Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.4, 3.11, 3.12 Application

Application Number: 2020-5022
Application: Changes to Product Labels - Application Method; New Pests; New Site or Host
Product: OxiDate 2.0
Registration Number: 32907
Active ingredients (a.i.): Hydrogen peroxide and peroxyacetic acid
PMRA Document Number: 3355635

Purpose of Application

The purpose of this application was to amend the registration of the end-use product OxiDate 2.0 to add new crops and new pests to the label.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

OxiDate 2.0 is expected to be slightly acutely toxic by the oral and dermal routes and moderately acutely toxic by the inhalation route. It is also expected to be corrosive to the eyes and severely irritating to the skin but is not expected to be a skin sensitizer.

Occupational risk to individuals is acceptable when OxiDate 2.0 is used according to label directions. Precautionary, personal protective equipment and directions for use statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to occupational exposure.

Bystander exposure will not result in health risks of concern when the product is used according to label directions. Consequently, the risk to bystanders and individuals in residential areas is acceptable.

There are no food, drinking water or consumer exposure concerns when the product is used according to label directions.

Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable,

Canada

this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act.*

The specification of an MRL is not required for either hydrogen peroxide or peroxyacetic acid.

Environmental Assessment

The registration amendment of OxiDate 2.0 to add new crops and new pests is acceptable from the perspective of environmental risk when used in accordance with label directions.

Value Assessment

Value information from 16 product performance field trials were reviewed along with rationales to extrapolate from registered uses, as well as published reports. The information collectively demonstrated that OxiDate 2.0 applied prior to, or at early disease onset, at a rate of 1.0% v/v of the spray solution can be expected to partially suppress botrytis bunch rot and sour rot on grape, suppress sooty blotch and fly speck on apple, partially suppress bacterial blight on onion (bulb and green) when applied in combination with non-ionic surfactant at 0.125% v/v, suppress grey mould on cannabis and industrial hemp (for cannabinoid extraction only) grown indoors or in the field, suppress powdery mildew on cannabis and industrial hemp (for cannabinoid extraction only) grown indoors, and partially suppress powdery mildew on field-grown cannabis and industrial hemp (for cannabinoid extraction only). These crops were demonstrated to be tolerant to OxiDate 2.0 applied at 1.0% v/v.

The expansion of the registration of OxiDate 2.0 to include value-supported use claims will offer growers of grape, apple, onion, cannabis and industrial hemp grown (for cannabinoid extraction only) an additional option to manage economically important diseases in these crops, whether conventionally or organically produced.

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 new crops and new pests to the product label of Oxidate 2.0.

References

PMRA Document Number	Reference
3167202	K.S. Yoder et al, 2016, Evaluation of OMRI-approved and conventional materials and mixtures for full season disease management on three apple cultivars, 2016., DACO: 10.2.3.3(D),10.3.2(B)
3167203	David A. Rosenberger et al, 2009, Controlling Apple Summer Diseases in 2009 with Fungicides Approved for Organic Production, DACO: 10.2.3.3(D),10.3.2(B)
3167204	A. M. C. Schilder, J. M. Gillett, and R. W. Sysak, 2009, Evaluation of fungicide programs for control of bunch rots and downy mildew in "Vignoles" grapes, 2008, DACO: 10.2.3.3(D),10.3.2(B)
3167205	Wendy McFadden-Smith, 2013, Management of Sour Rot and Volatile Acidity in Grapes Ontario Grape and Wine Research Incorporated, DACO: 10.2.3.3(D),10.3.2(B)
3167206	Megan E. Hall et al, 2018, Control of Sour Rot Using Chemical and Canopy Management Techniques, DACO: 10.2.3.3(D),10.3.2(B)
3167209	2019, 2019 BiosafeHemp Botrytis, DACO: 10.2.3.3(D),10.3.2(B)
3167210	2003, Efficacy of OxiDate in Controlling Phytophthora infestans (Late Blight of Potatoes), DACO: 10.2.3.3(D),10.3.2(B)
3167212	2014, Evaluation of fungicides for potato late blight control, Presque Isle, ME, 2014, DACO: 10.2.3.3(D),10.3.2(B)
3167213	2011, Evaluation of OxiDate 2.0 for Control of Bacterial Leaf Blight in Onions, 2011, DACO: 10.2.3.3(D),10.3.2(B)
3167214	2016, Evaluation of biofungicides for control of downy mildew on spinach, 2016, DACO: 10.2.3.3(D),10.3.2(B)
3167218	B. Mueller et al, 2019, Evaluation of Foliar Fungicide Treatments for Control of Sclerotinia Stem Rot of Soybeans in Hancock Wisconsin, 2019, DACO: 10.2.3.3(D),10.3.2(B)
3167219	Anonymous, 2019, Report - Iowa State University Soybean White Mold Management Trial 2019 for BioSafe Systems, DACO: 10.2.3.3(D),10.3.2(B)
3266703	Cameron Scott & Zamir K. Punja, 2020, Evaluation of disease management approaches for powdery mildew on Cannabis sativa L. (marijuana) plants, DACO: 10.2.1
3266704	2007, Evaluation of fungicides for control of foliar, cane and fruit diseases of red raspberries, 2007., DACO: 10.2.3.3(D)
3266705	2012, Evaluation of ZeroTol® for Efficacy against Xanthomonas on Ornamental Kale, DACO: 10.2.3.3(D)
3266711	2011, Late Blight Organic Potato Screening Trial Final Report, DACO: 10.2.3.3(D)
3266713	2019, OxiDate® for Control of White Mold in Irrigated AC Island Dry Beans - Revised, DACO: 10.2.3.3(D)
3266715	2021, Response to Notice of Deficiencies OxiDate 2.0, Submission Number: 2020-5022, DACO: 10.2,10.2.3.1

PMRA Document Number	Reference
3266716	2020, Tolerance to, and efficacy of OxiDate 2.0® for the control of Yellow Rust (*Phragmidium rubai-idaei*) in Red Raspberry, DACO: 10.2.3.3(D)
3269193	2021, Response to Notice of Deficiencies – DACO 10.2 OxiDate 2.0, Submission Number: 2020-5022, DACO: 10.2,10.2.3.1
3269194	2010, Evaluation of fungicides for the control of anthracnose on watermelon, 2010., DACO: 10.2.3.3(D)
3277920	2021, Summary of Value for the Addition of Crops and Pest Claims to the OxiDate® 2.0 Label, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3(D),10.3.1,10.4,10.5.1,10.5.2,10.5.3,10.5.4
3321875	2022, Use Pattern Clarifications for Oxidate 2.0, Submission 2020-5022, DACO: 5.2
3321875	2022, Use Pattern Clarifications for Oxidate 2.0, Submission 2020-5022, DACO: 5.2