

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

**Application Number:** 2009-1733  
**Application:** Amendment to product label to include new host  
**Product:** Odyssey WDG Herbicide  
**Registration Number:** 25111  
**Active ingredients (a.i.):** Imazethapyr (IMP), Imazamox (IMZ)  
**PMRA Document Number :** 1961736

### Purpose of Application

The purpose of this application is to amend the Odyssey WDG Herbicide label (Reg. No. 25111) to include application to imazethapyr and imazamox tolerant sunflowers (Clearfield trait).

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Maximum Residue Limits

Recommendations for MRLs for imazamox and imazethapyr in/on sunflower seed were based on guidance provided in PRO2005-04 (“Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data”).

Based on MRL statistical methodology and residue data from field trials conducted according to label directions, maximum residue limits (MRLs) to cover residues of imazamox and imazethapyr in/on sunflower seed will be established as shown in Tables 1 and 2, respectively. Residues of imazamox and imazethapyr in processed commodities not listed in Tables 1 and 2 are covered under the MRLs for the raw agricultural commodities (RACs).

<b>TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limits (MRLs) for Imazamox.</b>							
Commodity	Application Method/ Total Application Rate	PHI (days)	Imazamox Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL (ppm)
			Min	Max			
Sunflower seed	Broadcast foliar/ 15-17 g a.e./ha	58-60	<0.05	0.20	No concentration into sunflower oil observed	0.05*	0.3

\* The current MRL of 0.05 ppm will be revised to 0.3 ppm.

<b>TABLE 2. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limits (MRLs) for Imazethapyr.</b>							
Commodity	Application Method/ Total Application Rate	PHI (days)	Imazethapyr Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL (ppm)
			Min	Max			
Sunflower seed	Broadcast foliar/ 15-17 g a.e./ha	58-60	<0.05	0.09	No concentration into sunflower oil observed	None	0.1

Following the review of all available data, an MRL of 0.3 ppm to cover residues of imazamox and an MRL of 0.1 ppm to cover residues of imazethapyr in/on sunflower seeds are recommended. Residues of imazamox and imazethapyr in sunflower commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors. From a food residue exposure point of view, the use expansion of Odyssey WDG Herbicide to sunflowers can be supported.

### Health Assessments

Residue data for imazamox and imazethapyr in sunflower seed were submitted to support the use expansion of these active ingredients on the Odyssey WDG Herbicide label. In addition, processing studies on treated sunflowers were assessed to determine the potential for concentration of residues of imazamox and imazethapyr into processed commodities.

A risk assessment was performed for imazethapyr during its re-evaluation (PMRA# 1728963) and a PRVD has been published (PRVD2010-02). The original risk assessment for imazamox was performed under sub 1995-0331. No post-application assessment was performed as re-entry activities were not expected to result in unacceptable exposure. A post-application assessment was conducted for imazamox on legumes (ex. field peas) during submission 2006-3730.

The addition of imazethapyr and imazamox tolerant sunflowers to the Odyssey WDG Herbicide label fits within the existing use pattern. The proposed use should not result in unacceptable exposure to the active ingredients, imazethapyr or imazamox. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

### **Environmental Assessment**

The proposal to add post-emergent weed control in Imazethapyr and Imazamox-tolerant varieties of sunflower *Helianthus annuus* (USC 13, 14 and 7) to the label of Odyssey WDG Herbicide (PCP # 25111, guarantee: 35% w/w each of Imazamox and Imazethapyr, Group 2 herbicides) does not pose additional risk to the environment. The proposed label has adequate environmental precautionary statements and buffer zone statements to mitigate the environmental concerns. No deficiencies were noted for this particular submission for part 1, 8 and 9. Therefore, no additional review is needed.

### **Value Assessment**

Data from 14 trials conducted in Alberta, Saskatchewan and Manitoba, were submitted for review in support of the use of Odyssey WDG Herbicide on imazethapyr and imazamox tolerant sunflowers (i.e. sunflowers with the Clearfield trait). The data indicate an acceptable level of crop safety, therefore the proposed use pattern is acceptable from a value point of view.

### **Conclusion**

The PMRA has completed an assessment of available information for Odyssey WDG Herbicide and has found the information sufficient to support the addition of a new genetically modified crop, sunflower varieties with the Clearfield Trait, to the label.

## References

PMRA Document Number	Reference
1758425	2009, Magnitude of Imazamox and Imazethapyr Residues in Sunflower RAC and Processed Fractions Following Applications of BAS 724 00H, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
1758421	Odyssey Herbicides on Imazethapyr and Imazamox Tolerant Sunflower (Confectionary and Oil Types) (e.g. Sunflower varieties with the Clearfield Trait). 19 pp.
1758422	Trial Reports. 197 pp.

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