

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.5 and 3.10 Application

Application Number: 2013-6737
Application: New end-use product chemistry: Guarantee, identity and type of formulation, tank mixes
Product: Simplicity GoDRI
Registration Number: 31916
Active ingredients (a.i.): Pyroxsulam
PMRA Document Number: 2463596

Purpose of Application

The purpose of this application was to register a new herbicide end-use product, Simplicity GoDRI (guarantee 21.5% w/w pyroxsulam), for selective weed control in wheat (spring, durum and winter) grown in the Prairie Provinces and Peace River Region of British Columbia. This end-use product is intended to eventually replace the currently marketed product Simplicity Herbicide (Registration Number 28887; guarantee 30 g a.i./L pyroxsulam).

Chemistry Assessment

Simplicity GoDRI is formulated as wettable granules containing pyroxsulam at a nominal concentration of 21.5%. This end-use product has a density of 0.44 – 0.54 g/mL and pH of 4.0 – 6.0 for a 1% dilution. The chemistry requirements for Simplicity GoDRI have been fulfilled.

Health Assessments

Simplicity GoDRI is of low acute toxicity via the oral and dermal routes of exposure and is considered to be of low acute inhalation toxicity. It is mildly irritating to the eyes and minimally irritating to the skin. It is not a dermal sensitizer.

No new residue data were submitted in support of the registration of the new end-use product Simplicity GoDRI, which contains pyroxsulam and the safener cloquintocet acid, for use on wheat (spring, durum and winter). The use pattern of Simplicity GoDRI was determined to be within that of currently registered products. Therefore, the previously reviewed data were reassessed in the framework of the current application and it was confirmed that the use of Simplicity GoDRI is not expected to result in an increase in the magnitude of pyroxsulam and cloquintocet-mexyl residues in/on wheat. As such, the use of Simplicity GoDRI will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The occupational exposure and risk from the use of Simplicity GoDRI on wheat was assessed. No health risks of concern are expected, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

The use pattern (rates, timing and method of application) for Simplicity GoDRI is within that of other registered products containing pyroxsulam. No increase in environmental exposure or environmental risk is expected from the use of Simplicity GoDRI compared to other registered products.

Value Assessment

In the growing seasons of 2012 and 2013, 21 small plot replicated trials were conducted across western Canada (Alberta, Saskatchewan and Manitoba; 12 efficacy trials and 9 crop tolerance trials) which evaluated the herbicidal efficacy and crop safety bioequivalency of the current commercial formulation of Simplicity Herbicide and the candidate formulation Simplicity GoDRI. The purpose of these trials was to determine the equivalence (efficacy and crop tolerance) of Simplicity Herbicide applied at the registered rate of 15 g ai/ha to Simplicity GoDRI applied alone or in tank mix combination with registered broadleaf herbicides. Based on all available information, agronomic equivalence was demonstrated between the precedent and candidate formulation of pyroxsulam and acceptable value would be expected for Simplicity GoDRI when used in accordance with the labelled use pattern. Accordingly, registering Simplicity GoDRI as a new end-use product for use in wheat (spring, durum and winter) grown in western Canada can be supported from a value perspective. This new dry formulation of pyroxsulam offers numerous conveniences and ergonomic attributes to the end user including smaller packaging size, easier spill clean-up and storage flexibility under freezing conditions.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Simplicity GoDRI, and has found the information sufficient to register this new end-use product.

References

PMRA Document Number	Reference
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2367857	2013, Crop Tolerance Summary for Simplicity (GF-2541) and GF-3015 Alone and in Tankmix Summary, Nov 2013, DACO: 10.3.2(A)
2367841	2013, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-3015, an End Use Product Containing Pyroxsulam and XDE-558, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.4.2 CBI
2367843	2013, Group B-Physical/Chemical Properties for GF-3015, A Solid End Use Product Containing XDE-558 and Pyroxsulam, 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
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2431625	2013, Determination of Color, Physical State, Odor, Oxidizing and Reducing Action, pH, and Bulk and Tap Density of GF-3015, an End Use Product Containing XDE-558 and Pyroxsulam under GLP, 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
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2367287	2013, ACUTE DERMAL TOXICITY STUDY OF GF-3015 IN RATS DACO:4.6.2
2367288	2013, Waiver Rationale for GF-3015 Acute Inhalation Study, DACO: 4.6.3
2367289	2013, ACUTE EYE IRRITATION STUDY OF GF-3015 IN RABBITS, DACO: 4.6.4
2367290	2013, ACUTE DERMAL IRRITATION STUDY OF GF-3015 IN RABBITS, DACO: 4.6.5
2367291	2013, SKIN SENSITISATION STUDY OF GF-3015 BY LOCAL LYMPH NODE ASSAY IN MICE, DACO: 4.6.6

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