



Evaluation Report for Category B, Subcategory 2.3, 2.4, 2.6, 3.12, 3.4 Application

Application Number: 2016-3018
Application: New end-use product: New combination of TGIAs, new formulation, new site and application method
Product: Orondis Ultra Fungicide
Registration Number: 32805
Active ingredients (a.i.): Oxathiapiprolin
Mandipropamid
PMRA Document Number: 2781594

Purpose of Application

The purpose of this application was to register the fungicide, Orondis Ultra Fungicide, containing a new combination of active ingredients, oxathiapiprolin and mandipropamid, for use on ground (foliar or soil) or aerial applications on various field or greenhouse vegetable crops.

Chemistry Assessment

Orondis Ultra Fungicide is formulated as a suspension containing oxathiapiprolin at a nominal concentration of 30 g/L and mandipropamid at 250 g/L. This end-use product has a density of 1.083 g/mL and pH of 6.8. The chemistry requirements for this product have been fulfilled.

Health Assessments

Orondis Ultra Fungicide is of low acute toxicity via the oral, dermal and inhalation routes of exposure in the rat. It is minimally irritating to the eye and non-irritating to the skin of the rabbit. It is not a skin sensitizer in mice.

The use pattern of Orondis Ultra Fungicide for ground (foliar or soil) applications on various field or greenhouse vegetable crops/crop groups is covered by the registered use pattern for oxathiapiprolin and mandipropamid. The requested aerial application on potatoes is registered for mandipropamid and has been updated for oxathiapiprolin for Orondis Fungicide (registration number 32103). No health risks of concern are expected when workers follow approved label directions and precautions

No residue data for each of oxathiapiprolin and mandipropamid were submitted to support registration of the new end-use product Orondis Ultra Fungicide for use on potatoes, Crop group 3-07 (Bulb vegetables), Crop subgroup 4-13A (Leafy vegetables), Crop subgroup 4-13B (*Brassica* leafy greens), Crop subgroup 5-13 (*Brassica* head and stem vegetables), Crop group 8-

09 (Fruiting vegetables), Crop group 9 (Cucurbit vegetables), and greenhouse grown tomatoes and cucumbers. Previously reviewed residue data for each of oxathiapiprolin and mandipropamid from field trials in potatoes, bulb vegetables, leafy greens, *Brassica* leafy greens, *Brassica* head and stem vegetables, fruiting vegetables and cucurbit vegetables, and from trials in greenhouse grown tomatoes and cucumbers were reassessed in the framework of this petition.

In addition, the approved use directions for Orondis Ultra Fungicide were compared to the labels of the precedent end-use products.

Residues of oxathiapiprolin in/on treated commodities will be covered under the MRLs currently established for oxathiapiprolin at:

- 0.01 ppm in/on Crop subgroup 1C (Tuberous and corm vegetables),
 - 0.04 ppm in/on Crop subgroup 3-07A (Bulb onion subgroup),
 - 2.0 ppm in/on Crop subgroup 3-07B (Green onion subgroup),
 - 15 ppm in/on Crop subgroup 4-13A (Leafy greens),
 - 1.5 ppm in/on Crop group 5-13 (Brassica head and stem vegetables),
 - 0.5 ppm in/on Crop group 8-09 (Fruiting vegetables), 3 ppm in/on dried tomatoes,
 - 0.2 ppm in/on Crop group 9 (Cucurbit vegetables),
- and under the MRL being proposed for promulgation for oxathiapiprolin in/on Crop subgroup 4-13B (*Brassica* leafy greens) at 10 ppm.

Residues of mandipropamid in/on treated commodities will be covered under the MRLs currently established for mandipropamid at:

- 0.09 ppm in/on Crop Subgroup 1C (Tuberous and corm vegetables),
- 0.05 ppm in/on Crop subgroup 3-07A (Bulb onion subgroup),
- 4.0 ppm in/on Crop subgroup 3-07B (Green onion subgroup),
- 20 ppm in/on Crop group 4 Leafy vegetables (except *Brassica*),
- 25 ppm in/on Crop subgroup 5B (Brassica leafy greens),
- 3.0 ppm in/on Crop subgroup 5A (Head and stem *Brassica*),
- 1.0 ppm in/on all crops in Crop group 8-09 (Fruiting vegetables), and
- 0.6 ppm in/on Crop group 9 (Cucurbit vegetables).

In order to cover residues of mandipropamid in/on all treated crops in the revised Crop group 4-13A (Leafy greens) as a result of this petition, MRLs are being proposed at 20 ppm for those additional crops not included in the established MRL of 20 ppm for the original Crop Group 4 (Leafy Vegetables, except *Brassica*): Indian asters, blackjack, cat's whiskers, cham-chwi, cham-na-mul, chipilin, fresh cilantro leaves, cosmos, dang-gwi, fresh dillweed leaves, dol-nam-mul, ebolo, escaroles, fameflowers, feather cockscombs, good King Henry, huazontles, jute leaves, bitter lettuce, common plantains, English primrose, tree spinach, tanier spinach, and Chinese violets.

In order to cover residues of mandipropamid in/on all treated crops in the revised Crop subgroup 4-13B (*Brassica* leafy greens) as a result of this petition, MRLs are being proposed at 25 ppm for those additional crops not included in the established MRL of 25 ppm for the original Crop subgroup 5B (Leafy *Brassica* greens): Abyssinian cabbages, arugula, cress (garden and upland), hanover salad, maca, mizuna, radish leaves, wild rocket, seakale cabbages, shepherd's purse, turnip greens and watercress.

Residues of oxathiapiprolin and mandipropamid as a result of this petition in/on treated commodities at the established and proposed MRLs will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The application rate for Orondis Ultra Fungicide is lower than the current labeled use rates. The environmental fate and behaviour and the environmental toxicity of oxathiapiprolin are summarized in the Proposed Registration Decision PRD2015-22, *Oxathiapiprolin*, and no outstanding environmental data were identified. Moreover, an evaluation report was published for mandipropamid (Evaluation Report ERC2009-01, *Mandipropamid Technical Fungicide*). The label for Orondis Ultra Fungicide was assessed against the current, relevant labels for environmental statements. The label conforms to the recommendations included in the regulatory decisions, Evaluation Report ERC2009-01, *Mandipropamid Technical Fungicide* and the Proposed Registration Decision PRD2015-22, *Oxathiapiprolin*. No additional environmental risks of concern were identified for Orondis Ultra Fungicide.

Value Assessment

A combination of efficacy data and scientific rationales were provided in support of the application to register Orondis Ultra Fungicide. The applicant referenced two Canadian-registered products, each containing one of the active ingredients, in order to contrast the use patterns of oxathiapiprolin and mandipropamid with the uses of Orondis Ultra Fungicide. The submitted efficacy trials, conducted in Canada, the United States, the Netherlands, Italy and Spain, demonstrated the level of disease management obtained when the active ingredients were used separately. The value of registering this product is to provide resistance management of the two active ingredients, which employ different modes of action, and provide growers with an effective product for several important diseases.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided for Orondis Ultra Fungicide, and has found the information sufficient to support the registration for use on ground (foliar or soil) or aerial applications on various field or greenhouse vegetable crops.

References

PMRA

Document

Number	Reference
2649504	2016, Oxathiapiprolin/Mandipropamid A21591C - Document MIII, Section 1 Product Chemistry Volume, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2649505	2016, Oxathiapiprolin/Mandipropamid A21591C-Document J Product Chemistry Volume, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2 CBI
2649506	2016, Oxathiapiprolin/Mandipropamid Analytical Method SF-840/1-Oxathiapiprolin and Mandipropamid in Formulation SC (030/250) by HPLC Analytical Method, DACO: 3.4.1 CBI
2649507	2016, Oxathiapiprolin/Mandipropamid A21591C-Physico-Chemical Studies of the Formulation Product Chemistry Volume, 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
2649508	2016, Oxathiapiprolin/Mandipropamid A21591C-Document H, DACO: 3.5.1 CBI
2649510	2016, Oxathiapiprolin/Mandipropamid SC (A21591C) Acute Oral Toxicity Study in the Rat (Up and Down Procedure), DACO: 4.6.1
2649511	2016, Oxathiapiprolin/Mandipropamid SC (A21591C) Acute Dermal Toxicity Study in Rat, DACO: 4.6.2
2649512	2016, Oxathiapiprolin/Mandipropamid SC Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2649513	2016, Oxathiapiprolin/Mandipropamid SC (A21591C) Acute Eye Irritation Study in Rabbits, DACO: 4.6.4
2649514	2016, Oxathiapiprolin/Mandipropamid SC (A21591C) Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2649515	2016, Oxathiapiprolin/Mandipropamid SC (A21591C) Local Lymph Node Assay in the Mouse, DACO: 4.6.6

ISSN: 1911-8082

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