



Evaluation Report for Category B, Subcategory 5.0 Application

Application Number: 2012-0245
Application: New maximum residue limit (MRL) for a previously assessed technical grade active ingredient
Product: Isoxaflutole Technical
Registration Number: 26141
Active ingredients (a.i.): Isoxaflutole
PMRA Document Number : 2273781

Purpose of Application

The purpose of this application was to establish a maximum residue limit (MRL) for isoxaflutole in/on imported soybeans.

Chemistry, Environmental and Value Assessment

Chemistry, environmental and value assessments were not required for this application.

Health Assessments

New residue data for isoxaflutole in glyphosate/HPPD-tolerant soybeans were submitted in support of the establishment of a maximum residue limit (MRL) for isoxaflutole in/on soybean commodities. A soybean processing study was reviewed to determine the potential for concentration of isoxaflutole into processed commodities.

Based on the residues observed in soybean commodities treated with isoxaflutole according to the USA label directions, an MRL of 0.05 ppm to cover residues of isoxaflutole in/on dry soybeans is proposed (Table 1). The MRL applies to the raw agricultural commodities, as well as any processed commodities, except where separate MRLs are specified for the processed fractions.

Commodity	Appli. Method/ Total	PHI (days)	Total Residues¹ (ppm)	Experimental Processing Factor	Currently Established	Recommended MRL (ppm)
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	Application Rate (g a.i./ha)		Min	Max		MRL	
Soybeans	Pre-plant, pre-emergence and/or post-emergence application / 98-130	62-151	<0.02	0.041	<1 (Oil and Soy milk)	None	0.05

¹ Total residues=Isoxaflutole and the metabolite RPA202248.

Following the review of all available data, an MRL of 0.05 ppm for isoxaflutole in/on dry soybean is recommended. Residues of isoxaflutole at this level are not expected to pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Conclusion

The PMRA has completed an assessment of available information for Isoxaflutole Technical and has found the information sufficient to support the establishment of an MRL in/on soybean of 0.05 ppm.

References

PMRA Document Number	Reference
2148649	2010, Metabolism of [phenyl-UL- ¹⁴ C]isoxaflutole in poppies, DACO: 6.3
2148650	2010, The metabolism of [phenyl-UL- ¹⁴ C]isoxaflutole in soybean with pre-plant and post-emergent application, DACO: 6.3
2148653	2010, Validation of Bayer method IS-004-P10-01 analytical method for the determination of residues of isoxaflutole (RPA 201772) and its metabolite RPA 202248 in plant matrices using LC/MS/MS, DACO: 7.2.1
2148654	2010, Analytical method for the determination of residues of isoxaflutole (RPA 201772) and its metabolite RPA 202248 in plant matrices using LC/MS/MS, DACO: 7.2.1,7.2.5
2148658	2010, Storage stability of isoxaflutole residues in poppy seeds and straw, DACO: 7.3
2148660	2010, Balance Pro 480 SC and Glyphos - Magnitude of the residue in/on soybeans, DACO: 7.2.5,7.4.1,7.4.6
2148661	2010, Balance Pro 480 SC - Magnitude of the residue in/on soybeans, DACO: 7.2.5,7.4.1,7.4.2,7.4.6
2148665	2010, Balance Pro 480 SC - Magnitude of the residue in soybean

PMRA Document Number	Reference
2148649	2010, Metabolism of [phenyl-UL- ¹⁴ C]isoxaflutole in poppies, DACO: 6.3
2148650	2010, The metabolism of [phenyl-UL- ¹⁴ C]isoxaflutole in soybean with pre-plant and post-emergent application, DACO: 6.3
	processed commodities and aspirated grain fractions, DACO: 7.4.5

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