

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5 Application

Application Number: 2009-0598
Application: Product chemistry – guarantee, identity and proportion of
formulants and formulation type
Product: Mesotrione 50WG Herbicide
Registration Number: 29655
Active ingredients (a.i.): Mesotrione (MER)
PMRA Document Number : 1876276

Purpose of Application

The purpose of this application was to register a new mesotrione-based end-use product, Mesotrione 50WG Herbicide, for use on Optimum *GAT* corn in eastern Canada.

Chemistry Assessment

Mesotrione 50WG Herbicide is formulated as a solution containing mesotrione at a nominal concentration of 50.0%. This end-use product has a density of 0.623 g/mL and pH of 4.8. The chemistry requirements for Mesotrione 50WG Herbicide are complete.

Health Assessments

Mesotrione 50 WG Herbicide is of low toxicity to rats via the oral ($LD_{50} > 5000$ mg/kg), dermal ($LD_{50} > 5000$ mg/kg), and inhalation routes ($LC_{50} > 2.58$ mg/L). It is minimally irritating to the eye but is not an irritant to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Exposure for mixing, loading and applying Mesotrione 50WG Herbicide was estimated using PHED Version 1.1. Risk estimates calculated for handlers wearing long sleeves, long pants, eye protection and gloves during mixing and loading are acceptable. Risk estimates calculated for handlers wearing long sleeves and long pants during application are acceptable.

The use on Optimum *GAT* corn should not result in an increase in worker or bystander (reentry) exposure over registered uses of the active ingredient, since the application rate, number of applications, frequency of application, and method of application are comparable to registered products containing mesotrione for corn uses.

Callisto 480SC Herbicide (Reg. No. 27833) is currently registered in Canada for use on corn with the same use pattern as proposed on the Mesotrione 50WG Herbicide label for Optimum *GAT* corn. The main difference between the two products is the formulation (soluble concentrate versus wettable granule). To register the new Mesotrione 50WG Herbicide, the applicant submitted side-by-side residue trials comparing the two formulations.

The side-by-side field trials, using the WG and SC formulations, in/on sweet corn are adequate and support the proposed use of mesotrione as a WG formulation in/on corn. The magnitude of residues was comparable between the SC and WG formulations. Therefore, the dietary exposure is not expected to increase, and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The post emergent application rate of Mesotrione 50WG Herbicide on Optimum *GAT* corn is the same as that registered for Callisto 480SC Herbicide for late post-emergent application on field corn. Therefore, no increased risk to the environment is expected from the use of Mesotrione 50WG Herbicide. Callisto 480SC Herbicide and Mesotrione Technical Herbicide recently underwent conversion from conditional registration to full registration. Although there were no outstanding environmental data requirements for Callisto 480 SC Herbicide and Mesotrione Technical Herbicide, the environmental risk assessment for mesotrione was revisited to reflect recent changes to the risk assessment methods. The results of the updated environmental risk assessment showed that the use of mesotrione may pose a risk to small wild mammals and to non-target terrestrial plants; precautionary label statements were required for the Callisto 480SC Herbicide label to identify and mitigate these risks. The recent label amendments required for Callisto 480SC Herbicide apply to the label for Mesotrione 50WG Herbicide.

Value Assessment

The applicant submitted data from five replicated field trials conducted in field corn which performance of a post-emergence application of 100 g ai/ha Mesotrione 50 WG Herbicide was directly compared to that of a post-emergence application of 100 g ai/ha Callisto 480SC Herbicide, in terms of both efficacy and crop injury. The efficacy of Mesotrione 50WG Herbicide was similar to that of Callisto 480SC Herbicide for control or suppression of labelled weeds. Field corn was similarly tolerant to Mesotrione 50WG Herbicide as it was to Callisto 480SC Herbicide. While only glyphosate tolerant corn hybrids were treated in these trials, non-glyphosate tolerant hybrids would be expected to exhibit a similar degree of tolerance to Mesotrione 50WG Herbicide.

Conclusion

The PMRA has conducted a review of the available information for this application and can support full registration for Mesotrione 50WG Herbicide.

References

A. List of Studies/Information Submitted by Registrant

Chemistry Assessment

PMRA No.	Title
1721830	2009, MESOTRIONE 50WG- Identification, DACO: 3.1.1,3.1.3,3.1.4 CBI
1721831	2009, MESOTRIONE 50WG- Identification, DACO: 3.1.2 CBI
1721832	2009, MESOTRIONE 50WG- Starting Materials, DACO: 3.2.1 CBI
1721833	2009, MESOTRIONE 50WG- Identification, DACO: 3.2.2 CBI

1721834	2009, MESOTRIONE 50WG- Note to Reviewer, DACO: 3.2.2 CBI
1721835	2009, MESOTRIONE 50WG- Discussion of Formation of Impurities, DACO: 3.2.3 CBI
1721836	2009, MESOTRIONE 50WG- Certification of Limits, DACO: 3.3.1 CBI
1721837	2004, MESOTRIONE 50WG- Enforcement Analytical Method, DACO: 3.4.1 CBI
1721839	2009, MESOTRIONE 50WG- 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
1721840	2005, MESOTRIONE 50WG- Corrosion Characteristics, DACO: 3.7 CBI
1721841	2005, MESOTRIONE 50WG- Storage Stability, DACO: 3.7 CBI
1828093	2009, MESOTRIONE 50WG- Response to clarifax for 2009-0598- All of DACO 3.5, DACO: 3.5 CBI

Health Assessment

PMRA No.	Title
1721843	2004, Acute Oral Toxicity Up and Down Procedure in Rats with Mesotrione WG (50), DACO: 4.6.1
1721844	2004, Acute Dermal Toxicity Study in Rats- Limit Test with Mesotrione WG (50), DACO: 4.6.2
1721845	2004, Acute Inhalation Toxicity Study in Rats with Mesotrione 50 WG, DACO: 4.6.3
1721846	2004, Primary Eye Irritation Study in Rabbits with Mesotrione WG (50), DACO: 4.6.4
1721847	2004, Primary Skin Irritation Study in Rabbits with Mesotrione WG (50), DACO: 4.6.5
1721848	2004, Dermal Sensitization Study in Guinea Pigs (Buehler Method) with Mesotrione WG (50), DACO: 4.6.6
1721849	2005, Dermal Sensitization Study in Guinea Pigs (Buehler Method) with Mesotrione 50 WG, DACO: 4.6.6
1721861	2009, Mesotrione- Comparison of the Magnitude of the Residues in Sweet Corn after Applications with the SC or WG Formulations, DACO: 7.4.1

Value Assessment

PMRA No.	Title
1811730	2009, Mesotrione 50WG - Efficacy Summary, DACO: 10.1,10.2.3.1
1811733	2009, Mesotrione 50WG - Tolerance Summary, DACO: 10.1,10.3.1

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