



Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 and 3.1 Application

Application Number: 2007-7031
Application: New end-use product chemistry guarantee, identify and proportion of formulants, as well as a rate increase on the label.
Product: Bravo 720
Registration Number: NA
Active ingredients (a.i.): Chlorothalonil (720 g a.i./L)
PMRA Document Number: 1712385

Purpose of Application

The purpose of this application is to register a new chlorothalonil fungicide, Bravo 720, with identical label uses as Bravo 500 (Reg No. 15723) but different guarantee and minor formulant modifications.

Chemistry Assessment

Bravo 720 is a liquid containing the active ingredient chlorothalonil at a nominal concentration of 720 g/L and the preservative 1,2-benzisothiazolin-3-one at a nominal concentration of 0.01%. This product has a density of 1.34 g/mL and pH of 7 to 9 for a 1% solution in water. The product contains seven Challenge substances at various levels. The chemistry requirements for Bravo 720 have been completed.

Health Assessments

Bravo 720 is of low toxicity via the dermal route ($LD_{50} > 2000$ mg/kg bw) but is of high toxicity via the inhalation route ($LC_{50} > 0.0095$ mg/L). It is moderately irritating to the rabbit eye (MAS of 18.22/110 with persistence) and minimally irritating to rabbit skin (MAS of 0.25-0.42/8). It is considered to be a potential skin sensitizer in guinea pigs. An acceptable acute oral toxicology study must be submitted by December 31, 2010.

A health assessment has been conducted for Bravo 720. It is not expected that exposure to mixer/loader/applicators and post-application workers will increase over the currently registered products containing chlorothalonil as an active ingredient.

To support the registration of Bravo 720, containing the registered active ingredient chlorothalonil, bridging residue data on potatoes, sweet corn and chickpeas from the applications of Bravo Ultrex, Bravo 720 and Bravo 500 were submitted. The magnitude of the residues of chlorothalonil and the metabolite SDS-3701 is similar regardless of the end-use product applied. Therefore, the dietary risk is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Maximum Residue Limit(s)

Based on the maximum residues observed in potato and sweet corn treated according to label directions, the maximum residue limits (MRLs) to cover residues of chlorothalonil at 0.02 ppm in/on sweet corn (kernels plus cob with husks removed) and 0.08 ppm in/on potatoes will be established as shown in Table 1.

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL (ppm)
			Min	Max			
Sweet corn (kernels plus cob with husks removed)	Broadcast applications/ 1.6	14	<0.02	<0.02	None	Currently covered under Part B, Division 15, subsection B.15.002(1) of the FDAR (≤ 0.1 ppm)	0.02
Potatoes	Broadcast applications/ 0.6-1.2	1	<0.02	<0.074	No concentration of residues observed in chips and granules		0.08

Residues of chlorothalonil at the recommended MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Bravo 720 fungicide is a new formulation of the currently registered product, Bravo 500 with no change in the use pattern. The only difference is the amount of active ingredient: Bravo 500 contains 500 g a.i./L, whereas Bravo 720 contains 720 g a.i./L. Use of Bravo 720 for the control of a broad spectrum of plant diseases, therefore, does not result in an additional unacceptable environmental risk. The formulants in Bravo 720 will not pose a TSMP concern.

Value Assessment

This application proposes registration of a new chlorothalonil formulation (Bravo 720). The data bridged efficacy from a similar formulation (Bravo 500). A total of 15 efficacy trials were submitted in support of the claims: Potatoes - four trials on early blight with Bravo 720 alone, four on early blight with Bravo 720 as a tank mix with Quadris, one on late blight with Bravo 720 alone; Tomatoes three on Septoria leaf spot with Bravo 720 alone and three on anthracnose with Bravo 720 alone. The field trials were conducted in Alberta, Manitoba, Ontario, Quebec and New Brunswick. In all cases, the efficacy of Bravo 720 was similar to that for Bravo 500, at

the registered rates. Since several different diseases and crops were tested it is expected that the efficacy of Bravo 720 will be comparable to that of Bravo 500 for all the crops/diseases currently registered for the latter formulation. No further data are required.

Conclusion

The PMRA has completed an assessment of available information for Bravo 720 and has found the information sufficient to support a conditional registration.

References

PMRA Document Number	Reference
1383315	2006, Chlorothalonil - Residue levels on chickpeas (seed) from trials conducted with Bravo 500, Bravo 720 or Bravo 82.5 in Canada during 2004, CER05102-04, DACO: 7.2.1, 7.2.3, 7.2.5, 7.3, 7.4.1, 7.4.2, 7.4.6
1383318	2006, Chlorothalonil - Residue levels on potatoes (tubers) from trials conducted with Bravo 500, Bravo 720 or Bravo 82.5 in Canada during 2004, CER05103-04, DACO: 7.2.1, 7.3, 7.4.1, 7.4.6
1383320	2006, Chlorothalonil - Residue levels on sweet corn (forage and K + CWHR) from trials conducted with Bravo 500, Bravo 720 or Bravo 82.5 in Canada during 2004, CER05104-04, DACO: 7.2.1, 7.3, 7.4.1, 7.4.6
1475760	2007, Bravo 720 Efficacy Summary. DACO 10.1, 10.2, 10.3.1, 10.3.2, 10.3.3
1475761	2007, Bravo 720 Efficacy Summary Table Excel Spreadsheets. DACO 10.2.3.1
1475779	2007, Bravo 720 - Product Identification, DACO: 3.1.1, 3.1.3, 3.1.4
1475794	2007, Bravo 720 - 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, 3.5.9
1475795	2002, Bravo 720 (WF2728): Determination of Storage Stability and Physico-Chemical Characteristics, 560-187, DACO: 3.5.10, 3.5.6
1475797	2003, Chlorothalonil Bravo 720 SC Formulation (A12531D): Acute Oral Toxicity Study in the Rat. CTL/AR7163/REG/REPT, DACO 4.6.1
1475798	1986, Acute Dermal Toxicity Study in Albino Rabbits with Bravo 720. WIL Research Laboratories, WIL-11005, Sponsor report number 760-5TX-85-0066-002 SDS-2787, DACO 4.6.2
1475799	2002, Chlorothalonil Bravo 720 SC Formulation (WF2728) Spray Strength Dilution (13.52 ml/l): 4-Hour Acute Inhalation Toxicity Study in Rats, CTL/HR2397/REG/REPT, DACO 4.6.3
1475801	2000, Chlorothalonil 720g/L SC Formulation Eye Irritation Study in Rabbits, CTL/FB5844/REG/REPT, DACO 4.6.4
1475803	1987, Primary Dermal Irritation Study in Albino Rabbits with Bravo 720 and Bravo 500 Formulations, 1674-97-0097-TX-001 (87-0097), DACO 4.6.5
1475804	1986, Dermal Sensitization Study (Close-Patch Repeated Insult) in Guinea Pigs with T-194-1, WIL-11007, Sponsor Document number 1105-85-0068-TX-002 (SDS-2787). 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 2010

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.