

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2021-6502
Application: New Technical Grade Active Ingredient Product Chemistry-New Source (Site) New Registrant
Product: Bug Buster TGAI
Registration Number: 35046
Active ingredient (a.i.): Canola oil
PMRA Document Number: 3500773

Purpose of Application

The purpose of this application was to register a new canola oil technical grade active ingredient, Bug Buster TGAI.

Chemistry Assessment

Common Name: Canola oil
 IUPAC* Chemical Name: Canola oil
 CAS† Chemical Name: Canola oil

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Bug Buster TGAI has the following properties:

Property	Result
Colour and physical state	Light yellow liquid
Nominal concentration	100%
Odour	Bland/pleasing odour
Specific gravity	0.85–0.90
Vapour pressure	6.2×10^{-4} mPa at (20 °C)
pH	N/A
Solubility in water	0.001 mg/L
n-Octanol/water partition coefficient	$\log P_{ow} = 23.3$ (pH 7, 20 °C)

The required chemistry data for Bug Buster TGAI have been provided, reviewed, and found to be acceptable.

Health Assessments

A detailed review of the toxicological database for Bug buster TGAI 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 TGAI. 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 TGAI 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 TGAI 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.

Residues of canola oil on treated food crops and cannabis or industrial hemp are possible at the time of harvest. Dietary risk to humans is acceptable due to the low toxicity profile of canola oil. Consumer exposure to remaining residues of canola oil 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 TGAI when label directions are followed.

An occupational exposure assessment was not required for this application.

Environmental Assessment

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

Value Assessment

A value assessment was not required for this application.

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 TGAI.

References

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3299733	2021, Chemistry Data Requirements - DACO 2.11, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI
3299734	2020, [PRIVACY Info removed] Canola Oil Information Sheet, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
3299735	2020, CoA for [PRIVACY Info removed] Canola Oil, DACO: 2.11.2,2.12.1,2.13.3,2.14,2.14.13,2.14.3,2.14.6
3299738	2021, Chemistry Requirements - DACO 2.13 and 2.14, DACO: 2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.14 CBI
3325975	University of Hertfordshire, 2021, Octanol/Water Partition Coefficient, DACO: 2.14.11
3325978	Mohammad E. Khosroshahi, 2018, Effect of Temperature on Optical Properties of Vegetable Oils Using UV-Vis and Laser Fluorescence Spectroscopy, DACO: 2.14.12
3340790	2022, DACO 2: Chemistry Requirements, DACO: 2.14.10,2.14.15,830.7000
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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
3299773	Food Standards Australia New Zealand, 2003, Food Derived From Bromoxynil-Tolerant Canola Line Westar-OXY-235, DACO: 4.6,4.6.1
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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

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3299790	Pal Magnusson, Michal Oczkowski, Johan Ovrevik, Malgorzata Gajewska, Jacek Wilczak, Jacek Biedrzycki, Katarzyna Dziendzikowska, Dariusz Kamola, Tomasz Krolikowski, 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
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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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