Proposed Re-evaluation Decision PRVD2022-05

1-Methylcyclopropene and Its Associated End-use Products

Consultation Document

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.info-arla@hc-sc.gc.ca

Canada

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Proposed re-evaluation decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

1-Methylcyclopropene is a plant growth regulator that inhibits production of ethylene, a plant hormone that promotes fruit ripening and senescence. It is used to preserve cut flowers and fruits (apples, bananas, pears and tomatoes) when applied as a post-harvest (in storage) use. It is also applied as a pre-harvest aid to apples, which delays ripening and prevents fruit drop. Currently registered products containing 1-methylcyclopropene are listed in Appendix I. This document presents the proposed regulatory decision for the re-evaluation of 1-methylcyclopropene.

When the current label directions are followed, the products are shown to have value, and potential risks to human health (occupational, dietary, residential and bystander) and the environment (aquatic and terrestrial organisms) are considered to be acceptable. Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of 1-methylcyclopropene, no additional risk mitigation measures are proposed by Health Canada. However, label updates are proposed to meet the current labelling standards (Appendix II).

Under the authority of the *Pest Control Products Act*, and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing 1-methylcyclopropene are acceptable for continued registration for sale and use in Canada, provided that the proposed updates to label directions (Appendix II) are in place. All products containing 1-methylcyclopropene registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation,[1] during which written comments and additional information may be submitted to PMRA Publications. The final re-evaluation decision will be published taking into consideration the comments and information received during consultation.

Next Steps

The public, including the registrants and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document[2], which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Other information

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on 1-methylcyclopropene (based on the Science Evaluation of PRVD2022-05). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room.

Additional Scientific Information

No additional data are required.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science evaluation

1.0 Human health assessment

1-Methylcyclopropene is a plant growth regulator. The available data indicates that 1-methylcyclopropene is rapidly absorbed and metabolized, and is considered to be of low acute toxicity by oral, dermal, and inhalation exposure routes. It is mildly irritating to skin and eyes, and it is not expected to cause dermal sensitization. Based on the toxicological data available, no reference values have been established for 1-methylcyclopropene, except for short-to intermediate-term inhalation exposure scenarios (Canada 2004), which was considered for the assessment of potential risk to post-application workers (post-harvest use).

1-Methylcyclopropene is registered for post-harvest use in storage rooms to preserve cut flowers and fruits (apples, bananas, pears and tomatoes). The product is applied in an enclosed and gas tight area. Potential applicator exposure to 1-methylcyclopropene is expected to be minimal as workers are not present during application (4-24 hours of treatment). There is a potential for inhalation exposure to workers re-entering areas treated with 1-methylcyclopropene prior to treatment completion. The margins of the exposure for post-application re-entering workers were considered acceptable after venting has occurred, and when workers wear protective eyewear (goggles or face shield), a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks (currently included on the labels). For early entry workers, a respirator is also required, and it is currently included on the labels. No additional occupational risk mitigation measures for post-harvest application scenarios are proposed. However, label update is proposed to meet the current labelling standard.

Exposure of workers to 1-methylcyclopropene from pre-harvest application (ground application equipment using in-line injector systems) in apple orchards is expected to be short- to intermediate-term in duration and to occur primarily by the dermal route, but incidental inhalation, oral, and eye exposure is also possible. The risk for workers due to exposure to 1-methylcyclopropene in the registered end-use product from mixing/loading, applying, clean-up, and maintenance of machinery is considered to be acceptable when the workers wear goggles or face shield, a long-sleeved shirt, long pants, chemical-resistant gloves, shoes, and socks. A restricted-entry interval (REI) of 4 hours is currently included on the label. Risk due to post-application exposure is minimal and acceptable, based on the volatility of the active ingredient and its use in an outdoor environment. If early re-entry is required, individuals are required to wear goggles or face shield, a long-sleeved shirt, long pants, chemical-resistant gloves, shoes, and socks. For pre-harvest application scenarios, no additional occupational risk mitigation measures are proposed. However, label update is proposed to meet the current labelling standard.

There are no domestic class products registered containing 1-methylcyclopropene. Therefore, residential exposure is not expected. There is a potential for inhalation exposure to bystanders during the outdoor commercial applications. Current end-use product label includes a standard spray drift label statement. On this basis, the bystander risk is considered to be acceptable. No additional mitigation measures are proposed.

Based on the current use pattern, the environmental fate characteristics, as well as the low toxicity profile of 1-methylcyclopropene, potential risk due to dietary exposure to food and drinking water is expected to be minimal. When the current label directions are followed, potential dietary risk is considered to be acceptable. No additional mitigation measures are proposed.

An MRL of 0.01 ppm (LOQ) for 1-methylcyclopropene on apples, pears, bananas and tomatoes was previously established. No changes to currently established MRLs are proposed. In the United States, tolerances for 1-methylcyclopropene are exempted.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Aggregate exposure to 1-methylcyclopropene is considered to be acceptable as there are no concerns for dietary exposure and non-occupational (bystander) exposures. No additional mitigation measures are proposed.

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify any information indicating that 1-methylcyclopropene shared a common mechanism of toxicity with other pest control products. Therefore, a cumulative assessment is not required at this time.

2.0 Environmental assessment

1-Methylcyclopropene is not expected to be persistent or bioaccumulated in the environment. It will readily volatilise from moist soil or water surfaces and will break down in air. 1-Methylcyclopropene does not cause harmful effects to birds, small mammals, bees, earthworms, terrestrial plants and aquatic organisms.

When applied as a post-harvest treatment of food and ornamental commodities in an enclosed storage area, no direct exposure of terrestrial and aquatic organisms to 1-methylcyclopropene is expected to occur. Thus, the potential risk to the environment from post-harvest applications is expected to be negligible. When applied as a pre-harvest treatment on apples, 1-methylcyclopropene is not expected to pose risks of concern to pollinators, non-target terrestrial and aquatic organisms due to its low toxicity and non-persistent nature in the environment.

Overall, given the currently registered use pattern and the low toxicity of 1-methylcyclopropene, the potential risk to non-target organisms and the environment is considered to be acceptable. Current label statements address environmental concerns and no additional mitigation measures are proposed. However, label updates are proposed to meet the current labelling standard (Appendix II).

1-Methylcyclopropene is not considered as a Track 1 substance as it does not meet all the Track 1 criteria as per the Toxic Substances Management Policy.

3.0 Value assessment

1-Methylcyclopropene is a plant growth regulator that inhibits production of ethylene, which causes flower and foliage senescence (on cut flowers), and fruit ripening. Thus, the use of 1-methylcyclopropene on fruits and ornamentals is expected increase product shelf life and reduce storage losses. It also has significant value to the floral industry as maintaining flower and foliage quality is critical to consumer's acceptance.

4.0 Incident reports

As of 20 September 2021, no human or environmental incident reports involving 1-methylcyclopropene have been reported to Health Canada.

Appendix I Pest control products containing 1-Methylcyclopropene

Table 1 Registered end-use products containing 1-Methylcyclopropene[1]

Registration number	Class	Registrant	Product name	Formulation type	Guarantee
27777	Technical	Agrofresh Inc.	1-Methylcyclopropene (1-MCP) Technical	Gas	97.2%
33071	Technical	Janssen Pharmaceutica NV	Fysium Technical	Gas	98.0%
33888	Technical	Fine Agrochemicals Limited	Fine 1-MCP Technical	Gas	98.93%
32751	Manufacturing concentrate	Agrofresh Inc.	1-Methylcyclopropene MUP - HAIP	Wettable Powder	4.5%
27778	Commercial	Agrofresh Inc.	SmartFresh Technology	Dust Or Powder	3.3%
28438	Commercial	Agrofresh Inc.	EthylBloc Technology	Soluble Powder	0.14%
28569	Commercial	Agrofresh Inc.	SmartFresh Technology For Tomatoes	Dust Or Powder	3.3%
28781	Commercial	Agrofresh Inc.	SmartFresh SmartTabs	Tablet	0.63%
30872	Commercial	Agrofresh Inc.	SmartFresh ProTabs	Tablet	2.0%
31590	Commercial	Agrofresh Inc.	Ripelock Tabs 2.0	Tablet	2.0%
32752	Commercial	Agrofresh Inc.	Harvista 1.3 SC	Suspension	1.3%
33072	Commercial	Janssen Pharmaceutica NV	Fysium	Dust Or Powder	98%
33215	Commercial	Agrofresh Inc.	EthylBloc Sachet	Wettable Granules	0.014%
33261	Commercial	Agrofresh Inc.	Ethylene Buster Sachets	Wettable Granules	0.014%
34124	Commercial	Fine Agrochemicals Limited	Easyfresh	Powder	3.3%

[1] as of 13 December 2021, excludes discontinued products or products with a submission for discontinuation.

Appendix II –Label amendments

To meet current standards the following label amendments are proposed:

TGAI labels:

The following label statement should appear under DISPOSAL:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean-up of spills, contact the manufacturer and the provincial regulatory agency.

End-use product labels:

Not all labels have the required PPE, therefore, all end-use product labels must be updated to include the following PPE:

Wear goggles or face shield, chemical resistant gloves, a long-sleeved shirt, long pants, shoes and socks.

References

Published Information

PMRA number	Reference
-	Canada, 2004. Regulatory Note, REG2004-07, 1-Methylcyclopropene, September 2004.
-	Canada, 2007, Proposed Registration Decision, PRD2007-11, 1-Methylcyclopropene November 2007
-	Canada 2008, Registration Decision, RD2008-03, 1-Methylcyclopropene, March 2008
-	Canada, 2017, Proposed Registration Decision, PRD2017-06, 1-Methylcyclopropene, April 2017
-	Canada, 2017, Registration Decision, RD2017-11, 1-Methylcyclopropene, June 2017
-	US, 2015, Preliminary Work Plan and Summary Document, 1-Methylcyclopropene (1-MCP), PC Code: 224459, Case: 6075. EPA-HQ-OPP-2014-0670-0002.
-	US, 2020, Proposed Interim Registration Decision, 1-Methylcyclopropene (1-MCP), PC Code: 224459, Case: 6075. EPA-HQ-OPP-2014-0670-0006.
-	European Commission, 2019. Renewing the approval of the active substance 1-methylcyclopropene, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, and amending the Annex to Commission Implementing Regulation (EU) 2015/408. COMMISSION IMPLEMENTING REGULATION (EU) 2019/1085 of 25 June 2019
-	EFSA, 2018, Peer review of the pesticide risk assessment of the active substance 1-methylcyclopropene. APPROVED: 24 May 2018, doi: 10.2903/j.efsa.2018.5308
-	EFSA, 2019, Evaluation of confirmatory data following the Article 12MRL review for 1-methylcyclopropene, APPROVED: 9 December 2019, doi: 10.2903/j.efsa.2020.5963
-	EFSA, 2019, Final Renewal report for the active substance 1- methylcyclopropene finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 20 and 21 May 2019 in view of the renewal of the approval of 1-methylcyclopropene in accordance with Regulation (EC) No 1107/2009, SANTE/11631/2018 Rev 5
-	FAO Specifications and Evaluations for Agricultural Pesticides - 1-Methylcyclopropene