Proposed Re-evaluation Decision PRVD2021-11

Dried Blood and Its Associated End-use Products

Consultation Document

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Proposed Re-evaluation Decision

Under the *Pest Control Products Act*, all registered pesticides must be re-evaluated regularly by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to have value and meet current health and environmental safety standards. 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.

Dried blood is an outdoor animal repellent used against deer, elk, hares and rabbits to prevent feeding/browsing damage to established and seedling conifers, as well as outdoor ornamentals. Dried blood end-use products are formulated either as a soluble powder (to be mixed with water and applied by dipping or spraying using pressurized hand or backpack equipment) or as a ready-to-use solution. Currently registered products containing dried blood are listed in Appendix I.

Dried blood is a biological substance with a non-toxic mode of action and has value in providing a pest management solution. Based on the current use pattern of dried blood, dietary exposure to dried blood is not anticipated. The potential occupational, residential, and bystander risks are considered to be acceptable when products containing dried blood are used according to label directions. The potential environmental risk is considered acceptable when products containing dried blood are used according to label directions. As a result of re-evaluation, no additional mitigation measures are proposed, however, updates to standard label statements as per current labelling standards are proposed (Appendix II).

Under the authority of the *Pest Control Products Act* and based on an evaluation of available scientific information, Health Canada is proposing that products containing dried blood are acceptable for continued registration for sale and use in Canada, provided that the proposed updates to label directions are in place. This document presents the proposed regulatory decision for the re-evaluation of dried blood. All products containing dried blood registered in Canada are subject to this proposed re-evaluation decision.

Next steps

The public including the registrant and stakeholders are encouraged to submit comments and information on this proposed decision during the 90-day public consultation period[1] upon publication of this proposed re-evaluation decision.

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 PMRA's responses.

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

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

Additional scientific information

Additional scientific data are not required at this time.

Science evaluation

1.0 Human health assessment

Dried blood is a biological substance. It does not have a toxic mode of action and does not in itself present a toxicological concern. Health Canada has not established toxicological reference values for risk assessment and has used a qualitative approach to the human health risk assessment.

Dried blood is not registered in Canada for food or feed uses and contamination of drinking water sources is not expected. Therefore, acute and chronic dietary exposures to dried blood are not anticipated under the current conditions of use.

There is a potential for occupational and residential exposure to dried blood as a result of application of products containing dried blood to conifers (established and seedlings) and outdoor ornamental plants. For good occupational hygiene, the current commercial-class product labels require workers to wear personal protective equipment consisting of long pants, a long-sleeved shirt, and chemical-resistant gloves during mixing/loading and application activities. A restricted-entry interval is not required for dried blood. No additional mitigation measures are proposed. However, as per current labelling standards, an update to the standard label statement (personal protective equipment) is proposed (Appendix II). For good hygiene practice, the domestic-class product labels inform the user to wear gloves during applications. No additional mitigation measures are proposed. However, as per current labelling standards, an update to the recommended PPE is proposed to indicate that users should be wearing waterproof gloves (Appendix II). Overall, the occupational and non-occupational risks are considered acceptable when the products containing dried blood are used according to label directions.

Exposure to dried blood from food and drinking water is not anticipated and there are no concerns for residential exposure. On this basis, an aggregate assessment is not required.

The *Pest Control Products Act* requires that Health Canada consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, notwithstanding that dried blood has a non-toxic mode of action, the PMRA did not identify any information indicating that dried blood shared a common mechanism of toxicity with other pest control products. Therefore, a cumulative assessment is not required at this time.

2.0 Environment

Dried blood is registered for use as an animal repellent. It is a biological substance with a non-toxic mode of action. Use of dried blood under the current conditions of use is not expected to adversely affect the environment. No additional mitigation measures are proposed. However, an update to the standard label statements for the environment is proposed (Appendix II) to reflect current labelling standards. Dried blood is not considered as a Track 1 substance as it does not meet all of the criteria as per the Toxic Substances Management Policy.

3.0 Incident reports

As of 3 August 2021, the PMRA received no incident reports (human or environment) for dried blood.

4.0 Value assessment

Registered products containing dried blood have value and offer an alternative to conventional products for both commercial and domestic users to prevent feeding/browsing damage by deer, elk, rabbits and hares on conifers (established and seedlings) as well as outdoor ornamentals and shrubs.

Appendix I Registered products containing dried blood in Canada as of 3 August 2021[1]

Registration Number	Marketing Class[2]	Registrant	Product Name	Formulation Type	Guarantee
27410	T	Tree World Plant Care Products, Inc.	Plantskydd Dried Blood Technical Grade Active Ingredient	Solid	99.84%
27411	C	Tree World Plant Care Products, Inc.	Plantskydd Deer Repellent Soluble Powder Concentrate	Soluble Powder Concentrate	99.84%
27656	C	Tree World Plant Care Products, Inc.	Plantskydd Deer Repellent Pre-Mixed RTU Solution	Pre-Mixed RTU Formulation	16.7%
27413	D	Tree World Plant Care Products, Inc.	Plantskydd Deer Repellent Pre-Mixed RTU Solution	Pre-mixed RTU Solution	16.7%
27657	D	Tree World Plant Care Products, Inc.	Plantskydd Deer Repellent Soluble Powder	Soluble Powder	99.84%

[1] as of 3 August 2021, excluding discontinued products or products with a submission for discontinuation

[2] T- technical grade; C – commercial-class; D – domestic-class; RTU – ready-to-use

Appendix II Proposed label updates for products containing dried blood

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

I. For domestic-class products containing dried blood

i. Under the PRECAUTIONS section, replace the following statement

"For good hygiene practice, wear gloves when handling this product."

With

"For good hygiene practice, wear waterproof gloves when handling this product."

ii. Under DIRECTIONS FOR USE section, add the following:

"DO NOT apply to any body of water."

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

iii. Under the DISPOSAL section, add the following statement:

"Unused or partially used products should be disposed at provincially or municipally designated hazardous waste disposal sites."

iv. Under the STORAGE section, include the following statement:

"Store this product away from food or feed."

II. For commercial-class products containing dried blood

i. Under the PRECAUTIONS section, replace the following statement

"For good occupational hygiene, wear long pants, long-sleeved shirt, and chemically-resistant gloves during mixing, loading, application, and clean-up and repair."

With

"For good hygiene practice, wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair."

ii. Under DIRECTIONS FOR USE, add the following:

"DO NOT apply to any body of water."

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

iii. Under the STORAGE section, include the following statement

"Store this product away from food or feed."

References

PMRA#	Reference
655634	Canada, 2003a. Proposed Regulatory Decision Document PRDD2003-01, Dried Blood. Pest Management Regulatory Agency. February 11, 2003.
665072	Canada, 2003b. Regulatory Decision Document PRDD2003-03, Dried Blood. Pest Management Regulatory Agency. February 11, 2003.
2700531	Canada, 2016. Evaluation Report for Category B, Subcategory 3.11, 3.12. Application Number: 2015-1803. Pest Management Regulatory Agency.
2700527	Canada, 2016b. Evaluation Report for Category B, Subcategory 3.11, 3.12. Application Number: 2015-1802. Pest Management Regulatory Agency.