Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.3, 3.4, 3.8 and 3.9 Application

Application Number: 2014-2759
Application: Changes to product label: Application number or frequency, application method, re-entry interval, level of control
Product: Timorex Gold
Registration Number: 30910
Active ingredients (a.i.): Tea tree oil
PMRA Document Number : **2531946**

Background

Timorex Gold (Registration Number 30910; guarantee 23.8% tea tree oil) was first conditionally registered for use in Canada in 2013 to control or suppress a variety of fungal diseases on several fruit and vegetable crops.

Purpose of Application

The purpose of this application was to amend the label of Timorex Gold to include the following:

- reduction in application rate for several crop-disease combinations;
- expression of product application rates on a L/ha basis and spray volumes on a L/ha basis (from a percent solution of product basis);
- upgrading registered claims of suppression to claims of control for powdery mildew (*Sphaerotheca macularis*) on strawberry, and powdery mildew (*Uncinula necator*) on grape;
- addition of a claim of control of late blight (*Phytophthora infestans*) on potato,
- addition of a claim of control of grey mold (*Botrytis cinerea*) on greenhouse tomato, strawberry, raspberry and blueberry,
- modifications to mixing/loading/application directions,
- changes to package sizes,
- removal of the restricted entry interval (REI) greenhouse ventilation requirements,
- reduction of the pre-harvest (PHI) interval from four to two days,
- addition of curative treatments with a 5–7 day re-application interval, and
- addition of statements on compatibility with other pesticides.

Chemistry Assessment

A chemistry assessment was not required for this application.

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Health Assessments

A toxicology assessment was not required for this application.

The changes that could potentially impact on occupational, bystander, food residue, and drinking water exposures and risks include the addition of new crops and a new pest, modifications to the application rates, modifications to directions for mixing/loading/application, changes to the package sizes, removal of the greenhouse ventilation requirements during the REI, reduction of the PHI, addition of curative treatments with a shorter re-application interval, and addition of statements on compatibility with other pesticides.

None of the label and use pattern changes are expected to increase occupational, bystander, food residue, and drinking water exposures and risks compared to the existing conditionally registered use patterns for Timorex Gold.

Given the removal of the greenhouse ventilation requirements during the REI, the REI for greenhouse applications will be increased to 24 hours to ensure the dissipation of any vapours and residues of tea tree oil and its components on treated crops.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the Pest Control Products Act (PCPA) for the purposes of adulteration provision of the Food and Drugs Act. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The specification of an MRL for tea tree oil was determined to not be necessary in the previous PMRA assessment of tea tree oil/Timorex Gold. Given that the dietary risks of tea tree oil and its components from food and drinking water are not expected to increase as a result of the label and use pattern changes, the specification of an MRL under the PCPA is not required for the revised conditional registration of Timorex Gold.

Environmental Assessment

The amendments to the Timorex Gold label do not pose any additional risk to the environment from the currently registered use pattern. The changes to existing label rates, and the addition of new rates for new crops, have resulted in similar or lower buffer zone distances compared to those already registered.

Value Assessment

Value information was provided in the form of 23 efficacy trials and a rationale to support the claims. The result of the value review was sufficient to support the change in expression of rates, new disease claims and lower rates and upgraded claims for several disease-crop combinations. The expansion of the Timorex Gold label will provide improved flexibility to Canadian growers for use of this product as a non-conventional alternative.

Conclusion

The PMRA has completed a review of all available information for Timerox Gold and has determined it is sufficient to support the requested changes to the label, with some amendments.

References

PMRA Document Number	Reference
2443152	2014, Efficacy Trial Summary Document, DACO: 10.1
2443153	2012, Efficacy Trial Summary Document for Potatoes, DACO: 10.1
2443154	2014, Rationale for Lower Application Rates, DACO: 10.2.1,10.2.2
2443156	2013, Effect of Timorex Gold in the Control of Grey Mold *(Botrytis cinerea* Pers.) on Blueberries, DACO: 10.2.3.3(D)
2443158	2013, Evaluation of Timorex Gold Efficacy in Spray Program, DACO: 10.2.3.3(D)
2443159	2014, Efficacy of the Natural Fungicide Timorex Gold in the Control of Gray Mold (*Botrytis cinerea* Pers.) in Strawberries cv. Camarosa, Huaral, Peru, 2013, DACO: 10.2.3.3(D)
2443163	2013, Final Report: Systemic Acquired Resistance (SAR) to Grape Powdery Mildew Using Timorex Gold 2013 Field Trial, DACO: 10.2.3.3(D)
2443164	2013, Evaluate the Efficacy of the Natural Fungicide Timorex Gold in the Control of Powdery Mildew (*Erysiphe necator*) in Table Grapes cv. Red Globe, Ica, Peru, 2013, DACO: 10.2.3.3(D)
2443167	2013, Evaluate the Efficacy of the Natural Fungicide Timorex Gold in the Control of Powdery Mildew (*Leveillula taurica*) in Paprika cv. King Ica, Peru, 2013, DACO: 10.2.3.3(D)
2443168	2013, Evaluate the Efficacy of the Natural Fungicide Timorex Gold in the Control of Powdery Mildew (Leveillula taurica) in Paprika cv. King Ica, Peru, 2013, DACO: 10.2.3.3(D)
2443171	2011, Efficacy of the Natural Fungicide Timorex Gold in the Control of Powdery Mildew (*Erysiphe polygoni*, *Leveillula taurica*), Early Blight (*Alternaria alternata*) and Gray Mold (*Botrytis cinerea*) on Industrial Tomato, Quillota, Chile, 2011, DACO: 10.2.3.3(D)
2443173	2014, Assessment Study of Biological Effectiveness of the Biofungicide Timorex Gold for Powdery Mildew Control in Tomato Under High Tech Greenhouse as a Part of a Spray Program, Mexico 2013., DACO: 10.2.3.3(D)
2443174	2012, Late Blight Organic Potato Screening Trial 2012 Final Report, DACO: 10.2.3.3(D)
2506530	2015, Value Summary expansion, DACO: 10.1
2506531	2014, Efficacy of the Natural Fungicide Timorex Gold in the Control of Powdery Mildew (*Sphaerotheca macularis* f sp. *Fragariae*) in Strawberries cv. Albion, San Pedro, Metropolitan Region, Chile, DACO: 10.2.3.3
2506532	2012, The Efficacy of Timorex Gorl against *Uncinula necator* in Table and Wine Grapes (*Vitis vinifera*), DACO: 10.2.3.3

2506533	2012, The Efficacy of Timorex Gorl against *Uncinula necator* in Table and Wine Grapes (*Vitis vinifera*), DACO: 10.2.3.3
2506534	2012, The Efficacy of Timorex Gorl against *Uncinula necator* in Table and Wine Grapes (*Vitis vinifera*), DACO: 10.2.3.3
2506535	2014, Efficacy of the Natural Fungicide Timorex Gold in the Control of Gray Mold (*Botrytis cinerea* Pers.) in Strawberries cv. Camarosa, San Pedro, Metropolitan Region, Chile, 2013, DACO: 10.2.3.3
2506537	2014, Evaluation of the Agricultural Efficiency & Practicality of Fungicide BM 608 (Fatty Acid Esters of Vegetable Origin 222.5 g/L) in the Control of Grey Mold (*Botrytis cinerea*) in Strawberry (*Fragaria vesca* L.) Cultivation. DACO: 10.2.3.3
2506538	2013, Determination of Efficacy of Timorex Gold against *Botrytis cinerea* (BOTRCI) in Tomatoes Indoor, 2 Sites in Bulgaria 2013, DACO: 10.2.3.3
2506539	2013, Control of Gray Mold (*Botrytis cinerea*) on Tomato by Foliar Applications of Timorex Gold, DACO: 10.2.3.3
2499299	2012, Prenatal Development Toxicity, DACO: 4.5.2
2499300	2012, Prenatal Development Toxicity - Study Profile, DACO: 4.5.2
2453523	2014, Exposure, DACO: 5.2
2453524	2014, Residue, DACO: 7.1
2499301	2015, Metabolism/Toxicokinetics Studies (Nature of Residue), DACO: 6.3
2499302	2015, Reduction of PHI, DACO: 7.8

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