



Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2010-0473
Application: Changes to product label: new site or host and rotational crops/plant back intervals.
Product: Authority 480 Herbicide
Registration Number: 29012
Active ingredients (a.i.): Sulfentrazone
PMRA Document Number (English PDF): 1975247

Background

Authority 480 Herbicide (Registration Number 29012), a Group 14 herbicide, is currently registered for use on chickpeas in Saskatchewan only, for the control of kochia, lamb's quarters, redroot pigweed and wild buckwheat at a rate of 105 to 140 g a.i./ha in medium and fine soils. Authority 480 Herbicide has been conditionally registered since May 2008. For the original review of sulfentrazone, please consult Evaluation Report ERC 2010-08 – *Sulfentrazone*.

Purpose of Application

The purpose of this application is to expand the registration of Authority 480 Herbicide to include field peas, flax and sunflower for the control of labelled weeds.

Applications for conversion from conditional to full registration status for Sulfentrazone Technical Herbicide and Authority 480 Herbicide have been assessed under application numbers 2010-0422 and 2010-0474, respectively. The conclusions for these applications can be found in a Proposed Registration Decision (PRD) for sulfentrazone.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

No new toxicological data were reviewed for this application. Please refer to ERC 2010-08 for a complete evaluation of Sulfentrazone Technical Herbicide.

The addition of field pea, flax and sunflower to the label of Authority 480 Herbicide should not result in an increase in potential occupational or bystander exposure over the registered use pattern of sulfentrazone. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data for sulfentrazone in flax and processed commodities were submitted to support the use expansion of this active on the Authority 480 Herbicide label. Previously reviewed residue data from field trials conducted in/on dry shelled peas and sunflower were reassessed in the framework of this petition. In addition, a processing study in treated sunflower was also reassessed to determine the potential for concentration of residues of sulfentrazone into processed commodities. In order to support the changes to the crop rotational chart, previously reviewed crop rotational trial studies were reassessed to determine the potential of sulfentrazone residues to accumulate in secondary (rotated) crops.

Based on the maximum residues observed in flax treated according to label directions, a maximum residue limit (MRL) to cover residues of sulfentrazone and the metabolites DMS and HMS in/on crops and processed commodities will be established as shown in Table 1. Residues of sulfentrazone and the metabolites DMS and HMS in/on dry field peas and sunflower seeds will be covered by the previously proposed MRLs. Residues of sulfentrazone and the metabolites DMS and HMS in processed commodities not listed in Table 1 are covered under proposed MRLs for the raw agricultural commodities (RACs).

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues ¹ (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL ¹
			Min	Max			
Dried Shelled Peas	Single pre-emergent or pre-plant incorporated spray/280	89-112	<0.075	0.107	Processing study not required	0.15 ppm (Crop Subgroup 6C; Dried shelled pea and bean, except soybean)	-
Flaxseed	Single broadcast spray to the ground after planting but before crop emergence/409-429	111-123	<0.15	<0.15	Could not be determined as residues were non-quantifiable in the RAC and all processed commodities	None	0.15 ppm

TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs)							
			Residues¹ (ppm)				
Sunflower Seeds	Single pre-emergent (after planting of sunflower)/407-423	85-155	<0.15	0.171	<1	0.2 ppm	-

¹Sulfentrazone and the metabolites DMS and HMS.

Following the review of all available data, an MRL of 0.15 ppm for flaxseed is recommended to cover residues of sulfentrazone and the metabolites DMS and HMS. Residues of sulfentrazone and the metabolites DMS and HMS in/on field peas and sunflower will be covered by the established MRLs. Residues of sulfentrazone and the metabolites DMS and HMS in these crop commodities at the proposed and established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The fate and environmental behaviour of sulfentrazone, as well as its impacts on non-target terrestrial and aquatic organisms, have previously been assessed. The original environmental review for the use of sulfentrazone on chickpeas in Saskatchewan may be found in the PMRA Evaluation Report (ERC2010-08).

Outstanding data requirements for the fate and environmental behaviour of sulfentrazone noted in ERC2010-08 were related to uncertainties regarding the fate and effects of the active ingredient and the SCA transformation product in surface water, groundwater and the terrestrial environment. These data were submitted and reviewed under the conversion request applications for Sulfentrazone Technical Herbicide and Authority 480 Herbicide and captured in a PRD for sulfentrazone. Please refer to the PRD for sulfentrazone for an executive summary of the assessment and conclusions based of the submitted data.

The previously identified concerns which resulted in limiting the use to chickpeas in Saskatchewan have been addressed with the data reviewed in the PRD for sulfentrazone. Based on the review of the data, risks were deemed acceptable. Since the rate, number, frequency and method of application of Authority 480 Herbicide on field peas, flax and sunflower in Prairie Provinces fall within the registered use pattern for chickpeas, the environmental risk assessment conducted for chickpeas covers the new uses. Environmental concerns have been mitigated by spray buffer zones on the product label and through communication of hazards by environmental statements on the label.

Value Assessment

To support the registration of Authority 480 Herbicide on flax and sunflower, the registrant submitted 7 trials for flax conducted in Saskatchewan in 2007 and 8 trials for sunflower

conducted in the Prairie Provinces in 2005 to 2007, which were reviewed in conjunction with data currently on file.

To support the registration of Authority 480 Herbicide on field peas, the registrant submitted reports of four trials, conducted in 2006-2007 in the Prairie Provinces and reports from 17 trials conducted in the United States of America (Idaho, New York, Washington and Wisconsin) in 1998 to 2001.

The addition of flax, sunflower and field peas to the Authority 480 Herbicide label for use in the Prairie Provinces was determined to be acceptable from a value perspective.

Conclusion

The PMRA has completed an assessment of available information for Authority 480 Herbicide and has found the information sufficient to support the addition of flax, sunflower and field peas to the Authority 480 Herbicide label for use in the Prairie Provinces. In addition, the PMRA has found the information sufficient to support the establishment of an MRL for sulfentrazone of 0.15 ppm on/in flaxseed.

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