Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6 Application

Application Number: 2013-5758
Application: New End-use Product Chemistry - Guarantee, Identity and Proportion of Formulants, New combination of TGIAs
Product: Callisto GT Herbicide
Registration Number: 31711
Active ingredients (a.i.): Glyphosate (present as potassium salt), Mesotrione
PMRA Document Number : 2420526

Purpose of Application

The purpose of this application was to register a new end use product, Callisto GT Herbicide, for post-emergent broadleaf weed control in glyphosate tolerant corn. Callisto GT Herbicide is a new combination of two active ingredients, 45.5 g/L mesotrione and 455 g/L glyphosate (present as potassium salt).

Chemistry Assessment

Callisto GT Herbicide is a liquid containing mesotrione and glyphosate (present as potassium salt) at 45.5 g/L and 455 g/L respectively. This end-use product has a density of 1.32 g/cm^3 and a pH of 4.8 (1% in pure water at 25ºC). The chemistry requirements for Callisto GT Herbicide have been fulfilled.

Health Assessments

Callisto GT Herbicide is of low acute oral, dermal and inhalation toxicity. It is minimally irritating to the eyes and non-irritating to the skin of the rabbit. The product is not a potential dermal sensitizer in the guinea pig.

The combination of mesotrione and glyphosate (present as potassium salt) in Callisto GT Herbicide fits within the registered use patterns of these active ingredients. Mixer/loader, applicator, and post-application risks to glyphosate and mesotrione are not considered to be of concern when label precautions, including wearing the required personal protective equipment, and restrictions are followed.

Environmental Assessment

No environmental concerns were identified as the proposed application of Callisto GT Herbicide for the control of labelled weeds on glyphosate tolerant corn falls within the existing registered use pattern.

Value Assessment

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The following value information was gathered to support the registration of Callisto GT Herbicide.

- Halex GT Herbicide (Registration Number 29341), consisting of mesotrione, s-metolachlor, and glyphosate (present as potassium salt), has been registered for post-emergent weed control in glyphosate tolerant corn since 2009. Compatibility of these active ingredients in one product was assessed and concluded to be acceptable in terms of product efficacy and crop safety when Halex GT Herbicide was initially registered. Efficacy claims labelled for mesotrione (Callisto 480SC Herbicide; Registration Number 27833), s-metolachlor (Dual II Magnum Herbicide; Registration Number 25729), and glyphosate (Touchdown iQ Liquid Herbicide; Registration Number 27192) were accepted for inclusion on the Halex GT Herbicide label.

- Major formulation components of Callisto GT Herbicide and Halex GT Herbicide are similar and any differences in the formulations would not negatively affect the product efficacy and crop safety of Callisto GT Herbicide as compared to Halex GT Herbicide. The rates of mesotrione and glyphosate that would be applied with Halex GT Herbicide are similar to those which would be applied with Callisto GT Herbicide.

- Confirmatory crop safety data were submitted from five trials conducted in Ontario at four locations in 2012. They confirmed that the tolerance of glyphosate tolerant corn to Callisto GT Herbicide was comparable to the registered tank mixture of Callisto 480SC Herbicide + Touchdown Total Herbicide (Registration Number 28072) applied at their respective labelled 1 x and 2 x rates.

Rotational crop tolerance claims for Callisto 480SC Herbicide can be extrapolated to Callisto GT Herbicide since the maximum mesotrione rate applied with Callisto 480SC Herbicide (i.e., 144 g a.i/ha) is significantly higher than that which would be applied with Callisto GT Herbicide (i.e., 102 g a.i./ha). Glyphosate does not have residual soil activity.

Registration of two active ingredients in a single formulation will be easy to handle and apply by farmers.

Based on the weight of evidence, the registration of Callisto GT Herbicide for control of weeds listed on the labels for Callisto 480SC Herbicide and Touchdown Total Herbicide on glyphosate tolerant corn is acceptable from a value standpoint.

Conclusion

The PMRA has completed a review of available information and has determined that it is sufficient to support the registration of Callisto GT Herbicide for post-emergent broadleaf weed control in glyphosate tolerant corn.

References

PMRA Document Number	Reference
2355344	Evaluate A19573B 495SC (mesotrione/glyphosate pre-mix) applied late post (7-8 leaf) for true corn crop tolerance, DACO: 10.3.2.
2355348	Evaluate A19573B 495SC (mesotrione/glyphosate pre-mix) applied late post (7-8 leaf) for true corn crop tolerance, DACO: 10.3.2.
2355349	Evaluate A19573B 495SC (mesotrione/glyphosate pre-mix) applied late post (7-8 leaf) for true corn crop tolerance, DACO: 10.3.2.
2355350	Evaluate A19573B 495SC (mesotrione/glyphosate pre-mix) applied late post (7-8 leaf) for true corn crop tolerance, DACO: 10.3.2.
2355351	Evaluate A19573B 495SC (mesotrione/glyphosate pre-mix) applied late post (7-8 leaf) for true corn crop tolerance, DACO: 10.3.2
2355340	2013, Callisto GT - Use Description/Scenario, DACO : 5.2
2355333	2012, Mesotrione/Glyphosate SC (A19573B) - Acute Oral Toxicity Up-and-Down Procedure in Rats, DACO: 4.6.1
2355334	2012, Mesotrione/Glyphosate SC (A19573B) - Acute Dermal Toxicity in Rats, DACO: 4.6.2
2355335	2012, Mesotrione/Glyphosate SC (A19573B) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2355337	2012, Mesotrione/Glyphosate SC (A19573B) - Primary eye irritation in rabbits, DACO: 4.6.4
2355338	2012, Mesotrione/Glyphosate SC (A19573B) - Primary skin irritation in rabbits, DACO: 4.6.5
2355339	2012, Mesotrione/Glyphosate SC (A19573B) - Dermal sensitization test - Buehler Method, DACO: 4.6.6
2355320	2013, Callisto GT starting materials and certification of limits, DACO: 3.2.1, 3.3.1 CBI
2355324	2012, Mesotrione/glyphosate SC (A19573B) - Manufacturing process description and supporting data, DACO: 3.2.2, 3.2.3 CBI
2355326	2012, Analytical method SF-539/1 and contains validation (TK0106939), DACO: 3.4.1 CBI
2355329	2013, Callisto GT chemical and physical properties, DACO: 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
2479336	2014, Updated DACO 3.2.2- Formulation Process for Callisto GT Herbicide, DACO: 3.2.2 CBI

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