Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2017-7848
Application: New end use product; new combination of active ingredients
Product: Zidua Pro
Registration Number: 33355
Active ingredients (a.i.): Imazethapyr, pyroxasulfone, and saflufenacil
PMRA Document Number : 2954387

Purpose of Application

The purpose of this application was to register Zidua Pro for pre-plant or pre-emergent weed control in soybean.

Chemistry Assessment

Zidua Pro is formulated as suspension containing imazethapyr, pyroxasulfone and saflufenacil at concentrations of 159.5 g/L, 273.5 g/L and 57.0 g/L respectively. This end-use product has a density of 1.186 g/mL and pH of 3.16. The required chemistry data for Zidua Pro have been provided, reviewed and found to be acceptable.

Health Assessments

Zidua Pro is of low acute oral, dermal and inhalation toxicity. It is minimally irritating to the eye and slightly irritating to the skin of the rabbit. It is not a dermal sensitizer in the guinea pig.

The occupational exposure and risk from the registration of Zidua Pro on soybeans was assessed. No risks of concern are expected from the use of the new end-use product on soybeans, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for saflufenacil, imazethapyr, and pyroxasulfone in soybeans were submitted to register Zidua Pro. Previously reviewed residue data from field trials conducted in/on soybeans were reassessed in the framework of this petition. The resulting residues on soybeans from the use of Zidua Pro are expected to be covered under the MRLs currently established for the active ingredients in/on soybeans. Residues in soybeans at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of herbicide Zidua Pro does not represent an increased environmental exposure and risk because use rates do not exceed registered rates for the active ingredients contained in this product. The label meets current environmental labeling standards, including

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buffer zones. The registration of Zidua Pro is acceptable from an environmental assessment perspective.

Value Assessment

The availability of Zidua Pro provides farmers in eastern Canada with an option to use a co-formulated product to manage both grassy and broadleaf weeds in soybean. The benefits of a co-formulated product include ease of application calculations, a reduction in packaging requirements, ease of shipping and storing product and a reduction in handling requirements, from production through to the farm end user (e.g. loading into the sprayer). Furthermore, the combination of three modes of action (WSSA Groups 2, 14 and 15), in addition to tank mixing with glyphosate (WSSA Group 9), may aid in the mitigation and/or management of herbicide resistant weeds.

Efficacy and host crop tolerance data from field trials conducted in Ontario, Manitoba, Iowa, Illinois and Nebraska between 2016 and 2017 were provided for review. The provided trial data demonstrated that Zidua Pro applied at 440 ml/ha (215 g ai/ha) in tank mix with glyphosate at labelled rates + Merge Adjuvant at 1 L/ha would be expected to perform in a similar manner (efficacy and crop tolerance) to that of the cited precedent products. Furthermore, the provided trial data demonstrated that Zidua Pro applied as per label directions would also be expected to provide burndown control of giant foxtail and common waterhemp (including Group 9 resistant biotypes) as well as residual control of Group 9 resistant biotypes of Canada fleabane and common waterhemp.

No rotational crop tolerance data were provided for review. However, given that 1) the proposed rotational crops for Zidua Pro are the most restrictive of those that appear on the precedent product labels and 2) residual soil carryover of the active ingredients in Zidua Pro are not typically influenced by formulation differences, all rotational cropping claims can be supported for the Zidua Pro label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to approve the registration of Zidua Pro.

References

PMRA Document Number	Reference
2833663	2017, Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered Sources of Active Ingredients, DACO: 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2833664	2016, BAS 858 00 H: Group A - Product identity, composition, and analysis, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.4.2

2833665 2016, GLP validation of analytical method AFR0116/01: Determination of active ingredients in BAS 858 00 H by HPLC and generation of a COA for lot: FD-150629-0018, DACO: 3.4.1

2833666 2016, BAS 858 00 H: Determination of physical properties and oxidation reduction, DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.8, 3.5.9

2833667 2016, BAS 858 00 H: Storage stability and corrosion characteristics in commercial type containers, DACO: 3.5.10, 3.5.14

2833668 2016, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11, 3.5.12

2833669 2017, Chemistry Requirements for the Registration of Manufacturing Concentrates and End- use Products Formulated from Registered Sources of Active Ingredients, DACO 3.5.5_3.5.13_3.5.15

2833658 2017, Efficacy Trial Reports, DACO: 10.2.3.3(B).

2833659 2017, Phytotoxicity Trial Reports, DACO: 10.2.3.3(B).

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