

Evaluation Report for Category B, Subcategory 2.1, 2.6, 3.1, 3.13 Application

Application Number: 2008-0813
Application: 2.1 – New Guarantee
2.6 – New Combination of TGAIs
3.1 – New Application Rate Increase
3.13 – New Precautions
Product: Halex GT Herbicide
Registration Number: 29341
Active ingredients (a.i.): s-metolachlor, glyphosate, mesotrione
PMRA Document Number: 1757272

Purpose of Application

The purpose of this application is to register the end use product Halex GT Herbicide, containing 250 g /L glyphosate present as potassium salt, 250 g/L s-metolachlor, and 25 g/L mesotrione, for post-emergent control of annual and perennial grassy and broadleaf weeds in glyphosate tolerant field corn.

Chemistry Assessment

Halex GT Herbicide is a liquid containing the active ingredients glyphosate, S-metolachlor, and mesotrione at nominal concentrations of 250 g/L, 250 g/L, and 25 g/L, respectively. This product has a density of 1.23 g/mL and pH of 3 – 5 for a 1 % solution in water. The chemistry requirements for Halex GT Herbicide have been completed.

Health Assessments

Acute toxicity is low via the oral ($LD_{50} > 5000$ mg/kg bw), dermal ($LD_{50} > 6147$ mg/kg bw), and inhalation ($LC_{50} > 1.20$ mg/L) routes in rats. In rabbits, irritation to the eye was minimal and irritation to the skin was non-existent to minimal. It is considered a potential skin sensitizer in guinea pigs.

Halex GT Herbicide is a solution formulation containing three active ingredients, S-metolachlor, glyphosate and mesotrione, to be applied by ground equipment on glyphosate tolerant field corn. The use pattern fits within the existing use pattern for the three actives. No increase in occupational exposure is expected and no changes to the personal protective equipment or directions for use are needed.

A field trial study conducted with Halex GT Herbicide on glyphosate tolerant field corn was submitted as bridging data to confirm the level of residues of each of the three active ingredients. The field trial data show the use of Halex GT Herbicide on glyphosate tolerant field corn will not result in any quantifiable residues in/on treated corn.

MRLs in corn have been established at 3 ppm for glyphosate, at 0.1 ppm for s-metolachlor and at 0.01 ppm for mesotrione. No increase in dietary exposure of s-metolachlor, glyphosate or mesotrione is anticipated for any population subgroup as a result of this use.

Environmental Assessment

Halex GT Herbicide is a product consisting of three currently registered active ingredients, S-metolachlor, glyphosate and mesotrione. All three active ingredients are currently registered for the same use pattern in Canada, and all rates are within the range of currently registered products. The physical form of glyphosate and mesotrione (emulsified solution) remains the same as in currently registered products. However, S-metolachlor is micro-encapsulated in order to prevent rapid degradation during storage. A bridging study found that the microencapsulated formulation of S-metolachlor is expected to behave similarly to the currently registered emulsifiable concentrate in three types of soil.

The levels of exposure and toxicity of each active ingredient in Halex GT Herbicide to non-target organisms are expected to be similar to those of currently registered products containing these active ingredients. No additional ecotoxicity studies are required. A buffer zone was calculated for Halex GT Herbicide using the most restrictive value calculated for each of the three active ingredients. A buffer zone of 25 m is required to protect aquatic habitats, and 15 m is required to protect the terrestrial habitats when Halex GT Herbicide is applied at the maximum rate of 4.2 l/ha on glyphosate tolerant field corn.

Value Assessment

All weeds listed on Halex GT Herbicide label are presently claimed on at least one end use product containing glyphosate, s-metolachlor, or mesotrione. Confirmatory efficacy data from a total of 14 field trials conducted in Ontario and Quebec in 2007 were submitted for review. Weed control was visually assessed on 1 to 3 occasions through the growing season following an application of Halex GT Herbicide alone or in a tank mix with Aatrex Liquid 480 Herbicide for 20 weed species. It was concluded from these field trials that treatments of Halex GT Herbicide alone or in a tank mix with Aatrex Liquid 480 Herbicide provided acceptable control of the specific weeds. In addition, the combinations of each of the active ingredients of Halex GT Herbicide (i.e., glyphosate, s-metolachlor, and mesotrione) are presently registered as tankmix treatments for control and residual control of grassy and broadleaf weeds in field corn. Therefore, a reduction in weed control is not anticipated when pre-formulating these 3 active ingredients in one end use product.

Crop safety data from 9 dedicated crop tolerance trials and 14 combined efficacy and crop tolerance trials were submitted. The trials were conducted in Ontario (13 locations) and Quebec (1 location) in 2007. A total of 12 corn hybrids were assessed for their tolerance to Halex GT Herbicide alone or in a tank mix with Aatrex Liquid 480 Herbicide. Crop tolerance, expressed as

% crop injury, and final yield, expressed as % of a weed-free check or an untreated weedy check, were reported in these trials. It was demonstrated from these trials that tolerance of glyphosate tolerant field corn to the application of Halex GT Herbicide alone or in a tank mix with Aatrex Liquid 480 Herbicide was acceptable.

A rationale in lieu of data was submitted to support rotational crop options on the Halex GT Herbicide label. Based on the registration of rotational crops on the currently registered end use products of mesotrione and s-metolachlor, rotational crop restrictions on the Halex GT Herbicide label can be supported.

Overall, the registration of Halex GT Herbicide can be supported from a value standpoint.

Conclusion

Halex GT Herbicide is acceptable for full registration.

References

- 155840 2008, HALEX GT - Efficacy Trials, DACO: 10.2.3.3(B)
4
- 155840 2008, HALEX GT - Crop Tolerance Trials, DACO: 10.3.2(A)
8
- 155839 2007, S-Metolachlor/Glyphosate K/Mesotrione SE (A15189G) Residue
5 Levels on Glyphosate Tolerant Field Corn (Forage, Grain and Fodder) from
Trials Conducted in Canada in 2007, CER 0915/07, DACO: 7.4.1
- 155837 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189A) -
9 Acute Oral Toxicity Study in Rats, 10450-06, DACO: 4.6.1
- 155838 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189A) -
0 Acute Dermal Irritation Toxicity Study in Rabbits, 10454-06, DACO: 4.6.2
- 155838 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189G)
1 - Acute Dermal Irritation Toxicity Study in Rabbits, 10651-07, DACO: 4.6.2
- 155838 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189A) -
2 Acute Inhalation Study in Rats, 10452-06, DACO: 4.6.3
- 155838 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189A) -
4 Acute Eye Irritation Study in Rabbits, 10453-06, DACO: 4.6.4
- 155838 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189G)
5 - Acute Eye Irritation Study in Rabbits, 10650-07, DACO: 4.6.4
- 155838 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189A) -
7 Acute Dermal Toxicity Study in Rats, 10451-06, DACO: 4.6.5
- 155838 2007, Mesotrione/S-Metolachlor/Glyphosate CS (025/250/250) (A15189A) -
8 Skin Sensitization Study in Guinea Pigs, 10455-06, DACO: 4.6.6
- 155836 2008, HALEX GT - HERBICIDE IDENTIFICATION, DACO: 3.1,3.1.3 CBI
8

- 155836 2008, HALEX GT - FORMULATING PLANT, DACO: 3.1.2,3.1.4 CBI
9
- 155837 2008, HALEX GT - STARTING MATERIALS, DACO: 3.2.1 CBI
0
- 155837 2008, HALEX GT - MANUFACTURING PROCESS, DACO: 3.2.2 CBI
2
- 155837 2008, HALEX GT - DISCUSSION OF FORMATION OF IMPURITIES,
3 DACO: 3.2.3 CBI
- 155837 2008, HALEX GT - CERTIFICATION OF LIMITS, DACO: 3.3.1 CBI
4
- 155837 2007, MESOTRIONE/ S-METOLACHLOR/GLYPHOSATE IN A15189A
5 FORMULATION BY HPLC, SF-209/1, DACO: 3.4.1 CBI
- 155837 2008, HALEX GT - PHYSICAL AND CHEMICAL PROPERTIES, DACO:
6 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 CBI
- 157525 2008, 3.2.1- Confidential Statement of Ingredients- Note to Reviewer,
0 DACO: 3.2.1 CBI
- 173486 2008, One Year Storage Stability at Ambient Temperature and Corrosion
5 Characteristics of Halex GT (115189A), PC-08-067, DACO:
3.5,3.5.10,3.5.14 CBI
- 155839 2006, Comparison of S-Metolachlor Degradation Rates and Desorption
9 Coefficients Using Two Different Formulations on Three Different Soils,
DACO: 8.2.3.4.2

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