

## Evaluation Report for Category B, Subcategory 3.12 Application

**Application Number:** 2017-2951  
**Application:** Changes to End-Use Product Label – New Site or Host  
**Product:** Delaro 325 SC Fungicide  
**Registration Number:** 31533  
**Active ingredients (a.i.):** Prothioconazole, Trifloxystrobin  
**PMRA Document Number :** 2895090

### Purpose of Application

The purpose of this application was to amend the label of the end-use product, Delaro 325 SC Fungicide, by adding the use on flax.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

A toxicology assessment was not required for this application.

The occupational exposure and risk from the addition of the use on flax to the label of Delaro 325 SC Fungicide was assessed. No health risks of concern are expected from the new use, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

### Prothioconazole

No new residue data for prothioconazole in flax were submitted to support the amendment of the registered Delaro 325 SC Fungicide label. Based on a comparison of the use directions of Delaro 325 SC Fungicide to the precedent end-use product, residues of prothioconazole in/on treated flax as a result of this action should not increase given that the method and timing of application, as well as the preharvest interval (PHI), are identical, and the application rate is within the approved range. As such, residues of prothioconazole in/on treated flax will be covered under the maximum residue limit (MRL) of 0.15 ppm currently established for residues of prothioconazole in/on flax (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>).

### Trifloxystrobin

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Delaro 325 SC Fungicide on flax. Trifloxystrobin was applied to flax at 129-135 g a.i./ha, and harvested according to label directions. In addition, a processing study in treated flaxseeds was reviewed to determine the potential for concentration of residues of trifloxystrobin into processed commodities.

### Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for trifloxystrobin was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of trifloxystrobin and metabolite CGA-321113 in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodity (RAC).

| <b>TABLE 1. Summary of Field Trial Used to Support Maximum Residue Limit (MRL) of Trifloxystrobin</b> |   |                   |                       |             |                                       |  |                              |
|---|---|-------------------|-----------------------|-------------|---------------------------------------|--|------------------------------|
| <b>Commodity</b>  | <b>Application Method/<br/>Total Application Rate<br/>(g a.i./ha)</b> | <b>PHI (days)</b> | <b>Residues (ppm)</b> |             | <b>Experimental Processing Factor</b> | <b>Currently Established MRL (ppm)</b> | <b>Recommended MRL (ppm)</b> |
|   |   |                   | <b>LAFT</b>           | <b>HAFT</b> |                                       |  |                              |
| Flax seed   | Foliar/ 129-135   | 34-42             | <0.02                 | 0.29        | Flaxseed oil: 0.8x                    | 0.02                                   | 0.4                          |

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of trifloxystrobin. Residues in flax commodities at the proposed MRL will not pose unacceptable health risks to any segment of the population, including infants, children, adults and seniors.

### Environmental Assessment

No additional risk to the environment is expected from the proposed addition of flax as a new crop to the Delaro 325 SC Fungicide label. The use falls within the registered use pattern for prothioconazole and trifloxystrobin. Label amendments to include buffer zones for the use on flax are required on the product label.

### Value Assessment

A total of eight efficacy trials and scientific rationales were submitted to support the claims on flax. Under moderate to high disease pressure, Delaro 325 SC Fungicide reduced pasmo similar to commercial standards and consistently increased yield. The weight of evidence supports the claim of control of pasmo on flax based on the performance of the commercial standards and yield improvements.

The current registration of the claim of control of sclerotinia stem rot on flax on a precedent product label supports extrapolation of the claim to the Delaro 325 SC Fungicide label. The efficacy data also shows that Delaro 325 SC Fungicide will control this disease.

The co-formulation provides value to the grower by managing the development of resistance, since both active ingredients are acting on the two diseases. The combination of prothioconazole and trifloxystrobin also demonstrated increased efficacy against pasmo compared to the active ingredients applied alone.

Only one active ingredient with a high risk of resistance development is currently registered for control of pasmo on flax. Registration of Delaro 325 SC Fungicide for this use provides growers with two alternate modes of action to manage the disease. Delaro 325 SC Fungicide also provides an additional tool to growers to manage this disease in flax.

## Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the addition of flax to the label of Delaro 325 SC Fungicide.

## References

| PMRA Document Number | References  |
|----------------------|---|
| 1913109              | 2009, Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays. Report Number AHE1004, DACO: 5.3, 5.4   |
| 2172938              | 2012, Agricultural Handler Exposure Scenario Monograph: Closed Cockpit Aerial Application of Liquid Sprays. Report Number AHE1007, DACO: 5.3, 5.4   |
| 2572745 and 5.3, 5.4 | 2015, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing Loading of Liquid Formulations. Report Number AHE1003-1, DACO: 5.3, 5.4  |
| 2773160              | 2013, Amendment no. 2: Storage stability of CGA 279202, CGA 357262, CGA 357261, CGA331409, CGA 321113 and CGA 373466 in plant matrices for 24 months, DACO: 7.3   |
| 2773155              | 2017, Trifloxystrobin: Magnitude of the residues in/on flax following a single application of Delaro 325 SC fungicide, DACO: 7.2.1, 7.4.1, 7.4.2  |
| 2773156              | 2017, Trifloxystrobin: Magnitude of the residues in/on flax following a single application of Delaro 325 SC fungicide at an exaggerated rate (5X), DACO: 7.4.5  |
| 2306663              | 2013, USF 0728 325 SC foliar fungicide - Control or suppression of listed diseases in field pea, lentil, chickpea, soybean and winter wheat, DACO: 10.1, 10.2.3.3   |
| 2773148              | 2017, Value assessment of Delaro 325 SC foliar fungicide - Label expansion to include pasmo and sclerotinia white mold control in flax, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3(D), 10.3.1, 10.3.2, 10.5.1, 10.5.2, 10.5.3 |
| 2773149              | 2017, Value assessment of Delaro 325 SC foliar fungicide - Label expansion to include pasmo and sclerotinia white mold control in flax, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3(D), 10.3.1, 10.3.2, 10.5.1, 10.5.2, 10.5.3 |
| 2773151              | 2017, Value assessment of Delaro 325 SC foliar fungicide - Label expansion to include pasmo and sclerotinia white mold control in flax, DACO: 10.2.3.3(D)   |

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services  
Canada 2018

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.