fate and toxicity.

In order to evaluate the relative toxicities of the active ingredient Indaziflam and the Esplanade 200 SC product, available mammalian and ecological toxicity information for both the active ingredient and formulated product were identified and compared.

The US EPA only requires applicants to submit acute, not chronic, toxicity information for a formulated product undergoing registration. This is because once a formulated product enters the environment, the individual compounds in the formulation will likely not remain together for a long (i.e., chronic) period of time due to their individual physical and chemical characteristics that will influence each compound's fate and transport within the environment. If toxicity data for a product having a similar formulation to the formulated product being registered is available, the US EPA will allow use of that information to fulfill this requirement.

Mammalian Toxicity

A summary of toxicological studies for the product formulation Indaziflam SC 200, a formulation

[1] MDAR website: http://www.mass.gov/eea/agencies/agr/pesticides/rights-of-way-vegetation-management.html
[2] Esplanade Herbicide Labels and SDS: https://www.environmentalscience.bayer.us/labels-and-sds
[3] MDAR/MassDEP, 2022. Review of Indaziflam for Application to Sensitive Areas of Rights-of-Way. Access at: https://www.mass.gov/service-details/rights-of-way-sensitive-area-materials-list

identical to Esplanade 200 SC, reports an oral LD_{50} value for female rats of >2,000 mg/kg bw.[4] US EPA also assessed the potential mammalian toxicity of formulated product based on acute toxicity studies in rats for four formulated products (US EPA, 2010). These data are listed in Table 2 and are compared to the data for the active ingredient (indaziflam technical grade) and Indaziflam SC 200. Two products were formulated with multiple active ingredients. A study with a formulated liquid product containing 2,4-D dimethylamine salt, dicamba (potassium salt), and mecoprop-P (potassium salt), in addition to indaziflam, derived an oral LD_{50} value for female rats of >2,000 mg/kg bw. A study with a granular formulation containing dicamba acid and penoxsulam, in addition to indaziflam, derived an oral LD_{50} value for female rats of >2,000 mg/kg bw. A third formulated product study with a water-soluble package formulation derived an oral LD_{50} value for female rats of >2,000 mg/kg bw. Studies with the technical grade indaziflam derived a 14-day oral LD_{50} value of > 2,000 mg a.i./kg bw.

US EPA concluded that the data on all the formulated products indicate that indaziflam mixed with other active ingredients is not more toxic than indaziflam alone based on the acute oral toxicity to the rat.

Table 2. Mammalian toxicity data (rat; 14-d LD_{50} (mg/kg bw)) for Indaziflam Technical, and several product formulations (US EPA, 2010 and Bayer, 2020)

	Product/Formulation				
Indaziflam Technical	Indaziflam SC 200[1]	Lawn 3FL Herbicide Concentrate (liquid)[2]	Lawn 3FL Herbicide Granule [3]	20 WSP [4]	2% MUP [5]
>2000	>2000	>2000	>2000	>2000	>2000

[1] The registrant indicated that this product formulation is identical to Esplanade 200 SC. Toxicity data is from Bayer, 2020.

[2]Product containing, indaziflam, 2,4-D dimethylamine salt, dicamba (potassium salt), and mecoprop-P (potassium salt)

[3] Product containing indaziflam, dicamba acid and penoxsulam

[4] Water-soluble-packages formulation

[5] Intended for manufacturers' use only for the purpose of manufacturing end-use herbicide products

Ecological Toxicity

Ecotoxicity data for the formulated product were also identified and evaluated. Toxicity data for the formulated product were compared with the data for the active ingredient to evaluate if product-specific characteristics significantly alter the toxicity of the active ingredient to ecological receptors. The toxicological characteristics of a mixture of compounds may differ from those of its constituent compounds due to possible interactive effects.

[4] Bayer, 2020. Summary of the toxicological studies for Indaziflam SC 200. Courtesy of Bayer.

Ecotoxicity study data for two formulated products were available in the ecological risk assessment document from US EPA (2010).[5] These data are listed in Table 1 and are compared to the data for the active ingredient (indaziflam technical grade). Such a comparison allows for an assessment of the effect of formulation mixtures on toxicity.

The toxicity data for the formulated product presented in Table 1 for a number of ecological receptors are in the same range as the toxicity values for the technical grade product, suggesting that the toxicity to these organisms of the formulated product is similar to the toxicity of the formulated product.

Table 1. Ecotoxicity data for Indaziflam Technical, and product formulations 500 SC and 200 SC

Species/Toxicity	Product (% indaziflam)		
	Indaziflam Technical (94.5%)	500 SC (45.08%)[1]	200 SC (19.2%)[1,2]
Bluegill Sunfish ($96\text{-h } LC_{50}$) (mg a.i./L)	0.32	0.372	
Water Flea (EC_{50}, 48-h) (mg a.i./L)	>9.88	>38	37.5
Green Algae ($96\text{-h } EC_{50}$) (mg a.i./L)	0.074	0.051	0.053
Duck weed ($7\text{-d } EC_{50}$) (mg a.i./L)	0.000067	0.000061	
Earthworm ($14\text{-d } LC_{50}$) (mg a.i./kg dry soil)	>1000	>1000	

[1] Toxicity endpoints for the product formulations is expressed in mg active ingredient (a.i.)/L.

[2] 200 SC is a formulation with the same active ingredient concentration than the Esplanade 200 SC Herbicide product.

Since the active ingredient by itself is of similar toxicity to fish and invertebrates as the formulated products, the results of the exposure assessment conducted for the active ingredient should apply to the formulated product. Exposure information for the active ingredient (see MDAR (2020) reference in active ingredient review[6]) shows estimated peak concentrations of indaziflam ranging from 0.00047 to 0.00619 mg a.i./L in surface water.

[5] US EPA, 2010. Environmental Fate and Ecological Risk Assessment for the Registration of Indaziflam. US EPA, Office of Pesticide Programs, Environmental Fate and Effects Division. Accessed at: www.regulations.gov, docket ID: EPA-HQ-OPP-2009-0636

[6] MDAR/MassDEP, 2022. Review of Indaziflam for Application to Sensitive Areas of Rights-of-Way. Access at: https://www.mass.gov/service-details/rights-of-way-sensitive-area-materials-list

MDAR calculated the soil exposure by assuming a scenario where the applied product was mixed in a top soil layer with thickness of 1 inch. The calculated concentration of the active ingredient was 2.68 mg/kg soil.

Based on the comparison of ecotoxicity data presented in Table 1 with the estimated peak environmental concentrations, it can be concluded that adverse acute effects to fish and aquatic invertebrates are not expected. For aquatic plants, the peak concentrations exceed the toxicity values for duckweed. As stated in the active ingredient review, there is potential for adverse effects to aquatic and terrestrial plant species. Adverse effects to earthworms are not expected.

Furthermore, the modeled peak environmental concentrations are conservative estimates as under actual, more realistic circumstances, exposure levels in water bodies are minimized by drift reduction measures and regulatory setbacks from such areas.

Surfactants in Esplanade 200 SC

The general policy for surfactant review is that compounds will be designated for additional review when available information indicates a potential for increased risk to non-target species. Information on the other formulation ingredients in the Esplanade 200 SC herbicide formulation was provided by the registrant, but cannot be disclosed here for proprietary reasons. The information for the surfactants is summarized in a separate document.[7]

Conclusions

The evaluation of the formulated product described above indicates that the product formulation does not substantially increase ecological toxicity and risks to non-target organisms. This is consistent with the review of the information on surfactants. The formulated product, when used as directed on the product label, would not be expected to result in exposure levels that would produce adverse effects in non-target organisms, except sensitive plant species.

Recommendation

The product is recommended, with restrictions, for pre-emergence use to manage vegetation in ROW areas. Within ROW areas, pre-emergent use of this product would be for use in railroad and roadside applications.

Restrictions

<u>Measures to minimize drift and runoff</u>:

1. Indaziflam is toxic to aquatic organisms and potential impacts to amphibian and reptilian species are uncertain. Rights-of-Way Vegetation managers and herbicide applicators must ensure that the various precautions and risk mitigation measures required by the product label and

[7] Evaluation of Surfactants in Formulation of Esplanade 200SC Herbicide, May 2020

regulations are implemented to protect aquatic biota. Product label mitigation measures include spray drift management that consider sensitive areas, wind, temperature inversion, control of droplet size and spray shields. The label states: "Applicators must take all precautions necessary to keep spray drift from reaching sensitive areas. Only apply this product when the potential for drift to adjacent sensitive areas is minimal (e.g., when wind is blowing away from the sensitive areas)."

In addition, applications must be done in adherence to the regulatory requirements specified in Rights-of-Way Vegetation Management regulations (333 CMR 11.00). Yearly Operational Plans (YOPs) for rights-of-way vegetation management require identification of sensitive areas, including wetlands, waters over wetlands, riverfront areas, and certified vernal pools, and specifications for application setbacks from water and application in such a manner that does not result in drift to any area within ten feet of standing or flowing water in a wetland. For the use of Esplanade 200SC herbicide, the requirements for certified vernal pools should be extended to areas identified as potential vernal pools. Both certified and potential vernal pools are considered areas containing potentially significant amphibian and/or reptilian habitat. Locations of certified and potential vernal pools as identified by Natural Heritage and Endangered Species Program of the MA Division of Fisheries and Wildlife are available at MassGIS:

- Certified vernal pools: https://www.mass.gov/info-details/massgis-data-nhesp-certified-vernal-pools; and
- Potential vernal pools: https://www.mass.gov/info-details/massgis-data-nhesp-potential-vernal-pools.

2. No applications to hardscape areas (e.g., paved areas along roadside, walkways) shall be made, except when applying to railroads. The application to hardscape areas within a railroad (e.g., railroad crossing areas) may be made to the area between the railroad tracks.