

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2019-4315
Application: Changes to product label; new pest and site
Product: Double Nickel 55
Registration Number: 31888
Active ingredient (a.i.): *Bacillus amyloliquefaciens* strain D747
PMRA Document Number: 3099304

Purpose of Application

The purpose of this application was to amend the label of Double Nickel 55 to add use on blueberries and canola to suppress listed diseases.

Product Characterization and Analysis

There were no changes to the formulation of Double Nickel 55, therefore a new assessment was not required for this application.

Health Assessments

There were no changes to the formulation of Double Nickel 55 for this application and the toxicological database is complete; therefore, a toxicological assessment was not necessary. Double Nickel 55 is of low toxicity and not infective or pathogenic via the oral, pulmonary, and intravenous routes, is not toxic and not irritating to skin and is a mild ocular irritant. Double Nickel 55 is potentially sensitizing. None of the other formulants in Double Nickel 55 present any additional concerns with respect to toxicity or irritation.

The label expansion for Double Nickel 55 as a commercial biopesticide on blueberries and canola are consistent with those currently on the label for other food crops and greenhouse uses.

The use expansion will not pose a health risk of concern on the basis of the low toxicity profile for the microbial pest control agent and the end-use product, and the expectation that the labels directions will be followed by commercial applicators when using the end-use product. 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

The use expansion is not expected to significantly increase dietary exposure or exposure via drinking water. Consequently, dietary (food + drinking water) risk from the use of Double Nickel 55 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 *Bacillus amyloliquefaciens* strain D747.

Environmental Assessment

There were no changes to the formulation of Double Nickel 55 for this application and the environmental toxicology database is complete.

Based on the information from various non-target terrestrial and aquatic organism studies, no adverse effects to terrestrial species (including avian animals, wild mammals, arthropods, non-arthropod invertebrates, and terrestrial plants) or to aquatic species (including freshwater fish, aquatic arthropods, and aquatic plants) are expected from the use expansion for Double Nickel 55 to blueberries or canola, when the product is used according to the label directions.

Value Assessment

The applicant submitted the results of efficacy trials and rationales to support the addition of claims of suppression of mummy berry and botrytis blight and fruit rot on blueberries as well as a claim of suppression of sclerotinia stem rot/white mold on canola. Based on the submitted value information, it is expected that Double Nickel 55 will provide suppression of these diseases on blueberries and canola. Double Nickel 55 will provide an alternative non-conventional product for the management of important diseases on blueberries and canola.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of Double Nickel 55 for use on blueberries and canola.

References

PMRA

Document

Number	Reference
3026120	2019, Summary of Value for Double Nickel 55 and Double Nickel LC, containing <i>Bacillus amyloliquefaciens strain D747</i> , for Control of Mummy berry and Botrytis blight and fruit rot of Blueberry and Control of Sclerotinia Stem Rot in Canola, DACO: M1.1,M1.2,M1.3,M10.1,M10.2.1,M10.2.2,M10.3.1,M10.4.2,M10.4.3,M10.4.4
3026112	2017, Evaluation of Double Nickel LC and BmJ WG to control white mold of canola, CAN trial., DACO: M10.2.2
3026113	2016, Evaluation of Double Nickel LC to control white mold of canola, CAN trial. - Minto, MB, DACO: M10.2.2
3026114	2017, To determine the efficacy of Double Nickel in controlling Sclerotinia in Canola., DACO: M10.2.2
3026115	2019, Evaluating fungicides for control of mummy berry and post-harvest fruit rot in blueberries, 2016., DACO: M10.2.2
3026116	2013, Evaluating fungicides and biocontrol products for control of mummyberry and post-harvest fruit rots in blueberries, 2013., DACO: M10.2.2
3026117	2013, Botrytis Blight and Septoria Leaf Spot Management Technologies for Wild Blueberry Production, DACO: M10.2.2
3026118	2016, Evaluating fungicides for control of Botrytis blossom blight and fruit rots in blueberries, 2016., DACO: M10.2.2
3026119	2015, Fungicide management of blueberry fruit rots, 2015., DACO: M10.2.2

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