

# **Evaluation Report for Category B, Subcategories 3.12, 3.3 Application**

<b>Application Number:</b>	2018-6246
Application:	Changes to Product Labels-New Site or Host
	Changes to Product Labels-Application Number or Frequency
Product:	ORONDIS Ultra Fungicide
<b>Registration Number:</b>	32805
Active ingredients (a.i.):	Oxathiapiprolin, Mandipropamid
<b>PMRA Document Number</b>	: 3063506

### **Purpose of Application**

The purpose of this application was to allow two sequential applications of ORONDIS Ultra Fungicide and to expand use to additional crops.

#### **Chemistry Assessment**

A chemistry assessment was not required for this application.

#### Health Assessments

A toxicological assessment was not required for this application.

The use pattern of ORONDIS Ultra Fungicide is not expected to increase the occupational exposure to oxathiapiprolin and mandipropamid for mixers, loaders, applicators and postapplication workers over the previously registered use of ORONDIS Ultra Fungicide. No health concerns are expected when workers or bystanders if label directions, precautions and restrictions are followed.

No new residue data for mandipropamid or oxathiapiprolin were submitted to support the change in sequential applications and additional crops.

The residue data on file for mandipropamid and oxathiapiprolin are adequate to support the changes to the ORONDIS Ultra Fungicide label. Based on this assessment, exposure to residues of mandipropamid and oxathiapiprolin in/on all the crops 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**

The expanded crop use and two sequential applications of ORONDIS Ultra Fungicide does not pose an increased risk to the environment.



### Value Assessment

An increase in the number of successive applications of ORONDIS Ultra Fungicide from one to two was requested for several labeled crop/disease combinations. Review of published scientific and Fungicide Resistance Action Committee reports supported the claim that the increase would not likely increase the likelihood of the development of fungal strains resistant to ORONDIS Ultra Fungicide. The addition of several fruiting vegetable crops were supported for some uses through extrapolation from registered crops.

An increase in the number of successive applications of ORONDIS Ultra Fungicide will provide growers with greater flexibility to manage the potential for resistance development to other active ingredients registered for use on these crops.

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the amendments to the label of ORONDIS Ultra Fungicide.

## References

PMRA Document	
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