

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2019-0296
Application: Changes to End-Use Product Labels – New Site or Host
Product: ORONDIS Ultra Fungicide
Registration Number: 32805
Active ingredients (a.i.): Mandipropamid, Oxathiaprolin
PMRA Document Number: 3016347

Purpose of Application

The purpose of this application was to amend the label of ORONDIS Ultra Fungicide by adding a use on basil (field and greenhouse) as a foliar application to control downy mildew.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The use of ORONDIS Ultra Fungicide on basil (field and greenhouse) is not expected to result in risks of concern for chemical handlers, post-application workers and bystanders provided that the product is used according to the approved label directions.

No residue data for oxathiapiprolin or mandipropamid in/on field or greenhouse basil were submitted to support the addition of a foliar application of these actives to basil on the ORONDIS Ultra Fungicide label. Previously reviewed residue data from field trials conducted in/on field and greenhouse basil were reassessed in the framework of this petition. Based on this assessment, exposure to residues of oxathiapiprolin and mandipropamid in/on fresh basil leaves and dried basil leaves treated according to the approved use directions for ORONDIS Ultra Fungicide will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Risk to non-target organisms in the environment will remain acceptable with the amendments to the ORONDIS Ultra Fungicide label, provided the product is used according to label directions.

Value Assessment

The claim for use of ORONDIS Ultra Fungicide to control downy mildew (*Peronospora belbahrii*) on greenhouse and field grown basil was based on similar claims registered for two precedent products. Comparison of the precedent and proposed product specifications and application rates indicated that ORONDIS Ultra Fungicide is expected to provide at least the same level of control as the precedent products.

The registration of this product, which contains two active ingredients that control downy mildew by different modes of action, will provide an additional tool for growers to manage this emerging disease and may delay development of resistance to these fungicides in the pathogen population.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the addition of basil (field and greenhouse) on the label of ORONDIS Ultra Fungicide.

References

PMRA Document Number	References
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2954565	10.1, Value Dossier, Rationale for Data Waiver
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