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Proposed Re-evaluation Decision

PRVD2022-11

Putrescent Whole Egg Solids 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 meet health and environmental safety standards and continue to have value. The re-evaluation considers data and information from various sources such as information from pesticide manufacturers, incident reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods, risk management approaches and policies to all re-evaluations.

This document presents the proposed regulatory decision for the re-evaluation of putrescent whole egg solids, including any proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based.

Putrescent whole egg solids is an outdoor animal repellent and feeding deterrent to protect a variety of non-edible plants, trees, and shrubs. A commercial-class product (formulated as a paste) can be applied via handheld equipment, backpack sprayers, pressurized tanks, and spray boom on commercial sites – including nurseries, greenhouses, and forestry plantations. Domestic-class products can be applied using handheld and backpack sprayers (paste formulation) or shaker duster (powder formulation) to deter deer, or as tulip bulb dip to repel squirrels. Currently registered products containing putrescent whole egg solids are listed in Appendix I.

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. Putrescent whole egg solids is a biopesticide with a non-toxic mode of action and has value in providing a pest management solution. Based on the current use pattern of putrescent whole egg solids, dietary exposure is not anticipated. The potential risks to human health (occupational, residential, and bystander) and environment are considered acceptable when products containing putrescent whole egg solids are used according to the proposed label directions. Proposed label amendments include standard personal protective equipment requirements for workers, restrict entry into treated areas until sprays have dried, a standard drift statement, waterproof gloves for domestic class products, a warning statement to protect aquatic habitats on all product labels, and additional label updates to clarify use sites and use instructions. As a result of re-evaluation, mitigation measures and updates to standard label statements are proposed (Appendix II).

Under the authority of the *Pest Control Products Act* and based on an evaluation of currently available scientific information, products containing putrescent whole egg solids (Appendix I) are being proposed for continued registration in Canada, with the proposed updates to label directions (Appendix II).

All products containing putrescent whole egg solids 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 the consultation period.

Next steps

The public, including the registrant and stakeholders, are encouraged to submit written comments and additional information during the 90-day public consultation period 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 Health Canada's responses.

Other information

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on putrescent whole egg solids (based on the Science Evaluation of PRVD2022-11). 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

Additional scientific data are not required at this time.

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*.

Science evaluation

1.0 Human health assessment

Putrescent whole egg solids 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 assess risks to human health. Since eggs are known to cause allergic reactions in certain sensitive individuals, putrescent whole egg solids end-use products are assumed to be a potential sensitizer, and appropriate warning and precautionary statement are present on all currently registered product labels. See PACR2004-02 and Application Number 2007-4749 Evaluation Report for further details.

There is a potential for occupational exposure as a result of workers mixing the paste end-use product, loading and applying the resulting solution as a spray to outdoor and greenhouse ornamental plants, or when re-entering treated site. Based on the toxicological profile, dermal and inhalation risk is not of concern for occupational exposure. However, there is currently no requirement for personal protective equipment or re-entry interval on the commercial-class label. Thus, label updates to require workers to wear a long-sleeved shirt, long pants, waterproof gloves, socks and shoes during mixing, loading, application, and clean-up and repair, and a label statement to restrict entry into the treated areas until sprays have dried is proposed. Further, bystander exposure is possible from spray drift. As such, a standard drift label statement is proposed for the commercial class product to limit exposure potential. Therefore, risks to workers and bystanders are considered acceptable when the commercial product containing putrescent whole egg solids is used according to the proposed label directions (Appendix II).

There is a potential for residential exposure to putrescent whole egg solids as a result of users mixing the domestic-class paste product with water and then either applying the resulting solution as a spray to conifers (established and seedlings) and outdoor ornamental plants, or by dipping tulip bulbs in the resulting solution prior to planting them. There is also a potential for dermal and inhalation exposure for users while applying the ready-to-use powder formulation by shaker duster to ornamental plants. Based on the toxicological profile, dermal and inhalation risk is not of concern from residential uses. There is currently no requirement for personal protective equipment on the domestic-class labels, however, for good hygiene practise, waterproof gloves is proposed to reduce potential exposure (Appendix II).

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). Putrescent whole egg solids is not registered in Canada for food or feed uses and contamination of drinking water sources are not anticipated. Thus, under the current condition of use, dietary exposure (food and drinking water) is not expected and potential residential risk is acceptable. 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. While putrescent whole egg solids may share a common moiety with other fatty acid-based active ingredients, the potential risks from

cumulative exposure to putrescent whole egg solids and other fatty acid-based pest control products are acceptable given the inherent low toxicity profile of putrescent whole egg solids. Therefore, a cumulative assessment for putrescent whole egg solids is not required at this time.

2.0 Environment assessment

Putrescent whole egg solids are registered for use as an animal repellent. It is a biological substance with a nontoxic mode of action. Under the current conditions of use, putrescent whole egg solids will biodegrade quickly; hence, it is not expected to adversely affect the environment. Label updates for the protection of aquatic habitats are proposed to reflect current labelling standards (Appendix II).

Putrescent whole egg solids 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 7 February 2022, one American domestic animal incident (death) involving putrescent whole egg solids had been reported to the PMRA. Based on the information provided, it was considered unlikely that the effects resulted from the exposure and therefore no health concerns associated with animal exposure to putrescent whole egg solids were identified.

4.0 Value assessment

Putrescent whole egg solids is an active ingredient, in pest control products, registered for use as a spray or pre-plant dip on trees and shrubs not grown for food or feed in nurseries, greenhouses, forestry plantations, and in residential outdoor settings to repel deer and elk. It is also registered as a pre-plant tulip bulb dip to repel squirrels. Putrescent whole egg solids products will provide an additional choice for deer, elk and squirrel repellent users to prevent feeding damage to the labelled plants.

Currently, the domestic-class paste product includes certain registered uses that are not appropriate for this label classification. As such, these uses are proposed to be removed. Further, label amendments are also proposed to improve the clarity of the label instructions (Appendix II).

Appendix I Registered products containing putrescent whole egg solids

Table 1 Registered products containing putrescent whole egg solids as of 22 February 2022³

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee (%)
29186	T	Woodstream Canada Corporation	Safer's Putrescent Whole Egg Solids Technical	Solid	100%
17667	C	Woodstream Canada Corporation	Deer-Away Big Game Repellent Concentrate 2103	Paste	37%
17955	D	Woodstream Canada Corporation	Deer-Away Big Game Repellent Concentrate 2103	Paste	37%
23455	D	Woodstream Canada Corporation	Horti-Kure Squirrel Repellent Concentrate 2103	Paste	37%
18122	D	Woodstream Canada Corporation	Deer-Away Big Game Repellent Powder BGR-P	Powder	36%

T = Technical grade; C = Commercial class; D = Domestic class

³ As of 22 February 2022, excluding discontinued products or products with a submission for discontinuation.

Appendix II Proposed label updates for products containing putrescent whole egg solids

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 putrescent whole egg solids:

- i. Under the PRECAUTIONS section, add the following statements:

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

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

“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, add or amend with the following:

“Store this product away from food or feed.”

II. For the commercial-class product containing putrescent whole egg solids:

- i. Under the PRECAUTIONS section, add the following statements:

“Wear a long-sleeved shirt, long pants, waterproof gloves, socks and shoes during mixing, loading, application, and clean-up and repair.”

“DO NOT enter or allow worker entry into treated areas until sprays have dried.”

“Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”

- ii. Under DIRECTIONS FOR USE, add the following statements:

“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. Label amendments are proposed to improve the clarity of the label instructions.

This includes but is not limited to:

- i. The principal display panel must reflect all the use locations (where to apply), that are stated in the DIRECTIONS FOR USE in the secondary panel of the label. For example, this product may be used to treat the following outdoor ornamental shrubs: Yew, Honeysuckle, Flowering Crab and the following conifer seedlings in outdoor nurseries and greenhouses: Scotch pine, Arborvitae, Douglas fir and Hemlock.
- ii. Locations of use must clearly be identified on the label and reflect the registered use-site categories. For example, use-site categories 4, forested areas and trees grown for use in forestry industry, including, but not limited to plantations and forest nurseries (for example, conifers seedlings of Scotch Pine, Arborvitae, Douglas Fir and Hemlock in established plantations and use-site categories 32 and 6: Conifer seedlings outdoors in nurseries and in greenhouses).
- iii. Nurseries and plantations are commercial sites therefore remove any reference and directions for use for nurseries and plantations on domestic labels.
- iv. Where there is a potential of damage, non-safety adverse effects statements should be added such as “It is advisable to treat a small portion of plants to determine if damage will occur.”
- v. Refer to the following PMRA regulatory policies and guidelines listed below for more details on the required labelling elements for pesticide products: Checklist of Labelling Requirements and LPS2011-02, Guidance to Improve Statements on Labels of Domestic Class Products.
- vi. For all uses on the labels, update the DIRECTIONS FOR USE to clearly state each of the following: locations of use (for example, conifer seedlings: Scotch pine, Arborvitae, Douglas fir, Hemlock in greenhouses); claims (for example, repels black-tailed deer, white-tailed deer, Roosevelt elk); timing of first application (for example, prior to out planting), and each of the additional applications (for example, re-spray before lifting if more than 6 weeks have elapsed between first application and lifting of stock); application rates for each use (for example, volume of diluted product/plant, including quantity of plants and size of plants treated); number of applications; minimum re-application interval expressed in days; and any limitations and restrictions.
- vii. Ensure that any use directions on the label are not contradictory. For example, application timing states for “dormant use only” however, general directions indicate “apply upon the onset of browsing, but preferably after bud break and before new shoots exceed 25 mm in length”.

- viii. Vague statements must be deleted or amended. For example, “recommended plants” the word “recommended” must be removed and “large greenhouses” be changed to “greenhouses”.

References

PMRA document number	Reference
697327	Canada, 2004. Proposed Acceptability for Continuing Registration PACR2004-02. Re-evaluation of Putrescent Whole Egg Solids. 15 March 2004.
1036966	Canada, 2005. Re-evaluation Decision Document. RRD2005-07. Putrescent Whole Egg Solids. 6 May 2005.
1764085	Canada, 2009. Evaluation Report for Category B, Subcategory 1.1, Application Number 2007-4749. Safer's Putrescent Whole Egg Solids Technical, Registration Number 29186.