



## Evaluation Report for Category B, Subcategory B.3.12 Application

**Application Number:** 2013-1877  
**Application:** Label amendment for new site  
**Product:** Callisto 480SC Herbicide  
**Registration Number:** 27833  
**Active ingredients (a.i.):** Mesotrione  
**PMRA Document Number:** 2401311

### Background

Callisto 480SC Herbicide (Registration Number 27833; guarantee 480g mesotrione/L) was first registered for use in Canada in 2004.

### Purpose of Application

The purpose of this application was to amend the Callisto 480SC Herbicide label to include an application to MGI tolerant soybeans and to include a tank mix with Liberty 200SN Herbicide (Registration Number 25337). MGI soybeans contain genes that confer tolerance to the active ingredients mesotrione, glufosinate-ammonium and isoxaflutole.

### Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

### Health Assessments

A toxicological assessment was not required for this application.

The use of Callisto 480SC Herbicide on MGI tolerant soybeans was compared to the currently registered use pattern for mesotrione on soybeans. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Metabolism and residue data for mesotrione on MGI tolerant soybeans were submitted to support the addition of this crop to the label of Callisto 480SC Herbicide. In addition, processing data on treated soybeans were assessed to determine the potential for concentration of residues of mesotrione into processed commodities.

## Maximum Residue Limit

The recommendation for maximum residue limits (MRLs) for mesotrione was based upon the residues observed in soybean commodities treated according to label directions or at exaggerated rates in the United States, including Canadian representative growing regions, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of mesotrione in/on soybean commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the recommended MRL for the raw agricultural commodity (RAC).

**TABLE 1 Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limits (MRLs).**

Commodity	Application Method/ Application Rate	Preharvest Interval (days)	Mesotrione Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
MGI-tolerant soybean seed	PPI or at planting (225 g a.i./ha) + postemergent ground spray (125 g a.i./ha)	43-106	<0.01	0.02 5	Soybean flour: 1.9x; No concentration observed in oil, meal, hulls	0.01 (dry soybeans)	0.03 (dry soybeans) <sup>a</sup> ; 0.05 (soybean flour)

PPI: preplant incorporated

<sup>a</sup> The MRL is proposed to replace the currently established MRL of 0.01 ppm for dry soybeans.

MRLs as proposed in Table 1 are recommended to cover residues of mesotrione in/on soybean commodities. Residues of mesotrione in these commodities at the proposed MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

## Value Assessment

The information submitted for review in support of the value requirement included data from eleven field trials conducted in the United States. The results indicate an acceptable level of crop tolerance to MGI soybeans with the application of labeled rates of Callisto 480SC Herbicide alone or in tank mix with Liberty 200SN Herbicide. The use of Callisto 480SC Herbicide on MGI soybeans may provide growers greater flexibility in weed control products due to the herbicide tolerant genes introduced in the crop, as well as an additional tool to combat weed resistance.

## Conclusion

The PMRA has reviewed the application for Callisto 480SC Herbicide and determined that the amendment to the Callisto 480SC Herbicide label to include an application to MGI tolerant soybeans alone and in tank mix with Liberty 200SN Herbicide has been approved. MRLs are proposed in Table 1 to cover residues of mesotrione in/on soybean commodities.

## References

### PMRA

#### Document

#### Number

#### Reference

2287110	2012, Nature of the Residue in Herbicide Tolerant (HT) Soybeans - Callisto add MGI tolerant soybeans, DACO: 6.2.
2287123	2012, Magnitude of the Residues in or on Mesotrione Tolerant Soybeans - Callisto add MGI tolerant soybeans, DACO: 7.4.1,7.4.2,7.4.5,7.4.6.
2328559	2013, Mesotrione SC (A12738A) - Magnitude of the Residues in or on Mesotrione Tolerant Soybean (Event SYHT0H2) USA 2012. Final Report, DACO: 7.4.1.
2287130	2013, Summary of non-safety adverse effects- Callisto 480SC Herbicide on MGI tolerant soybeans, DACO 10.1,10.2.3.1,10.31.

ISSN: 1911-8082

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