

## Evaluation Report for Category B, Subcategory B.2.1, 2.3, 2.4, 2.6, 3.1, 3.12 Application

**Application Number:** 2014-0145  
**Application:** New Product Chemistry - Guarantee, identity and proportion of formulants, new combination of TGAIs  
New Product Labels - Application rate increase or decrease and new site or host  
**Product:** Laudis Herbicide  
**Registration Number:** 31721  
**Active ingredients (a.i.):** Tembotrione  
**PMRA Document Number :** 2410272

### Purpose of Application

The purpose of this application was to register a new end-use product, Laudis Herbicide (guarantee 420 g/L tembotrione), for post-emergent control of grasses and broadleaf weeds in field and sweet corn in Eastern Canada and Manitoba.

### Chemistry Assessment

Laudis Herbicide is formulated as a suspension containing tembotrione at a nominal concentration of 420 g/L. This end-use product has a density of 1.22 g/mL and pH of 3.0 (10% dilution). The chemistry requirements for Laudis Herbicide have been fulfilled.

### Health Assessments

The end-use product, Laudis Herbicide, was slightly acutely toxic via the oral route to rats, of low toxicity via the dermal and inhalation routes to rats, slightly irritating to the skin of rabbits and mildly irritating to the eyes of rabbits. It was not a dermal sensitizer. Consequently, the statements “Caution – Poison” and “Eye Irritant” were required on the label.

An updated health risk assessment was conducted for chemical handlers, re-entry workers and bystanders. With revised precautions, no risks of concern were identified for the use of tembotrione on field and sweet corn. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in representative NAFTA (North American Free Trade Agreement) growing regions with tembotrione on sweet corn were submitted to support registration of the new end-use product, Laudis Herbicide. During these sweet corn trials, tembotrione was applied at the label rate, and forage, K + CWHR (kernels plus cob with husks

removed) and stover were harvested according to label directions. Previously reviewed residue data from field trials conducted with tembotrione in/on field corn were reassessed in the framework of this application. In addition, a processing study with tembotrione in treated field corn was reassessed to determine the potential for concentration of residues into processed commodities.

The formulation of Laudis Herbicide contains the safener isoxadifen-ethyl. No new dietary residue data were submitted for isoxadifen-ethyl. Previously reviewed residue data from field trials conducted with isoxadifen-ethyl in/on field and sweet corn were reassessed in the framework of this application. In addition, a processing study with isoxadifen-ethyl in treated field corn was reassessed to determine the potential for concentration of residues into processed commodities.

### Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for tembotrione was based upon the submitted sweet corn field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of tembotrione in/on sweet corn are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs). The currently established MRL of 0.02 ppm in/on field corn for tembotrione is sufficient to cover residues (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>).

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Tembotrione Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
Sweet corn kernels plus cob with husks removed	Single Foliar broadcast application/ 89-96	36-70	<0.01	<0.01	Not applicable	0.04 <sup>1</sup>	0.01 <sup>2</sup>

<sup>1</sup>For the combined residues of tembotrione and the metabolite 2-[2-chloro-4-(methylsulfonyl)-3-[2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexane-1,3-dione. The MRL of 0.04 ppm on imported sweet corn was based on residue data from sweet corn field trials conducted at a total exaggerated rate of 182-190 g a.i./ha.

<sup>2</sup>The MRL of 0.01 ppm for residues of tembotrione only is proposed to replace the established MRL of 0.04 pm for the combined residues of tembotrione and the metabolite 2-[2-chloro-4-(methylsulfonyl)-3-[2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexane-1,3-dione for sweet corn kernels plus cob with husks removed.

No increase to the dietary burden of livestock is expected for either tembotrione or the safener isoxadifen-ethyl when field and sweet corn are treated according to the approved label of Laudis Herbicide.

Following the review of all available data, the MRL for sweet corn as proposed in Table 1 is recommended to cover residues of tembotrione. The currently established MRL of 0.02 ppm in/on field corn is sufficient to cover residues of tembotrione. Tembotrione residues in field and sweet corn at the listed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors. No revisions are needed to the MRLs established for isoxadifen-ethyl in/on corn (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>). Isoxadifen-ethyl residues in sweet corn at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

Tembotrione enters the environment when used as a weed control product in field and sweet corn in Eastern Canada and Manitoba. Tembotrione exhibits variable persistence in both soil and water. It does not break down by reacting with light or water, but in the presence of microorganisms it can break down in both aquatic and terrestrial environments. Tembotrione dissolves readily in water and has the potential to move through soil and enter groundwater. Thus, a leaching statement is still required on end-use product labels that contain tembotrione. Tembotrione is unlikely to enter the atmosphere and be transported to areas far removed from where it was applied. There is limited potential for tembotrione to bioaccumulate in organisms.

Tembotrione is toxic to small mammals, terrestrial plants, freshwater vascular plants, and estuarine/marine invertebrates. Tembotrione poses a negligible risk to earthworms, honey bees, birds, freshwater invertebrates, freshwater and marine fish, and freshwater and marine algae.

Tembotrione has six transformation products relevant to the environment. They are labeled M1 through M4, and M6 and M7. Though they show moderate to very high mobility in soil, they are not persistent. None of the transformation products were shown to be of ecotoxicological concern.

Non-target organisms that may be vulnerable to adverse effects resulting from potential tembotrione exposure include terrestrial plants, freshwater aquatic plants, estuarine/marine invertebrates, and small mammals.

Due to the risks identified for tembotrione, specific mitigation measures are necessary to protect the environment. In order to protect terrestrial and nearby freshwater and estuarine/marine habitats, both aquatic spray buffer zones (1 m) and terrestrial spray buffer zones (10 m) have been determined to be necessary for tembotrione-containing end-use products. If tembotrione is applied in combination with other active ingredients, the most restrictive spray buffer zones must be observed. Toxicity label statements are required for sensitive organisms including non-target plants, aquatic invertebrates, and small mammals.

### **Value Assessment**

Value information submitted included efficacy data from 134 trials conducted in Canada and the US between 2002 and 2006. Efficacy of herbicide treatments, a single application of Laudis Herbicide alone or in a tank mixture with atrazine and two applications of Laudis Herbicide

applied in sequence with the second application made at least 10 days after the first, was visually assessed for control of velvetleaf, redroot pigweed, common lamb's-quarters, common ragweed, wild buckwheat, barnyard grass, giant foxtail, green foxtail, proso millet, and old witchgrass.

Efficacy claims supported for Laudis Herbicide alone are summarized in Table 1.

Table 1. Efficacy claims for Laudis Herbicide

Application	Rate	Supported weed claims
Single application	145 mL/ha	Control of velvetleaf, redroot pigweed, lamb's-quarters, and common ragweed and suppression of giant foxtail
	220 mL/ha	Above weed claims plus suppression of green foxtail and wild buckwheat
Sequential applications	145 mL/ha	Late emerged weeds controlled and suppressed at the rate of 145 mL/ha.
	220 mL/ha	Above weed claims plus control of green foxtail and wild buckwheat

Efficacy claims supported for the tank mixture of Laudis Herbicide plus Aatrex Liquid 480 are summarized in Table 2.

Table 2. Efficacy claims for Laudis Herbicide plus Aatrex Liquid 480

Products	Rate	Supported weed claims
Laudis + Aatrex Liquid 480	220 mL/ha + 1.2 L/ha	Control of velvetleaf, redroot pigweed, lamb's-quarters, common ragweed, and wild buckwheat and suppression of green foxtail.

Value information submitted also included crop tolerance data from 128 trials conducted in Canada and the US between 2002 and 2005. Crop tolerance to a single application of Laudis Herbicide at the 1 x, 2 x, and 3 x maximum rates or at the 1 x maximum rate in a tank mixture with atrazine was assessed on 60 field corn hybrids in 111 trials. Crop tolerance to sequential applications of Laudis Herbicide at 1 x and 2 x maximum rates was directly compared to the single application of Laudis Herbicide at the same rates in nine of the trials.

Data from these field trials demonstrated that field corn exhibited an adequate margin of crop safety to a single application of 220 mL/ha Laudis Herbicide alone or in a tank mixture with 560 g a.i./ha atrazine, and two applications of 220 mL/ha Laudis Herbicide applied in sequence with the second application made at least 10 days after the first.

Crop tolerance to a single application of Laudis Herbicide at 1 x, 2 x, and 3 x maximum rates was assessed on 41 sweet corn hybrids in 17 trials. Crop safety information demonstrated that sweet corn exhibited an adequate margin of crop safety to a single application of 220 mL/ha Laudis Herbicide.

Data from 16 field trials conducted in Canada and the US between 2002 and 2006 were

submitted to support rotational crop options. Rotational crop safety information supported field and sweet corn as immediate plant back crops; sweet corn, field corn, and potatoes as rotational crops with a ten month re-cropping interval; soybeans with an 11 month re-cropping interval; and, dry bean with a 22 month re-cropping interval.

In considering field data submitted and as well the reviews on the soil dissipation characteristics of tembotrione conducted by the Environmental Assessment Directorate, the inclusion of winter wheat as a rotational crop with a four month re-cropping interval, spring wheat with a ten month re-cropping interval, and the revision of the soybean re-cropping interval to 10 months from 11 months, were supported.

Data from one field study conducted in Germany in 2005 was submitted to support a one hour rainfastness claim. Data supported a two hour rainfastness claim for Laudis Herbicide applied alone.

Although several herbicides for post-emergence control of grasses in field corn are available, they are limited to Herbicide Groups 2 and 15. Group 2 resistant green foxtail has been identified in Canada and is a concern to farmers. It has also been well documented that corn hybrids have differential sensitivity to rimsulfuron and nicosulfuron. Recently, a few Group 27 herbicides have been registered in Canada for use in corn. However, the registered Group 27 herbicides do not provide post-emergence control of grasses and cannot be applied to sweet corn as a post-emergence treatment. The availability of Laudis Herbicide provides an HPPD inhibitor herbicide (Group 27) for post-emergence grass and broadleaf weed control.

## Conclusion

The PMRA has completed a review of available information and has determined that it is sufficient to support the registration of Laudis Herbicide for post-emergent control of grasses and broadleaf weeds in field and sweet corn in Eastern Canada and Manitoba.

An MRL in/on sweet corn of 0.01 ppm is recommended to cover residues of tembotrione. The currently established MRL of 0.02 ppm in/on field corn for tembotrione is sufficient to cover residues. Tembotrione residues in field and sweet corn at the listed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
1274616	2006, AE 0172747 02 SC 52 Herbicide - Data to support the registration in field and sweet corn for control of annual grass and broadleaf weeds, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(B), 10.3, 10.3.1, 10.3.2, 10.3.2(A), 10.3.3, 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4
1443022	2006, AE 0172747 02 SC 52 Herbicide - Part 10 – Addendum 01, DACO: 10.2, 10.2.3, 10.2.3.3, 10.2.3.3(B), 10.3, 10.3.2, 10.3.2(A)

1443024	2006, AE 0172747 02 SC 52 Herbicide - Part 10 – Addendum 02, DACO: 10.2, 10.2.3, 10.2.3.3, 10.2.3.3(B), 10.3, 10.3.2, 10.3.2(A)
1443026	2006, AE 0172747 02 SC 52 Herbicide - Part 10 – Addendum 03, DACO: 10.2, 10.2.3, 10.2.3.3, 10.2.3.3(B), 10.3, 10.3.2, 10.3.2(A)
1443028	2007, AE 0172747 02 SC 52 Herbicide - Part 10 – Addendum 04, DACO: 10.3, 10.3.3
1443031	2007, AE 0172747 02 SC 52 Herbicide - Part 10 – Addendum 05, DACO: 10.2, 10.2.3, 10.2.3.3, 10.2.3.3(B), 10.3, 10.3.2, 10.3.2(A)
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1274629	2005, Product Chemistry of AE 0172747 02 SC 52 A1, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.6 CBI
1274630	2006, BCS-DER-Part 3-Product Chemistry of AE 0172747 02 SC 52 A1, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.6 CBI
1274631	2006, BCS-DER-Part 3-Product Chemistry of AE 0172747 02 SC 52 A1, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4, 3.4.1, 3.4.2, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.6 CBI
1335753	2006, Supplemental Product Chemistry of AE 0172747 02 SC 52, DACO: 3.2.2 CBI
1443035	2006, AE 0172747 02 SC 52 Herbicide – Recipes for 747 Formulations in Part 10, DACO: 3.2.1, 3.3.2 CBI
2381203	2008, Laudis 52 SC - Magnitude of the residue in/on sweet corn, DACO: 7.4.1, 7.4.2

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