

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2019-1825
Application: Changes to Product Labels – New Site or Host
Product: Contans WG
Registration Number: 29066
Active ingredient (a.i.): *Coniothyrium minitans* strain CON/M/91-08
PMRA Document Number: 3055180

Purpose of Application

The purpose of this application was to amend the product label of Contans WG to extend the storage period and to include additional crops.

Product Characterization and Analysis

Data were provided to support a storage interval for Contans WG for up to 24 months when the product is stored at 4°C. No further information is required to complete the product characterization and analysis database for Contans WG.

Health Assessments

No changes to the formulation of Contans WG have been proposed and the toxicological database for Contans WG is complete; therefore, a toxicological assessment was not necessary. *Coniothyrium minitans* strain CON/M/91-08 is of low toxicity via oral, pulmonary, dermal, and inhalation exposure and is not pathogenic/infective via pulmonary and intraperitoneal injection exposure routes. It is not a dermal irritant or an ocular irritant.

The use expansion for Contans WG follows the same rates and use directions as those currently specified for terrestrial food and feed crops. On the basis of the low toxicity profile for the MPCA and the end-use product, and the expectation that the label directions will be followed by commercial applicators when using the end-use product, it is not expected that the use expansion will pose a health risk of concern.

The existing risk mitigation measures, such as personal protective equipment, will minimize exposure and protect applicators, mixer/loaders, and handlers that are likely to be exposed. No further measures are required to mitigate the risk from the proposed new uses.

The use expansion for Contans WG to additional terrestrial food and feed crops is not expected to significantly increase dietary exposure or exposure via drinking water. Consequently, dietary (food and drinking water) risk from the use of Contans WG is acceptable when used according to the label directions.

Maximum Residue Limit

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 MRLs, under the *Pest Control Products Act*, is not required for *Coniothyrium minitans* strain CON/M/91-08.

Environmental Assessment

The use expansion for Contans WG includes the addition of pepper, eggplants and alfalfa to the list of terrestrial food and feed crops; these crops fall within use site categories for which the product is already registered. The rates, timing, and methods of application are the same as those currently specified for other crops.

Environmental exposure is not expected to significantly increase by the use expansion and the current end-use product label has the appropriate environmental hazard and precautionary statements to limit runoff from treated fields. No adverse effects on the environment are anticipated.

Value Assessment

Value information reviewed in support of Contans WG consisted of a rationale for extrapolation of product efficacy from similar, currently registered crops with similar production practices to the crops eggplant, pepper and alfalfa. Because Contans WG is not applied directly to plants but works in the soil and on crop residues to reduce the sclerotinia inoculum load, the rationale was considered acceptable.

Increasing the spectrum of crops that can be protected by Contans WG will allow growers greater flexibility when using this biopesticide product to control a common disease, sclerotinia, of many agriculturally important plants.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the amendments to the Contans WG product label.

References

PMRA Document Number	References
2987056	2016, Shelf life of <i>Coniothyrium minitans</i> CON M9108 WG - Packaging material: LDPE, DACO: M2.11 CBI
3021889	2014, Biological Method: Determination of the total spore number and spore viability in different biological formulations based on fungal spores, DACO: M2.10.1 CBI
2987057	2019, Canadian Use Description Scenario for Contans WG: Addition of Crops, DACO: 5.2,M5.0

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