

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2013-4076
Application: New or Changes to Product Labels – New Site or Host
Product: Fortenza Red
Registration Number: 30898
Active ingredients (a.i.): Cyantraniliprole
PMRA Document Number : 2368511

Purpose of Application

The purpose of this application was to amend the Fortenza Red label, to include seed treatment uses in/on corn (field and pop). This application was a workshare with the US Environmental Protection Agency.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The amendment to the label did not impact the acute toxicity of this end-use product.

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Fortenza Red on field and popcorn. In addition, a processing study in treated corn was reviewed to determine the potential for concentration of residues of cyantraniliprole into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for cyantraniliprole was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of cyantraniliprole 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 MRLs for the raw agricultural commodities (RACs).

Table 1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
Field corn	Seed treatment/0.5 mg ai/seed	na	<0.01	<0.01	na	None	0.01
Popcorn grain	Seed treatment/0.5 mg ai/seed	na	<0.01	<0.01	na	None	0.01

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of cyantraniliprole. Residues in these crops at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

A human health risk assessment was completed for Fortenza Red for use as a commercial seed treatment. Fortenza Red is to treat corn (field and pop) seed. Dermal exposure was not calculated as systemic toxicity was not identified at short- to intermediate-term exposure durations for cyantraniliprole. Only inhalation exposure was calculated and not considered to be of concern if label amendments are adhered to.

Environmental Assessment

Cyantraniliprole is currently registered on a number of crops for foliar, soil and seed treatments, at higher rates. The seed treatment expansion is not expected to result in increased risk to birds and mammals. Current residue data indicate low levels of cyantraniliprole in pollen and/or nectar from other seed treatment crops, and a negligible oral risk. However, corn pollen residues are needed in order to confirm negligible risk from oral exposure for pollinators. Best Management Practice for dust reduction will also be implemented on the label.

Value Assessment

Submitted value information included 5 efficacy trials (2 greenhouse trials and 3 field trials) on cutworm in corn, 3 field trials on wireworm in corn, 1 field trial on northern masked chafer (*Cyclocephala borealis*) in corn, and 3 field trials on cutworms in canola. A rationale was submitted to extrapolate from data submitted on northern masked chafer to a claim of control of European chafer based on similarity of pest biology and behavior.

Information was only submitted on black cutworm in corn and black cutworm and army cutworm in canola. Despite the variable behavior and biology of cutworms (e.g. climbing cutworms vs army cutworm), it is expected that Fortenza Red, because it is systemic, will provide similar control of all cutworms. The submitted value information supported a claim for cutworms at an application rate of 83 to 167 ml product (50 to 100 g a.i.) per 100 kg seed and a claim for wireworms and European chafer at an application rate of 167 ml product (100 g a.i.) per 100 kg seed for corn.

A tank mix with Cruiser 5 FS insecticide seed treatment was supported from a value perspective based on the applicant rationale that this mix will increase the pest spectrum compared to each insecticide seed treatment alone. Tank mixes with Apron XL LS, Maxim XL, Dynasty 100 FS, Maxim Quatro Seed Treatment, and/or Vibrance 500 FS for additional disease control were also supported. These tank mixtures with registered fungicides will allow broadening the pest spectrum and should provide economical returns to the growers.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Fortenza Red, and has found the information sufficient to include seed treatment uses in/on corn (field and pop) on the label.

References

PMRA Document Number	Reference
2331987	2013, FORTENZA. Document M-III, Section 7: Efficacy Data and Information - Canada, DACO: 10.2.3.3, 10.2.3.4, 10.3.2, 12.7, Document M, IIIA 6.1.2, IIIA 6.1.3, IIIA 6.1.4.1, IIIA 6.1.4.3, IIIA 6.2.1
2332004	2013, Data Summary Table - Fortenza for use on corn, Crop Subgroup 20A, Brassica carinata and condiment mustard, DACO: 10.2.3.4, IIIA 6.1.3
2332005	2011, CORN-GRUB-11-01: Screening new insecticides for control of white grubs on corn, DACO: 10.2.3.4, IIIA 6.1.3
2332006	2012, CANO-CUT-12-01: A17960A seed treatment solutions for canola, DACO: 10.2.3.4, IIIA 6.1.3
2332007	2012, CANO-CUT-12-02: A17960A seed treatment solutions for canola, DACO: 10.2.3.4, IIIA 6.1.3
2332008	2013, CANO-CUT-13-01: Evaluate cutworm control with Fortenza in canola, DACO: 10.2.3.4, IIIA 6.1.3
2332009	2013, CANO-FLE-13-01: Develop new Helix Vibrance Premixes (SDX/TMX/MFX/FDL/DFZ/plus Sulfoxaflor or CYNT) to control Crucifer and Striped flea beetles in canola, DACO: 10.2.3.4, IIIA 6.1.3
2332010	2013, CANO-FLE-13-02: Develop new Helix Vibrance Premixes (SDX/TMX/MFX/FDL/DFZ/plus Sulfoxaflor or CYNT) to control Crucifer and Striped flea beetles in canola, DACO: 10.2.3.4, IIIA 6.1.3
2332011	2013, CANO-FLE-13-03: Develop new Helix Vibrance Premixes (SDX/TMX/MFX/FDL/DFZ/plus Sulfoxaflor or CYNT) to control Crucifer and Striped flea beetles in canola, DACO: 10.2.3.4, IIIA 6.1.3
2332012	2013, CORN-CUT-13-01: Greenhouse assessment of Fortenza against cutworms on corn, DACO: 10.2.3.4, IIIA 6.1.3
2332013	2013, CORN-CUT-13-02: Greenhouse assessment of Fortenza against cutworms on corn, DACO: 10.2.3.4, IIIA 6.1.3
2332014	2011, CORN-CUT-11-01: Screening new insecticides for control of wireworm on corn, DACO: 10.2.3.4, IIIA 6.1.3
2332015	2009, CORN-CUT-09-01: Evaluation for black cutworm activity in field corn, DACO: 10.2.3.4, IIIA 6.1.3
2332016	2009, CORN-CUT-09-02: Evaluation of insecticides for black cutworm activity in field corn, DACO: 10.2.3.4, IIIA 6.1.3
2332017	2012, CORN-WIRE-12-01: Insecticidal seed treatments for wireworm and white grub protection in corn, DACO: 10.2.3.4, IIIA 6.1.3
2332018	2012, CORN-WIRE-12-02: Insecticidal seed treatments for wireworm protection in corn, DACO: 10.2.3.4, IIIA 6.1.3
2332019	2011, CORN-WIRE-11-01: Screening new insecticides for control of wireworm on corn, DACO: 10.2.3.4, IIIA 6.1.3
2358103	DACO: 10.1 Value Summary
2406748	Deficiency response
1349637	2000, Occupational Risk Exposure Assessment for HELIX 289FS, DACO: 5.4

- 1571553 2007, Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy, DACO: 5.4
- 2332022 2013, Laboratory Dust-Off Measurements of Corn and Canola Seed Treated with FORTENZA, DACO: 4.6.8, 4.7.7, 4.8, 5.14, IIIA 7.11
- 2332023 2013, Cyantraniliprole FS and WG (A17960B and A16971B) - Magnitude of the Residues in or on Field and Pop Corn Resulting from Seed Treatment Only and from Seed Treatment and Foliar Applications USA 2011, DACO: 7.4.1, 7.4.2, 7.4.6, IIIA 8.3.1
- 2070705 2009, IN-J9Z38: Acute oral toxicity to the honey bee, *Apis mellifera* L., DACO: 9.2.4.2, Document K, IIA 8.7.1
- 2070706 2009, IN-HGW87: Acute oral toxicity to the honey bee, *Apis mellifera* L., DACO: 9.2.4.2, Document K, IIA 8.7.1
- 2070707 2009, IN-HGW87: Acute effects to the honey bee, *Apis mellifera* L. at low dose levels, DACO: 9.2.4.2, Document K, IIA 8.7.1
- 2070708 2009, IN-K5A78: Acute oral toxicity to the honey bee, *Apis mellifera* L, DACO: 9.2.4.2, Document K, IIA 8.7.1
- 2070709 2009, Cyantraniliprole (DPX-HGW86) 100 g/L SE: Acute oral and contact toxicity to the honey bee, *Apis mellifera* L., DACO: 9.2.4.1, 9.2.4.2, Document K, IIA 8.7.1, IIA 8.7.2
- 2070710 2007, DPX-HGW86 100 g/L OD: Acute oral and contact toxicity to the honey bee, *Apis mellifera* L., DACO: 9.2.4.1, 9.2.4.2, Document K, IIA 8.7.1, IIA 8.7.2
- 2070711 2005, DPX-HGW86 technical: Acute oral and contact toxicity to the honeybee, *Apis mellifera* L., DACO: 9.2.4.1, 9.2.4.2, Document K, IIA 8.7.1, IIA 8.7.2
- 2070713 2008, DPX-HGW86 200 g/L SC: Acute oral and contact toxicity to the honeybee, *Apis mellifera* L., DACO: 9.2.4.1, 9.2.4.2, Document K, IIA 8.7.1, IIA 8.7.2
- 2070715 2010, Magnitude of cyantraniliprole and metabolite residues in canola nectar and pollen following seed treatment with 625 g/L FS - NAFTA, 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070716 2010, Cyantraniliprole (DPX-HGW86) 100 g/L OD plus codacide oil: A study to evaluate effects on the honey bee (*Apis mellifera* L.; hymenoptera, apidae) under semi-field conditions applied after daily bee-flight in *Phacelia tanacetifolia* L. with additional assessments on colony and brood development, DACO 9.2.4.1
- 2070717 2009, The translocation of [14C]DPX-HGW86 into pollen and stamens of *Phacelia tanacetifolia*, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070718 2007, The translocation of [14C]DPX-HGW86 into pollen and stamens of sunflower, canola, tomatoes and zucchini, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070719 2010, Cyantraniliprole 100 g/L SE plus codacide oil: A semi-field study to evaluate effects on the honey bee (*Apis mellifera*; Hymenoptera, Apidae) in nectarines in Spain 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070720 2010, DPX-HGW86 100SE plus codacide oil: A semi-field study to evaluate effects on the honey bee (*Apis mellifera*; Hymenoptera, Apidae) in apple in Spain 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070721 2011, Cyantraniliprole 100SE plus codacide oil: A field study to evaluate residues in nectar and pollen in nectarine flowers in Italy 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3

- 2070722 2011, DPX-HGW86 100OD plus codacide oil: A field study to evaluate residues in nectar and pollen in melon flowers at two different locations in Spain 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070723 2011, Cyantraniliprole 200 g/L SC: A semi-field study to evaluate effects on the honeybee (*Apis mellifera*; Hymenoptera, Apidae) in melon in Spain 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070724 2011, Cyantraniliprole 100 OD plus Codacide Oil: A field study to evaluate residues in pollen in tomato flowers in Spain 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070725 2011, Cyantraniliprole 100SE: A field study to evaluate residues in pollen in olive flowers in Spain 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070726 2011, Cyantraniliprole 100 g/L OD: A field study to evaluate residues in pollen and nectar in melon flowers in Italy 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070727 2011, Cyantraniliprole 100SE: A field study to evaluate residues in pollen in olive flowers in Italy 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070728 2011, Cyantraniliprole 100 g/L OD plus codacide oil: A field study to evaluate residues in pollen in tomato flowers in Italy 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070729 2011, Cyantraniliprole 100 g/L OD: A field study to evaluate residues in pollen and nectar in melon flowers in Spain 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070730 2011, Cyantraniliprole 100SE plus codacide oil: A field study to evaluate residues in nectar and pollen in citrus flowers in Italy 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070731 2011, Cyantraniliprole 100SE plus codacide oil: A field study to evaluate residues in nectar and pollen in nectarine flowers in Spain 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070732 2011, Cyantraniliprole 100SE plus codacide oil: A field study to evaluate residues in nectar and pollen in citrus flowers in Spain 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070733 2011, DPX-HGW86 100OD plus codacide oil: A field study to evaluate residues in nectar and pollen in winter oilseed rape flowers at two different locations in Spain 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070734 2011, DPX-HGW86 200SC: A semi-field study to determine residues in nectar and pollen from foraging honey bees (*Apis mellifera*; Hymenoptera, Apidae), residues in fresh honey, pollen and wax combs after exposure of the honey bees to drip-irrigated melon in Spain 2009, DACO: 9.2.4.1
- 2070735 2011, Cyantraniliprole 100SE plus codacide oil: A laboratory study to evaluate residues in nectar in citrus flowers collected in study S09-00518 in Spain 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070736 2011, DPX-HGW86 100SE plus codacide oil: A field study to evaluate residues in nectar and pollen in citrus flowers at two different locations in Spain 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070737 2011, DPX-HGW86 100 g/L SE plus codacide oil: A field study to evaluate residues in nectar and pollen in apple flowers at two different locations in Germany 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3

- 2070739 2011, Cyantraniliprole 100 g/L OD: A field study to evaluate residues in pollen of potato flowers in Germany 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070740 2011, Cyantraniliprole 100 g/L OD: A field study to evaluate residues in pollen of potato flowers in Italy 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070741 2011, 100 g/L SE: Bee pollen residue - Cyantraniliprole 100 g/L OD: A field study to evaluate residues in pollen and nectar in grapevine flowers in Italy 2010grapes/Italy, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070743 2011, Cyantraniliprole 100 g/L SE: A field study to evaluate residues in pollen and nectar in grapevine flowers in Germany 2010, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070745 2011, Cyantraniliprole (DPX-HGW86) 100 g/L OD: A study to evaluate effects on the honey bee (*Apis mellifera carnica*) in the field in brassica napus l. following application after and during bee-flight in southern Germany (Tubingen) in 2010 and 2011: Interim Report, DACO: 9.2.4.1
- 2070746 2010, DPX-HGW86 100 g/L OD and DPX-HGW86 100 g/L OD plus codacide oil: A semi-field study to evaluate effects on the honey bee (*Apis mellifera carnica*; Hymenoptera, Apidae) in *Phacelia tanacetifolia* in South Germany 2010, DACO: 9.2.4.1, Document K, IIA 8.
- 2070748 2011, DPX-HGW86 100SE plus codacide oil: A field study to evaluate residues in nectar and pollen in apple flowers at two different locations in Spain 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070749 2010, DPX-HGW86 100 g/L OD plus codacide oil and DPX-HGW86 100 g/L SE plus codacide oil: A semi-field study to evaluate effects on the honey bee (*Apis mellifera carnica*; Hymenoptera, Apidae) in *Brassica napus* in Southern Germany (Niefern) 2009, DACO: 9.
- 2070750 2011, DPX-HGW86 100 g/L OD: A semi-field study to determine residues in nectar and pollen from foraging honey bees (*Apis mellifera carnica*; Hymenoptera, Apidae), residues in fresh nectar, pollen and wax from combs and residues in plants and flowers after exposure of the honey bees to treated *Phacelia tanacetifolia* in Germany in 2008, DACO: 9.2.4.1
- 2070751 2010, DPX-HGW86 20SC and DPX-HGW86 100D: A greenhouse study to evaluate effects on the bumble bee (*Bombus terrestris* L; Hymenoptera, Apidae) in tomato in Spain in 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070752 2010, DPX-HGW86 100 g/L OD plus codacide oil and DPX-HGW86 100 g/L SE plus codacide oil: A semi-field study to evaluate effects on the honey bee (*Apis mellifera carnica*; Hymenoptera, Apidae) in *Brassica napus* in southern Germany (Tubingen) 2009, DACO: 9.
- 2070753 2011, DPX-HGW86 100 g/L OD plus codacide oil: A study to evaluate effects on the honey bee (*Apis mellifera carnica*) in the field in *Brassica napus* L. following application after and during bee-flight in southern Germany (Tubingen) in 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070754 2011, DPX-HGW86 100 g/L OD plus Codacide Oil: A study to evaluate effects on the honey bee (*Apis mellifera carnica*) in the field in *Brassica napus* L. following application after and during bee-flight in Northern Germany (Celle) in 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3

- 2070756 2011, DPX-HGW86 100 g/L OD plus codacide oil: A study to evaluate effects on the honey bee (*Apis mellifera carnica*) in the field in *Brassica napus* L. following application after and during bee-flight in northern Germany (Stade) in 2009, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070757 2011, Cyantraniliprole (DPX-HGW86) 100 g/L OD plus codacide oil: A study to evaluate effects on the honey bee (*Apis mellifera carnica*) in the field in *Brassica napus* L. following application after and during bee-flight in Northern France (Alsace) in 2010 and 2011: Interim Report, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070758 2006, DPX-HGW86 100 G/L OD: A semi-field study (non-GLP) to evaluate effects on the honey bee (*Apis mellifera carnica*; hymenoptera, apidae) in *Phacelia* in Germany 2006, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070759 2009, DPX-HGW86 100 g/L OD: A semi-field study to evaluate effects on the honey bee (*Apis mellifera carnica*; hymenoptera, apidae) in *Phacelia tanacetifolia* in Germany 2008, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070760 2008, DPX-HGW86 100 g/L OD: A semi field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; hymenoptera, apidae) on wheat treated with artificial honeydew in France 2008, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070761 2008, DPX-HGW86 100 G/L OD: A semi field study to evaluate effects on the honey bee (*Apis mellifera mellifera*; hymenoptera, apidae) on *phacelia* in France 2008, DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070762 2008, DPX-HGW86 100 g/L OD: Foliage residue toxicity to the honeybee, *Apis mellifera* L., DACO: 9.2.4.1, Document K, IIA 8.7.3
- 2070706 2009, IN-HGW87: Acute oral toxicity to the honey bee, *Apis mellifera* L., DACO: 9.2.4.2, Document K, IIA 8.7.1

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2015

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.