

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

**Application Number:** 2021-6503  
**Application:** New End-use Product (Product Chemistry) – Guarantee, Identity of Formulants, Proportion of Formulants  
**Product:** Bug Buster  
**Registration Number:** 35047  
**Active ingredient (a.i.):** Canola Oil  
**PMRA Document Number:** 3534469

### Purpose of Application

The purpose of this application was to register a new commercial product, Bug Buster, containing canola oil for use as an insecticide, acaricide, and fungicide on terrestrial food and feed crops, greenhouse food and non-food crops (including cannabis), indoor plants and platescapes, and outdoor ornamentals.

### Chemistry Assessment

Bug Buster is formulated as an emulsifiable concentrate containing canola oil at a concentration of 95%. This end-use product has a specific gravity of 0.9185 and pH of 5.48. The required chemistry data for Bug Buster have been provided, reviewed and found to be acceptable.

### Health Assessments

A detailed review of the toxicological database for Bug Buster was conducted. No guideline studies were submitted for review. The reviewed toxicological data for canola oil consisted of published scientific literature with conclusions of International food safety assessments for canola oil and regulatory decisions for canola oil's use as a pesticide active ingredient. The rationales were considered acceptable to adequately characterize the hazard profile of the end-use product. The database is complete.

Canola oil and its associated end-use product are of low toxicity by the oral, dermal and inhalation routes. Dermal and eye irritation studies for the end-use product were not submitted; however, based on the submitted information, concentrations of canola oil over 75% may cause dermal irritation but are not expected to be irritating to the eyes. Bug Buster is considered to be a skin irritant, but not an eye irritant. Canola oil is not expected to be a dermal sensitizer. For further information on the active ingredient see Proposed Registration Decision, PRD2016-24 Canola oil.

The methods of application, rate and frequency for Bug Buster are currently encompassed by the registered uses of the active ingredient. The formulants are not expected to contribute to the toxicity of the formulation.

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, however, the risk is acceptable provided workers follow label directions and use personal protective equipment (PPE) as instructed. Dermal exposure can be minimized if applicators, mixer/loaders, handlers workers wear a long-sleeved shirt, long pants, chemical-resistant gloves and socks and shoes.

Appropriate label statements and requirements for basic personal protective equipment and restricted entry will minimize exposure for individuals with repeated or prolonged exposure.

Label warnings, directions for use, and risk mitigation measures are adequate to protect users of Bug Buster. Overall, risks to workers are acceptable when the precautionary statements on the labels are followed, which include PPE.

Residential and non-occupational exposure to the end-use product is expected to be low when label directions are observed. Consequently, the risk to bystanders and individuals in residential areas and the general public is acceptable.

Residues of canola oil on treated food crops and cannabis or industrial hemp are possible at the time of harvest. Dietary risk to humans from the use of Bug Buster is acceptable due to the low toxicity profile of canola oil. Consumer exposure to remaining residues of Bug Buster on treated indoor grown cannabis are not expected to result in health risks of concern. In addition, the likelihood of residues contaminating drinking water supplies is minimal and not expected to contribute to increased dietary exposure. Therefore, the PMRA determined that a specification of a maximum residue limit (MRL) under the *Pest Control Products Act* is not required for canola oil (refer to Proposed Registration Decision: PRD2016-24 – Canola Oil).

The available information is sufficient to support the registration of Bug Buster when label directions are followed.

## **Environmental Assessment**

The environmental risks associated with the uses of Bug Buster are acceptable when used according to the label directions, which includes statements to mitigate risks to the environment.

## **Value Assessment**

To support these claims to control insect and mite pests and to suppress powdery mildew, the applicant submitted scientific reports and rationales. This scientific information was sufficient to support the efficacy of Bug Buster against aphids, mealybugs, mites, scales, whiteflies, adelgids (exposed stages only), psyllids, and phylloxerans (exposed stages only) on roses, flowering plants, some ornamental and shade trees or shrubs, cucurbit vegetables, fruiting vegetables, some cruciferous vegetables, onion, lettuce celery, chards, apple, pear, apricots, cherries, nectarines, peaches, plums, prunes, sour cherry trees, certain berry crops and grape, some nut trees, hops, alfalfa (animal feed) and indoor cannabis at 2% solution in a spray volume of 700-1900 L/ha. Overall, applications of Bug Buster or biologically comparable products, in accordance with use directions, reduced certain types of powdery mildew disease by at least 60%. Based on the available data and detailed precautions on the label, the risk of phytotoxicity is not of concern

when the product is applied according to label directions. Powdery mildew slows plant growth and reduces the yield and quality of food and feed crops and the aesthetic value of ornamental crops. Bug Buster will provide growers of these crops with an additional canola oil product that may be used to suppress species of powdery mildew that damage high-value horticultural crops in Canada.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Bug Buster.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
3299756	2021, Determination of the Accelerated Storage Stability and Corrosion Characteristics for Bug Buster, DACO: 3.4.1,3.5.10,3.5.14 CBI
3299759	2021, Determination of Physical State, Color, Odor, Density, pH, and Viscosity for Bug Buster, DACO: 3.5,3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI
3299760	2021, Determination of Flammability and Oxidation/Reduction Chemical Incompatibility for Bug Buster, DACO: 3.5.11,3.5.12,3.5.8 CBI
3340820	2022, DACO 3: Chemistry Requirements, DACO: 3.0,3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2,3.5,3.5.1, 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
3340823	2022, DACO 5.2 - use site descriptions, DACO: 5.2
3299765	2021, DACO 4: Toxicology, DACO: 4.1,4.6.1,4.6.3,4.6.4,4.6.5,4.6.6
3299767	2021, DACO 6: Metabolism/Toxicokinetic studies, DACO: 6.2
3405405	2022, Bug Buster Insecticide / Fungicide / Acaricide (canola oil) DACO 10 EFFICACY/VALUE Deficiency Response, DACO: 10.1,10.2.3.1,10.2.3.3
3405406	2022, Bug Buster EFFICACY Table, DACO: 10.2.3
3405407	2022, Non-safety Adverse-effects Table PHYTO, DACO: 10.3.2
3405408	2022, Compilation of Canadian Pest Species, DACO: 10.6
3412748	2022, Bug Buster Compilation of trial reports, DACO: 10.6
3299770	2021, DACO 10: Value, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.4,10.3,10.3.2,10.5,10.5.1,10.5.2,10.5.3
3299773	Food Standards Australia New Zealand, 2003, Food Derived From Bromoxynil-Tolerant Canola Line Westar-OXY-235, DACO: 4.6,4.6.1
3299775	Cosmetic Ingredient Review, 2010, Vegetable Oils and Nut Oils, DACO: 4.6.4,4.6.5,4.6.6
3299777	Cosmetic Ingredient Review, 2015, Safety Assessment of Polysorbates as Used in Cosmetics, DACO: 4.6.3,4.6.5,4.6.6
3299779	EFSA Panel on Food Additives and Nutrient Sources added to Food, 2015, Scientific opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives, DACO: 4.6.1,4.6.4
3299782	Paul Gateau, Francois Van Dievoet, Vincent Bouillon, Georges Vermeersch, Sylvain Claude, Frederic Staat, 2005, Environmentally friendly properties of vegetable oil methyl esters, DACO: 4.6,4.6.1
3299786	NV Hendricks, H Collings MD, AE Dooley, JT Garrett, JB Rather Jr, 2013, A Review of Exposures to Oil Mist, DACO: 4.6,4.6.3

<b>PMRA Document Number</b>	<b>Reference</b>
3299790	Pal Magnusson, Michal Oczkowski, Johan Ovrevik, Malgorzata Gajewska, Jacek Wilczak, Jacek Biedrzycki, Katarzyna Dziendzikowska, Dariusz Kamola, Tomasz Krolkowski, Marcin Kruszewski, Anna Lankoff, Remigiusz Mruk, Gunnar Brunborg, Christine Instanes, Joanna Gromadzka-Ostrowska & Oddvar Myhre, 2017, No adverse lung effects of 7- and 28-day inhalation exposure of rats to emissions from petrodiesel fuel containing 20% rapeseed methyl esters (B20) with and without particulate filter - the Fuel Health project, DACO: 4.6.3
3299793	Julia K. Metz, Lara Scharnowske, Fabian Hans, Sabrina Schnur, Katharina Knoth, Horst Zimmer, Markus Limberger, Henrik Grob, Claus-Michael Lehr and Marius Hittinger, 2020, Safety Assessment of Excipients (SAFE) for Orally Inhaled Drug Products, DACO: 4.6.3
3299799	Oklahoma State University, 2021, Canola Oil: The Myths Debunked, DACO: 4.6,4.6.1
3299800	US Environmental Protection Agency, 1998, Canola Oil: Exemption from the requirement of a tolerance, DACO: 4.6,4.6.1,6.2
3340825	2022, DACO 7: Residue Data, DACO: 6.2,7.4,7.4.1,7.8
3340826	United States Environmental Protection Agency, 1998, EPA Exemption from requirement of tolerance, DACO: 7.4.1
3340827	Raphael O. Idem, Sai P. R. Katikaneni, and Narendra N. Bakhshi, 1996, Thermal Cracking of Canola Oil: Reaction Products in the Presence and Absence of Steam, DACO: 7.8

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