Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.1 Application

Application Number: 2021-2777
Application: Change to End-Use Product Label – Application Rate Increase
Product: Zeltera Fungicide
Registration Number: 33820
Active ingredient (a.i.): Inpyrfluxam
PMRA Document Number: 3384428

Purpose of Application

The purpose of this application was to amend the label of Zeltera Fungicide, Reg. No. 33820, to amend the application rate of rapeseed (including canola) from 13 mL/100 kg seed (5 g a.i./100 kg seed) to a range of 13-26 mL/100 kg seed (5-10 g a.i./100 kg seed) to control blackleg.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

The increase of the seed treatment rate for rapeseed/canola from 5 to 10 g a.i./100 kg seed on the label of Zeltera Fungicide represents an expansion of the use pattern for the active ingredient inpyrfluxam; however, updated quantitative risk assessments for commercial seed treaters and planters were not required since the most recent risk assessments on file were conducted with input parameters applicable to the proposed exposure scenarios. Bystander exposure is expected to be minimal since the product is used in commercial seed treatment facilities or in on-farm settings, and there is negligible chances for drift during seed treatment or planting of treated seeds. Therefore, no health risks of concern were identified and the use can be supported from an occupational exposure perspective provided that workers wear the appropriate personal protective equipment and follow all label directions.

No new residue data for inpyrfluxam in canola were submitted to support the use expansion of this active on the Zeltera Fungicide label. Previously reviewed residue data from radiotracer studies conducted in/on canola were reassessed in the framework of this application.

Based on this assessment, no quantifiable residues are expected in canola seeds and residues will be covered by the established maximum residue limits (MRL. Consequently, dietary exposure to residues of inpyrfluxam is not expected to increase and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

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Environmental Assessment

The proposed increase in application rate to control blackleg on rapeseed (including canola) of Zeltera Fungicide is not expected to pose any additional risks to the environment compared to currently registered uses. The required environmental precaution statements to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for Zeltera Fungicide.

Value Assessment

Reports of five efficacy trials (three field and two greenhouse) were submitted which included treatments of Zeltera Fungicide applied to canola at 13 and 26 mL/100 kg seed. Application of 26 mL/100 kg seed resulted in consistently greater reduction of blackleg under a range of disease infestation levels than the lower rate. A claim to control blackleg for Zeltera applied at the rate of 26 mL/100 kg seed is justified based on a direct comparison to relevant treatments of other seed treatment fungicides included in the field trials and that are registered to control this disease.

Zeltera Fungicide applied at 26 mL/100 kg seed will provide growers of rapeseed (including canola), an additional option to control blackleg, which if not adequately managed, can result in serious economic losses.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the amendment of the label of Zeltera Fungicide to amend the application rate of rapeseed (including canola).

References

PMRA Document Number	Reference
3240462	2021, Zeltera Fungicide: Value Summary for Zeltera Fungicide, containing Inpyrfluxam, to Amend Application Rate and Disease Claim for Canola, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.4,10.5.1,10.5.2,10.5.3,10.5.4
3240464	2021, APPENDIX 1: Trial Reports for "Zeltera Fungicide: Value Summary for Zeltera Fungicide, containing Inpyrfluxam, to Amend Application Rate and Disease Claim for Canola", DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3, 10.3.1,10.4,10.5.1,10.5.2,10.5.3,10.5.4