

## Evaluation Report for Category B, Subcategory 3.4, 3.8, 3.12 Application

**Application Number:** 2022-1288  
**Application:** Changes to Product Labels- New Site or Host, Application Method, and Re-entry Interval  
**Product:** Cimegra  
**Registration Number:** 33666  
**Active ingredient (a.i.):** Broflanilide  
**PMRA Document Number:** 3453671

### Purpose of Application

The purpose of this application was to expand the Cimegra product label to include pre-plant application to sweet potatoes as well as foliar application to potatoes, brassica head and stem vegetables (Crop Group 5-13), leafy vegetables (Crop Group 4-13), fruiting vegetables (Crop Group 8-09), leaf petioles vegetables (Crop Subgroup 22B), and soybeans to control specified insect pests.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

A toxicology assessment was not required for this application.

Updated non-cancer and cancer health risk assessments were conducted for chemical handlers and post-application re-entry workers for the use of Cimegra on sweet potatoes, potatoes, soybeans, fruiting vegetables (Crop Group 8-09), *Brassica* head and stem vegetables (Crop Group 5-13), leafy vegetables (Crop Group 4-13), and leaf petioles vegetables (Crop Subgroup 22B). No risks of concern are expected from the new uses, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in Canada and the United States were submitted to support the foliar use of Cimegra on *Brassica* head and stem vegetables (Crop Group 5-13), leafy vegetables (Crop Group 4-13), fruiting vegetables (Crop Group 8-09), leaf petioles vegetables (Crop Subgroup 22B), and soybeans. Broflanilide was applied to head lettuce, leaf lettuce, spinach, mustard greens, broccoli, cabbage, tomatoes, bell peppers, non-bell peppers, celery, and soybeans at exaggerated rates and harvested according to label directions. In addition, tomato and soybean processing studies were reviewed to determine the potential for concentration of residues of broflanilide into processed commodities. No new residue data for broflanilide in potatoes were submitted to support the use expansion of this active ingredient on the Cimegra label as a foliar treatment, or as a preplant incorporated soil application to

sweet potato. Previously reviewed residue data from field trials conducted in/on potatoes were reassessed in the framework of this application.

### Maximum Residue Limits (MRLs)

The recommendation for the maximum residue limits (MRLs) for broflanilide was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of broflanilide in/on crops and processed commodities are shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the MRLs for the raw agricultural commodities (RACs).

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Head Lettuce	Foliar / 48-52	1	0.006	1.036	---	---	4.0
Leaf Lettuce	Foliar / 50	1	0.328	1.232	---	---	
Spinach	Foliar / 49-51	1	0.417	2.190	---	---	
Mustard Greens	Foliar / 50-53	1	0.365	2.400	---	---	
Broccoli	Foliar / 49-53	1	0.004	0.445	---	---	0.7
Cabbage	Foliar / 50-53	1	0.008	0.250	---	---	
Dry soybeans	Foliar / 48-53	14	0.001	0.052	Refined oil: 0.11x Flour: 0.03x Soy milk: 0.02x	---	0.07
Tomatoes	Foliar / 49-52	1	0.002	0.076	Tomato paste: 2.2x Tomato purée: 0.7x Tomato juice: 0.2x Dried tomatoes: 6.8x	---	0.15 0.2 (tomato paste) 0.6 (dried tomatoes)
Bell Pepper	Foliar / 44-52	1	0.006	0.056	---	---	
Non-Bell Pepper	Foliar / 49-52	1	0.035	0.058	---	---	
Celery	Foliar / 49-50	1	0.065	1.001	---	---	1.5

ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, the MRLs in Table 1 are recommended to cover residues of broflanilide. Dietary risks from exposure to residues of broflanilide in these crop commodities at the recommended MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults, and seniors. Thus, the foods that contain residues as listed in Table 1 are considered safe to eat.

## **Environmental Assessment**

Cimegra Insecticide is currently registered for in-furrow application to control certain below ground chewing insect pests, such as wireworm and corn rootworm, in corn and potato. Broflanilide is also registered as a seed treatment in small cereal grains. For details regarding the original registration of the active ingredient and end-use products, refer to [PRD2020-06, Broflanilide, Cimegra, Teraxxa and Teraxxa F4](#) and [RD2020-16, Broflanilide, Cimegra, Teraxxa and Teraxxa F4](#).

The maximum annual rate of application for the new crop uses (50 g a.i./ha) is twice what is currently registered (25 g a.i./ha); however, application rates and methods vary amongst the new crops. The new foliar application is also outside the currently registered methods of application. Consequently, a revised environmental risk assessment was required to assess risks from the new uses, and to address newly submitted ecotoxicity studies. A summary of the environmental risk assessment conclusion and risk management measures is provided as follows:

When broflanilide is used according to the label directions, the risks to the environment have been determined to be acceptable.

Broflanilide enters the environment when applied as a foliar, soil or seed treatment to control specified insect pests on labelled crops. Cimegra will be used on labelled fruit and vegetable crops as a foliar or soil application. Broflanilide is persistent in soil, but is not expected to move through the soil and reach groundwater because it binds strongly to soil. In water bodies, it will move to sediments where it may remain. Broflanilide is not expected to be found in the air or to travel long distances from where it was applied. It is not expected to build-up in the tissues of organisms. It is not systemic and its residues will remain mostly where applied, in the soil or in leaves. It can move across leaf tissue after a foliar application (from one side of the leaf to the other), otherwise known as translaminar movement.

When used according to the label directions, broflanilide does not present a risk of concern to wild mammals, birds, soil-dwelling organisms, terrestrial and aquatic plants, fish, or amphibians. Exposure to broflanilide may affect aquatic invertebrates if they are exposed to high enough levels; therefore, precautionary label statements, spray drift buffer zones, and mandatory vegetative filter strips are required for the protection of aquatic organisms. Precautionary label statements, application timing restrictions during bloom for pollinator-attractive crops, and best management practices are also required for beneficial insects and pollinators to minimize potential exposure during applications. These statements are present on the product label.

### **Value Assessment**

Value information submitted included 51 field trials and scientific rationales to extrapolate from currently registered uses of Cimegra and from data submitted on certain crops and pests to other crops and pests. The results of the field trials, taking into account the scientific rationales, were sufficient to support a claim that Cimegra will control diamondback moth, cabbage looper, imported cabbageworm and flea beetle in brassica head and stem vegetables; Colorado potato beetle, tomato hornworm, and tobacco hornworm in fruiting vegetables; diamondback moth, cabbage looper, imported cabbageworm, flea beetle and red-headed flea beetle in leafy and leaf petiole vegetables; Colorado potato beetle in potatoes; and soybean looper, bean leaf beetle, and

adult Japanese beetle in soybean when applied at rates of 125.0-187.5 mL/ha (12.5-18.75 g a.i./ha) as a foliar insecticide treatment, up to two applications with a 7-day interval. The value information was also sufficient to support a claim that Cimegra will control wireworms in sweet potatoes when applied at a rate of 250 mL/ha (25 g a.i./ha) with one application per season as a pre-plant incorporated and with a minimum application volume of 50 L per ha.

Broflanilide is a novel chemistry for the control of chewing pests in horticultural crops and soybean and will offer a new option for chewing pest management. Cimegra will also provide value to growers as an insecticide with a new mode of action when incorporated into current pest management programs to aid in insecticide resistance management. This label expansion will provide Canadian growers with an additional product for managing the listed insects.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the expansion of use to include pre-plant application to sweet potatoes as well as foliar application to listed vegetables on the Cimegra label.

## References

PMRA Document Number	Reference
3335241	2020, Magnitude and Decline of Broflanilide Residues Following Applications of BAS 450 I to Fruiting Vegetables (Crop Group 8), DACO: 7.4.1,7.4.2
3335245	2017, Magnitude of the residue of BAS 450 I after applications of BAS 450 00 I to leafy vegetables, DACO: 7.4.1,7.4.2
3335246	2017, Magnitude of the Residue of BAS 450 I After Applications of BAS 450 00 I to Legume Vegetables, DACO: 7.4.1,7.4.2
3335247	2017, Magnitude of the Residue of Broflanilide in Brassica Vegetables Following Applications of BAS 450 I, DACO: 7.4.1,7.4.2
3335252	2020, Magnitude of BAS 450 I Residues in Tomato Processed Fractions, DACO: 7.4.5
3335253	2017, Magnitude of the Residue of BAS 450 I In Legume Vegetables Process Fractions Following Treatment With BAS 450 00 I, DACO: 7.4.5
3335697	2022, 10.2.3.3 Efficacy: Small-Scale Trials (Field) and 10.3.2 Non-Safety Adverse Effects (eg. To Crop): Field Data Trials, DACO: 10.2.3.3,10.3.2
3335699	2022, Summary Tables - Brassica Veg, DACO: 10.2.3.1,10.3.1
3335703	2022, CIMEGRA as an insecticide for foliar use in brassica vegetables, fruiting vegetables, leafy vegetables, leaf petiole vegetables, potato, and soybean; and CIMEGRA as an insecticide for pre-plant incorporated use in sweet potato, DACO: 10.1,10.2,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.3,10.3.1,10.3.2,10.3.3,10.4,10.5, 10.5.2,10.5.3,10.5.4,10.5.5
3335705	2022, Survey of Alternatives, DACO: 10.5.1
3335708	2022, Efficacy Tables - Early Formulation Trials, DACO: 10.2.3.1,10.3.1
3335709	2022, Efficacy Summary Tables - Fruiting Veg, DACO: 10.2.3.1,10.3.1
3335711	2022, Efficacy Summary Tables - Leaf Petiole Veg, DACO: 10.2.3.1,10.3.1
3335713	2022, Efficacy Summary Tables - Potato, DACO: 10.2.3.1,10.3.1
3335715	2022, Efficacy Summary Tables - Soybean, DACO: 10.2.3.1,10.3.1
3335718	2022, Efficacy Summary Tables - Sweet Potato, DACO: 10.2.3.1,10.3.1
3335259	2017, Acute toxicity of BAS 450 06 I to the earthworm Eisenia andrei in artificial soil with 10 % peat, DACO: 9.2.3.1
3335260	2017, Acute toxicity of BAS 450 06 I to the earthworm Eisenia andrei in artificial soil with 10 % peat, DACO: 9.2.3.1
3335261	2017, Acute toxicity of BAS 450 06 I to the earthworm Eisenia andrei in artificial soil with 10 % peat, DACO: 9.2.3.1
3335262	2017, Acute toxicity of BAS 450 06 I to the honeybee Apis mellifera L. under laboratory conditions, DACO: 9.2.4.1
3335263	2017, Acute toxicity of BAS 450 06 I to the honeybee Apis mellifera L. under laboratory conditions, DACO: 9.2.4.1
3335264	2017, Acute toxicity of BAS 450 06 I to the honeybee Apis mellifera L. under laboratory conditions, DACO: 9.2.4.1
3335265	2017, Acute toxicity of BAS 450 06 I to the honeybee Apis mellifera L. under laboratory conditions, DACO: 9.2.4.1
3335266	2017, Amendment No. 1 to Final Report - Acute toxicity of BAS 450 06 I to the honeybee Apis mellifera L. under laboratory conditions, DACO: 9.2.4.1

<b>PMRA Document Number</b>	<b>Reference</b>
3335267	2017, Determination of Side-Effects of BAS 450 00 I (100 g/L Broflanilide, Reg No. 5672774) on Honey Bees ( <i>Apis mellifera</i> L.) in the Semi-Field Study after Two Pre-Flowering Applications on Winter Oilseed Rape ( <i>Brassica</i> sp.), DACO: 9.2.4.6
3335268	2017, Determination of Side-Effects of BAS 450 00 I (100 g/L Broflanilide, Reg No. 5672774) on Honey Bees ( <i>Apis mellifera</i> L.) in the Semi-Field Study after Two Pre-Flowering Applications on Winter Oilseed Rape ( <i>Brassica</i> sp.), DACO: 9.2.4.6
3335269	2017, Determination of Side-Effects of BAS 450 00 I (100 g/L Broflanilide, Reg No. 5672774) on Honey Bees ( <i>Apis mellifera</i> L.) in the Semi-Field Study after Two Pre-Flowering Applications on Winter Oilseed Rape ( <i>Brassica</i> sp.), DACO: 9.2.4.6
3335270	2017, Determination of side-effects of BAS 450 00 I (100 g/L SC) on the honeybee <i>Apis mellifera</i> L after two pre-bloom applications (BBCH 45-59) on phacelia under semi-field conditions (tunnel test), DACO: 9.2.4.6
3335271	2017, Determination of side-effects of BAS 450 00 I (100 g/L SC) on the honeybee <i>Apis mellifera</i> L after two pre-bloom applications (BBCH 45-59) on phacelia under semi-field conditions (tunnel test), DACO: 9.2.4.6
3335272	2017, Determination of side-effects of BAS 450 00 I (100 g/L SC) on the honeybee <i>Apis mellifera</i> L after two pre-bloom applications (BBCH 45-59) on phacelia under semi-field conditions (tunnel test), DACO: 9.2.4.6
3335273	2018, Effects of BAS 450 00 I on the honey bee <i>Apis mellifera</i> L. under semi-field conditions (tunnel test), DACO: 9.2.4.6
3335274	2018, Effects of BAS 450 00 I on the honey bee <i>Apis mellifera</i> L. under semi-field conditions (tunnel test), DACO: 9.2.4.6
3335275	2018, Effects of BAS 450 00 I on the honey bee <i>Apis mellifera</i> L. under semi-field conditions (tunnel test), DACO: 9.2.4.6
3335276	2018, Effects of BAS 450 00 I on the honey bee <i>Apis mellifera</i> L. under semi-field conditions (tunnel test) with additional assessments on colony and brood development, DACO: 9.2.4.6
3335277	2018, Effects of BAS 450 00 I on the honey bee <i>Apis mellifera</i> L. under semi-field conditions (tunnel test) with additional assessments on colony and brood development, DACO: 9.2.4.6
3335278	2018, Effects of BAS 450 00 I on the honey bee <i>Apis mellifera</i> L. under semi-field conditions (tunnel test) with additional assessments on colony and brood development, DACO: 9.2.4.6
3335279	2017, Semi-field brood study to evaluate potential effects of BAS 450 00 I (100 g/L Broflanilide, Reg. No. 5672774) on brood development of honeybees ( <i>Apis mellifera</i> L.), DACO: 9.2.4.6
3335280	2017, Semi-field brood study to evaluate potential effects of BAS 450 00 I (100 g/L Broflanilide, Reg. No. 5672774) on brood development of honeybees ( <i>Apis mellifera</i> L.), DACO: 9.2.4.6
3335281	2017, Semi-field brood study to evaluate potential effects of BAS 450 00 I (100 g/L Broflanilide, Reg. No. 5672774) on brood development of honeybees ( <i>Apis mellifera</i> L.), DACO: 9.2.4.6

<b>PMRA Document Number</b>	<b>Reference</b>
3335618	2016, DETERMINATION OF RESIDUES OF BAS 450 00 I (A.I. REG NO. 5672774) IN BEE-RELEVANT MATRICES AFTER ONE PRE-FLOWERING APPLICATION IN A SEMI-FIELD HONEY BEE (APIS MELLIFERA L.) STUDY IN CANOLA (BRASSICA SP.), DACO: 9.2.4.8
3335623	2016, Determination of the Residues of BAS 450 00 I (100 g/L BAS 450 I, a.i. Reg No. 5672774) in Bee Relevant Matrices Collected from Tomatoes Following Two Pre-bloom Foliar Applications, DACO: 9.2.4.8
3335628	2016, DETERMINATION OF RESIDUES OF BAS 450 00 I (A.I. REG NO. 5672774) IN BEE-RELEVANT MATRICES AFTER ONE PRE-FLOWERING APPLICATION IN A SEMI-FIELD HONEY BEE (APIS MELLIFERA L.) STUDY IN CANOLA (BRASSICA SP.), DACO: 9.2.4.8
3335630	2016, DETERMINATION OF RESIDUES OF BAS 450 00 I (A.I. REG NO. 5672774) IN BEE-RELEVANT MATRICES AFTER ONE PRE-FLOWERING APPLICATION IN A SEMI-FIELD HONEY BEE (APIS MELLIFERA L.) STUDY IN CANOLA (BRASSICA SP.), DACO: 9.2.4.8
3335632	2016, Determination of the Residues of BAS 450 00 I (100 g/L BAS 450 I, a.i. Reg No. 5672774) in Bee Relevant Matrices Collected from Tomatoes Following Two Pre-bloom Foliar Applications, DACO: 9.2.4.8
3335634	2016, Determination of the Residues of BAS 450 00 I (100 g/L BAS 450 I, a.i. Reg No. 5672774) in Bee Relevant Matrices Collected from Tomatoes Following Two Pre-bloom Foliar Applications, DACO: 9.2.4.8
3335640	2018, Determination of Residues of BAS 450 I (Broflanilide; Reg No. 5672774) in Bee-Relevant Matrices after Two Pre-Flowering Applications of BAS 450 00 I (100g/L SC) in a Semi-Field Honey Bee ( <i>Apis mellifera</i> L.) Study in Canola ( <i>Brassica</i> sp.), DACO: 9.2.4.8
3335643	2018, A non-GLP Indicator Study to Determine Residues of BAS 450 I (Broflanilide; Reg No. 5672774) in Bee-Relevant Matrices after Two Pre-Flowering Applications of BAS 450 00 I (100g/L SC) in a Semi-Field Honey Bee ( <i>Apis mellifera</i> L.) Study in Soybean ( <i>Glycine max.</i> ), DACO: 9.2.4.8
3335654	2018, Determination of Residues of BAS 450 I (Broflanilide; Reg No. 5672774) in Bee-Relevant Matrices after Two Pre-Flowering Applications of BAS 450 00 I (100g/L SC) in a Semi-Field Honey Bee ( <i>Apis mellifera</i> L.) Study in Canola ( <i>Brassica</i> sp.), DACO: 9.2.4.8
3335656	2018, Determination of Residues of BAS 450 I (Broflanilide; Reg No. 5672774) in Bee-Relevant Matrices after Two Pre-Flowering Applications of BAS 450 00 I (100g/L SC) in a Semi-Field Honey Bee ( <i>Apis mellifera</i> L.) Study in Canola ( <i>Brassica</i> sp.), DACO: 9.2.4.8
3335658	2018, A rate-response laboratory test to evaluate the acute effects of fresh residues of BAS 450 06 I on the green lacewing, <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae), DACO: 9.2.5
3335661	2018, A rate-response laboratory test to evaluate the acute effects of fresh residues of BAS 450 06 I on the green lacewing, <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae), DACO: 9.2.5
3335662	2018, A rate-response laboratory test to evaluate the acute effects of fresh residues of BAS 450 06 I on the green lacewing, <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae), DACO: 9.2.5

<b>PMRA Document Number</b>	<b>Reference</b>
3335689	2017, MCI-8007 technical (Broflanilide) A laboratory test to determine acute effects on the larvae of the lacewing <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae), DACO: 9.2.5
3335693	2017, MCI-8007 technical (Broflanilide) A laboratory test to determine acute effects on spiders of the genus <i>Pardosa</i> (Araneae, Lycosidae), DACO: 9.2.5
3335701	2022, Broflanilide: Non-Target Arthropods (NTAs) Screening-level Risk Assessment and Off-Field Refinement for Foliar Submission in Canada, DACO: 9.9

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

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.