

# **Evaluation Report for Category B Subcategory 2.6 Application**

| Application Number:           | 2013-2256                         |  |  |  |
|-------------------------------|-----------------------------------|--|--|--|
| Application:                  | B.2.6 – New End Use Product       |  |  |  |
| Product:                      | Bravo Top Fungicide               |  |  |  |
| <b>Registration Number:</b>   | 31537                             |  |  |  |
| Active ingredients (a.i.):    | Chlorothalonil and Difenoconazole |  |  |  |
| PMRA Document Number: 2375023 |                                   |  |  |  |

#### **Purpose of Application**

The purpose of this application was to register a new end-use product, Bravo Top Fungicide, containing 500 g/L chlorothalonil and 50 g/L difenoconazole based on three precedent products: Bravo 500 Fungicide (Reg. No. 15723), Inspire Fungicide (Reg. No. 30004), and Quadris Top Fungicide (Reg. No. 30518).

#### **Chemistry Assessment**

Bravo Top Fungicide is formulated as a suspension containing chlorothalonil at 500 g/L, difenoconazole at 50 g/L and 1,2-benzisothiazolin-3-one at 0.010 % as a preservative. This end-use product has a density of 1.26 g/mL and pH of 6.21. The chemistry requirements for Bravo Top Fungicide are fulfilled.

#### **Health Assessments**

Bravo Top Fungicide is slightly toxic by the oral route and moderately toxic by the inhalation route in rats. It is of low acute toxicity by the dermal route in rats, minimally irritating to the eyes and non-irritating to the skin of rabbits and a dermal sensitizer in guinea pigs.

No new occupational data were submitted for chlorothalonil or difenoconazole to support the use of the product Bravo Top Fungicide on carrots, tomatoes, potatoes, bulb onion and green onion, broccoli, brussels sprout, cabbage and cauliflower. The precedent products, Bravo 500 Fungicide label (Reg. No. 15723), Inspire Fungicide (Reg. No. 30004) & Quadris Top Fungicide (Reg. No. 30518) and the new product Bravo Top Fungicide are considered to be equivalent; therefore, all of the currently registered uses on the Bravo 500 Fungicide label, Inspire Fungicide & Quadris Top Fungicide labels can be supported on the Bravo Top Fungicide label. Based on this assessment, no risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new food residue chemistry data were submitted to support the registration of the end-use product Bravo Top Fungicide containing 500 g chlorothalonil/L and 50 g difenoconazole/L for use on broccoli, Brussels sprouts, cabbages, cauliflower, carrot, dry bulb



1

onions, green onions, tomatoes and potatoes. The precedent products, Bravo 500 Fungicide (Reg. No. 15723; 500 g/L chlorothalonil) and Inspire Fungicide (Reg. No. 30004; 250 g/L difenoconazole) or Quadris Top Fungicide (Reg. No. 30518; 200 g/L azoxystrobin and 125 g/L difenoconazole) are considered to be biologically equivalent to Bravo Top Fungicide; therefore, the directions for use for the requested crops on the Bravo 500 Fungicide and Inspire/Quadris Fungicide labels can be extrapolated to Bravo Top Fungicide label.

The seasonal application rate for carrots on the Bravo Top Fungicide label of 0.5 kg difenoconazole./ha is higher than the currently registered maximum seasonal application rate of 0.375 kg a.i./ha on the Quadris Top Fungicide label. However, previously reviewed data are available to support the higher seasonal rate at the proposed and registered PHI of 7days. These data were used to support the current maximum registered seasonal application and PHI for difenoconazole in/on carrots and to establish the MRL of 0.5 ppm for difenoconazole in/on this crop.

| Commodity | Total App.<br>Rate (g | PHI<br>(days) | Analyte        | Residue Levels<br>(ppm) |        |       | Established | Proposed MRL |
|-----------|-----------------------|---------------|----------------|-------------------------|--------|-------|-------------|--------------|
|           | a.i./ha)              |               |                | Ν                       | Min.   | Max.  | WIKL        |              |
| Carrots   | 516-528               | 7             | difenoconazole | 16                      | < 0.01 | 0.203 | 0.5         | Not required |

## Summary of Residue Data for Difenconazole in/on Carrots.

Based on this assessment, the dietary exposure to chlorothalonil and difenoconazole is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## **Environmental Assessment**

To mitigate potential environmental impacts of spray drift resulting from the application of Bravo Top Fungicide, spray buffer zones were determined on the basis of the toxicity endpoints and the maximum seasonal rates of the two active ingredients (chlorothalonil + difenoconazole).

## Value Assessment

The applicant submitted a rationale to extrapolate uses for carrot, potato, bulb onion, green onion, broccoli, brussels sprouts, cabbage, cauliflower, and tomato registered on the labels of three precedent products to the Bravo Top Fungicide label. Based on the previously demonstrated value of one or both of the active ingredients on the target pests, the use claims on Bravo Top Fungicide were supported at rates and timings similar to those registered on the precedent labels. Aerial application was also supported for potato.

Bravo Top Fungicide contains two active ingredients offering convenience to growers. The activity of two modes of action contributes to resistance management; however, since the efficacy of both active ingredients was not demonstrated for all diseases, resistance management practices should be employed.

# Conclusion

PMRA has reviewed information provided in support of the subject product as described above. Based on this review, the subject product are acceptable for registration.

#### References

| 2296196 | 2013, Efficacy Rationale, DACO: 10.1,10.2.3.1,10.2.3.3                                     |
|---------|--|
| 2296161 | 2013, Product Identification, DACO: 3.1.1, 3.1.3, 3.1.4 CBI                                |
| 2296162 | 2013, Formulating Plant name and Address, DACO: 3.1.2 CBI                                  |
| 2296163 | 2013, Starting Material and Certification of Limits, DACO: 3.2.1, 3.3.1<br>CBI             |
| 2296164 | 2013, Description Formulation Process, DACO: 3.2.2 CBI                                     |
| 2296165 | 2010, Analytical Method SF-325/2, DACO: 3.4.1 CBI  |
| 2296166 | 2013, Chemical and Physical Properties, DACO: 3.5.1, 3.5.10, 3.5.11,                       |
|         | 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.0 CPL |
| 2348363 | 2013 Details about the clarification request $D\Delta CO$ : 3.3.2 CBI                      |
| 2413528 | 2014, Response to SPSF clarification, DACO: 3.3.1 CBI                                      |
| 2296168 | 2010. Difenoconazole/Chlorothalonil SC (A16976A) - Acute Oral Toxicity                     |
|         | Study in Rats, DACO: 4.6.1   |
| 2296169 | 2010, Difenoconazole/Chlorothalonil SC (A16976A) - Acute Dermal Toxicity                   |
|         | Study in Rats, DACO: 4.6.2   |
| 2296170 | 2010, Difenoconazole/Chlorothalonil SC (A16976A) - Acute Inhalation Toxicity               |
|         | Study in Rats, DACO: 4.6.3   |
| 2296171 | 2011, Difenoconazole/Chlorothalonil SC (A16976A) - at in use Concentration -               |
|         | Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3                                       |
| 2296172 | 2010, Difenoconazole/Chlorothalonil SC (A16976A) - Acute Eye Irritation                    |
|         | Study in Rats, DACO: 4.6.4   |
| 2296173 | 2010, Difenoconazole/Chlorothalonil SC (A16976A) - Acute Dermal Irritation                 |
|         | Study in Rats, DACO: 4.6.5   |
| 2296174 | 2011, Difenoconazole/Chlorothalonil SC (A16976A) - Acute Eye Irritation                    |
|         | Study in Rats, DACO: 4.6.6   |

#### ISSN: 1911-8082

# © Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2019

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.