

Evaluation Report for Category B, Subcategory 3.11,12 Application

Application Number: 2020-1078
Application: Changes to Product Labels-New Pests and Host
Product: Double Nickel 55
Registration Number: 31888
Active ingredient (a.i.): *Bacillus amyloliquefaciens*, Strain D747
PMRA Document Number: 3171983

Purpose of Application

The purpose of this application was to expand the label of Double Nickel 55 to include claims to partially suppress white mould (*Sclerotinia sclerotiorum*) and powdery mildew (*Golovinomyces cichoracearum* sensu lato, *Podosphaera macularis*) and suppress grey mould (*Botrytis cinerea*) on cannabis and hemp grown indoors and outdoors.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

There was no change to the formulation of Double Nickel 55; therefore, no additional toxicological information is required for the end-use product or for the active ingredient, *Bacillus amyloliquefaciens* strain D747. *Bacillus amyloliquefaciens* strain D747 is of low toxicity and not infective or pathogenic to rats via the oral, pulmonary and intravenous routes and a potential sensitizer. The formulants in Double Nickel 55 do not pose any significant concerns with respect to toxicity or irritation.

The methods of application on cannabis and hemp grown indoors or outdoors are consistent with what is currently on the label for other greenhouse and field crops. The potential for dietary and other consumer, and occupational exposure from the foliar application of Double Nickel 55 to cannabis and hemp grown for flowers is not expected to increase, and therefore, no additional exposure information is required.

The available information is sufficient to support the foliar application of Double Nickel 55 on cannabis and hemp grown indoors or as field crops, from a health perspective.

Environmental Assessment

There was no change to the formulation of Double Nickel 55; therefore, no additional environmental toxicological information is required for the end-use product or for the active ingredient, *Bacillus amyloliquefaciens* strain D747.

The methods of application on cannabis and hemp grown indoors or outdoors are consistent with what is currently on the label for other greenhouse and field crops. The use on cannabis and hemp is not expected to pose an additional risk to the environment.

The available information is sufficient to support foliar applications of Double Nickel 55 on commercial cannabis and hemp grown indoors or outdoors, from an environmental perspective.

Value Assessment

To support the addition of claims against white mould, grey mould and powdery mildew on cannabis and hemp to the label of the fungicide Double Nickel 55, the results of five suitable field trials conducted in Canada and the US, extrapolations from eleven registered claims and a rationale based on value to growers were submitted. This information, as well as the limited availability of alternative products, supported the use of Double Nickel 55 to partially suppress white mould and powdery mildew and suppress grey mould in the field and indoors when Double Nickel 55 is applied to cannabis and hemp according to label directions.

White mould, grey mould and powdery mildew are common diseases that challenge growers of hemp and cannabis because they reduce both crop yield and product quality. Double Nickel 55 is a non-conventional, biological fungicide product that colonizes plant surfaces to manage these diseases. Furthermore, as no products were registered in Canada against white mould on cannabis and hemp and only three products were registered against grey mould on cannabis and hemp, the availability of Nickel 55 will serve as an additional option for growers to manage important diseases on cannabis and hemp.

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 cannabis and hemp.

References

PMRA

Document

Number	Reference
3103770	2019, Evaluate Efficacy of LifeGard WG and Double Nickel LC for Control of Powdery Mildew on Caneberries for Registration of LifeGard WG in OR, DACO: M10.2.2, M10.3.1
3103771	2015, Evaluation of Fungicide Programs for Control of Grapevine Powdery Mildew on Rosette grapes, 2015, DACO: M10.2.2, M10.3.1
3103772	2018, Evaluation of sustainable products for control of powdery mildew and botrytis fruit rot in tunnel-grown raspberries, 2018., DACO: M10.2.2, M10.3.1
3103773	2019, Evaluate efficacy of Lifeguard and Double Nickel for the control of hemp diseases. Botrytis, DACO: M10.2.2, M10.3.1
3103774	2019, Evaluate efficacy of Lifeguard and Double Nickel for the control of hemp diseases.-white mold, DACO: M10.2.2, M10.3.1
3103769	2020, Summary of Value for Double Nickel 55 and Double Nickel LC, containing <i>Bacillus amyloliquefaciens</i> strain D747, for Control of Powdery Mildew, White Mold and Grey Mold on Field and Greenhouse (Indoor) Cannabis and Hemp (<i>Cannabis sativa</i>), 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
3114116	2020, Exposure Assessment for Double Nickel 55 and Double Nickel LC, containing <i>Bacillus amyloliquefaciens</i> strain D747, for use on Field and Greenhouse (Indoor) Cannabis and Hemp (<i>Cannabis sativa</i>).

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2020

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.