Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 3.9, 3.12 Application

Application Number: 2020-5930
Application: Changes to Product Labels-New Site or Host, Level of Control
Product: Timorex Gold
Registration Number: 30910
Active ingredient (a.i.): Tea tree oil
PMRA Document Number: 3285686

Purpose of Application

The purpose of this application was to expand the label of Timorex Gold to include use on cannabis (commercially indoor-, greenhouse- and field-grown) to control grey mould (*Botrytis* sp.), and suppress white mould (*Sclerotinia sclerotiorum*) and powdery mildew (*Podosphaera macularis*).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Timorex Gold is considered to be of low acute toxicity via the oral, dermal, and inhalation routes, moderately irritating to the eyes and skin, and a skin sensitizer. Because of its eye and skin irritancy, it is considered to be a potential respiratory irritant if inhaled.

Occupational risk to individuals handling and applying Timorex Gold is acceptable when the product 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.

Canada

Maximum Residue Limit (MRL)

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 an MRL under the Pest Control Products Act (PCPA) for the purposes of adulteration provision of the Food and Drugs Act (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The specification of an MRL is not required for tea tree oil on cannabis.

Environmental Assessment

The addition of commercially indoor-, greenhouse- and field grown cannabis to the Timorex Gold label poses acceptable risk to the environment when label recommendations are followed. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Value information in the form of a field study and rationales based on registered claims for other crops were submitted in support of the use of Timorex Gold on greenhouse-, commercially indoor- and field-grown cannabis. Based on this information, it was concluded that Timorex Gold applied at 2 L/ha every 7-14 days can be expected to control grey mould and suppress both white mould and powdery mildew on greenhouse-, commercially indoor- and field-grown cannabis.

Cannabis can be expected to be sufficiently tolerant of Timorex Gold, as no injury was observed to hemp in the field trial and given that multiple botanically diverse crops on the label are tolerant of Timorex Gold applied at the rate of 2 L/ha.

The availability of Timorex Gold for use on cannabis (greenhouse-, commercially indoor- and field-grown) will present growers with a new option to manage economically important diseases in this crop.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to expand the label of Timorex Gold to include use on cannabis (commercially indoor-, greenhouse- and field-grown).

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3183074	Dr. Duke's Phytochemical and Ethnobotanical Databases, 2010, Plants Containing 1,8-cineole, DACO: 7.4.1
3183075	Dr. Duke's Phytochemical and Ethnobotanical Databases, 2010, Plants Containing alpha terpinene, DACO: 7.4.1
3183076	Dr. Duke's Phytochemical and Ethnobotanical Databases, 2010, Plants Containing gamma terpinene, DACO: 7.4.1
3183077	Dr. Duke's Phytochemical and Ethnobotanical Databases, 2010, Plants Containing terpinen-4-ol, DACO: 7.4.1
3183078	Marais, J., 1983, Terpenes in the aroma of grapes and wines: A review, S. Afr. J. Enol. Vitic., Vol. 4. No.2., pp. 49-58, DACO: 7.4.1
3183079	Kamil, M.M., Mohamed, G.F., and Shaheen, M.S. , 2011, Fourier Transformer Infrared Spectroscopy for Quality Assurance of Tomato Products, Journal of American Science, 7(6), pp. 559-572, DACO: 7.4.1
3183080	G Strano, T., Ruberto, G., Patanè, C. and La Rosa, S., 2011, Fourier Transformer Infrared Spectroscopy for Quality Assurance of Tomato Products, Proc. XXVIIIth IHC – IIIrd IS on Plant Genetic Resources, pp. 517-524, DACO: 7.4.1
3183081	McGorrin, R.J. and L. Gimelbarb, 1998, Comparison of Flavour Components in Fresh and Cooked Tomatillo with Red Plum Tomato, Food Flavors: Formation, Analysis and Packaging Influences, Vol. 40, pp. 295-313, DACO: 7.4.1
3183082	Shahidi F. and Y. Zhong, 2005, Bailey's Industrial Oil and Fat Products, Sixth Edition, Citrus Oils and Essences, pp. 49-65, DACO: 7.4.1
3183087	Singh, H and P.B. Zimmerman, "Atmospheric Distribution and Sources of Nonmethane Hydrocarbons", Gaseous Pollutants: Characterization and Cycling, John Wiley and Sons Inc., 1992, pp 177-255, DACO: 7.4.1
3183088	Mitsuyoshi, Y., 1984, Terpenes Emitted from Trees, Mokuzai Gakkaishi, Vol. 30, No. 2. p. 190-194, DACO: 7.4.1
3183089	Kesselmeier, J., Schafer, L., Ciccioli, P., Brancaleoni, E., Cecinato, A., Frattoni, M., Foster, P., Jacob, V., Denis, J., Fugit, J.L., Dutaur, L., and Torres, L., 1995, Emission of Monterpenes and Isoprene from a mediterranean Oak Species *Quercus ilex* L. Measured Within the BEMA (Biogenic Emissions in the Mediterranean Area) Project, Atmospheric Environment, Vol 20., Nos 10/11, pp.1841-1850, DACO: 7.4.1

3183098	Geron C., Rasmussan, R., Arnts, R.R., and Guenther, A, 2000, A review and synthesis of monoterpene speciation from forests in the United States, Atmospheric Environment, Vol 34., pp.1761-1781, DACO: 7.4.1
3183109	Bleeker, P.M., Diergaarde, P.J., Ament, K., Guerra, J., Weidner, M., Schutz, S., de Both, M.T.J., Haring, M.A., and Schuurink, R.C., 2009, The Role of Specific Tomato Volatiles in Tomato-Whitefly Interaction, Plant Physiology, Vol. 151, pp.925-935, DACO: 7.4.1
3183126	2020, Tea Tree Oil: MRL exemption in Cannabis in Canada Position paper, DACO: 7.4.1
3183131	2020, Use Description Scenario (Mixer/Loader/Applicator and Post-application) for Timorex Gold Fungicide, DACO: 5.2
3211529	US EPA, 2014, Biopesticides Registration Action Document - Tea Tree Oil, DACO: 7.4.1
3277701	2021, Correspondence, Response to Clarification. DACO: 0.8, 7.4
3277702	2021, Assessing the Terrestrial Biogenic Emissions of Volatile Organic Compounds in Alberta, DACO: 7.4.1
3183132	2020, Value Summary for Timorex Gold Fungicide Label Expansion for Control of Botrytis, Powdery Mildew and Sclerotinia in Cannabis (marihuana), DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.2,10.2.3.3,10.3,10.3.1,10.3.3,10.4, 10.5,10.5.1,10.5.2,10.5.3,10.5.4

B. Additional Information Considered

Published Information

PMRA Document Number	Reference
3283977	Papamichail, S., 2021, What are Terpenes and How Do They Enhance Cannabis? Vaping360, https://vaping360.com/learn/cbd-terpenes/ accessed October 25th 2021, DACO: 4.8