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Proposed Re-evaluation Decision

PRVD2023-04

***Agrobacterium radiobacter* strain K84 and Its Associated End-use Product**

Consultation Document

(publié aussi en français)

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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 *Agrobacterium radiobacter* strain K84.

Agrobacterium radiobacter strain K84 is a naturally occurring soil-dwelling, gram-negative, short-rod aerobic bacterium used as a bactericide to control crown gall disease on seeds and nursery stock of stone fruit, pome fruit, berries, tree nuts, ornamental flowers, shrubs and trees as well as grapes and hops. The mode of action of *Agrobacterium radiobacter* strain K84 is through direct competition that is primarily facilitated by the production of a bacteriocin specific against certain pathogenic strains of *Agrobacterium* spp.

There is one Commercial Class end-use product containing *Agrobacterium radiobacter* strain K84 registered in Canada (Appendix I). The product is formulated as a live organism in damp powder and is mixed with water then applied to seeds, seedlings and cuttings (rootstock and rooted) at planting as a dip treatment only, before potential exposure to the disease. It acts as a preventative treatment and therefore is applied at a high application rate to protect any wound sites against pathogenic invasion.

Agrobacterium radiobacter strain K84 is of value to commercial nursery growers as it is the only pesticide registered to prevent crown gall disease in plants. The potential risks to human health (occupational, residential, bystander and dietary) and the environment are considered to be acceptable when the product containing *Agrobacterium radiobacter* strain K84 is used according to current label directions.

Under the authority of the *Pest Control Products Act* and based on an evaluation of currently available scientific information, the product containing *Agrobacterium radiobacter* strain K84 (Appendix I) is being proposed for continued registration in Canada with the proposed label updates (a best practice statement and a label amendment to meet the current labelling standards, as outlined in Appendix II). Proposed label changes include amending the existing personal protective equipment statement and adding a precaution statement for children and animals.

The product containing *Agrobacterium radiobacter* strain K84 registered in Canada is 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.

Additional scientific information

Additional scientific data are not required.

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

Agrobacterium radiobacter strain K84, also classified as *Agrobacterium tumefaciens* strain K84, is non-pathogenic to humans and animals. It is considered to be of low acute toxicity via the oral, dermal and pulmonary routes and is moderately irritating to the eyes. There were no treatment related signs of toxicity or pathogenicity via several routes of exposure (USEPA, 2012).

Agrobacterium radiobacter strain K84 is applied as a dip treatment to the seeds, seedlings and rootstock cuttings of various nursery plants by trained nursery personnel only. Potential dermal exposure may occur during mixing/loading/applying and potential inhalation exposure may occur during mixing/loading (USEPA, 2012). The current label states that personal protective equipment (PPE) including a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter are required to minimize exposure and protect handlers, mixers/loaders and applicators. Post-application exposure is not expected and a re-entry interval is not required based on the current use pattern as the seeds, seedlings or cuttings are planted immediately after treatment. No further mitigation measures are proposed. However, label amendment will be required to update to current labelling standard (Appendix II).

Bystander exposure from dip treatment application is expected to be minimal and there are no registered domestic class products containing *Agrobacterium radiobacter* strain K84. Direct residential exposure is not expected as the product label states it is to be used by trained nursery personnel. Therefore, the risks from non-occupational exposure to *Agrobacterium radiobacter* strain K84 are acceptable. As a result of this re-evaluation, a best practice statement to keep treated seeds away from children and animals is proposed. No additional mitigation measures are proposed.

The end-use product registered in Canada, Dygall, is used only for treatment of seeds and nursery stock and a dietary exposure assessment is not required. Dietary exposure from consumption of commodities treated with *Agrobacterium radiobacter* strain K84 was not expected for the current registered uses and is not expected in drinking water (USEPA, 2012). No additional mitigation measures are proposed and the specification of a maximum residue limit (MRL) is not required for *Agrobacterium radiobacter* strain K84.

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. *Agrobacterium radiobacter* strain K84 is a naturally occurring bacterium and is considered to be of low toxicity by the oral, pulmonary, and dermal routes. The end-use product is used as a treatment on plant seeds and roots and will not be directly applied to food crops or drinking water. Furthermore, non-occupational exposure is not expected when the end-use product is used as directed on the label. Therefore, there is reasonable certainty that no harm will result from aggregate exposure of residues of *Agrobacterium radiobacter* strain K84 from the uses of the end-use product.

The *Pest Control Products Act* requires that the Health Canada considers the cumulative exposure to pesticides with a common mechanism of toxicity. In its assessment of common mechanism of toxicity, Health Canada considers both the taxonomy of microbial pest control agents (MPCAs) and the production of any potentially toxic metabolites. For the current re-evaluation, Health Canada has determined that *Agrobacterium radiobacter* strain K84 does not share a common mechanism of toxicity with other registered MPCAs. Consequently, no cumulative effect from exposure with other related MPCAs is anticipated and a cumulative assessment is not required at this time.

2.0 Environment

Agrobacterium radiobacter strain K84 is a naturally occurring soil dwelling bacterium in the environment (USEPA, 2012). *Agrobacterium radiobacter* strain K84 is also specific to the target pest of crown gall bacteria and is not known or expected to be infective or to cause toxicity or pathogenicity in non-target organisms.

Environmental exposure to non-target organisms is not expected to exceed natural background levels based on the current registered use as a dip treatment for seeds and roots since the application is restricted to the area immediately on or around the plant (USEPA, 2012), and therefore, potential risks to the environment is considered to be acceptable.

Agrobacterium radiobacter strain K84 does not meet the Track 1 criteria because the active ingredient is a biological organism and hence not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products.

3.0 Incident reports

As of June 2023, no human, domestic animal or environmental incidents involving *Agrobacterium radiobacter* strain K84 have been reported to Health Canada.

4.0 Value assessment

Agrobacterium radiobacter is a bacterium that occurs naturally in many types of soils near plant roots. *Agrobacterium radiobacter* strain K84 is used as a bactericide to preventatively treat seeds and nursery stock from infection by crown gall bacteria. Crown gall disease can reduce plant growth and vigor and can ultimately lead to plant death. Preventing infection at planting, prior to potential exposure is the best method of control. *Agrobacterium radiobacter* strain K84 is of value to commercial nursery growers as it is the only pesticide registered to prevent crown gall disease in plants.

Appendix I Registered products containing *Agrobacterium radiobacter* strain K84 in Canada

Table 1 Registered products containing *Agrobacterium radiobacter* strain K84 in Canada¹

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
21106	C	AGBIORESEARCH LTD.	DYGALL	Live organism	5E9 CFU/g

C = Commercial; CFU = Colony Forming Units

¹ As of 17 July 2023, excluding discontinued products or products with a submission for discontinuation.

Appendix II Proposed label updates for products containing *Agrobacterium radiobacter* strain K84

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

1. Under PRECAUTIONS section, update the personal protection equipment with:

“a long-sleeved shirt, long pants, protective eyewear (goggles), waterproof gloves, socks and shoes, and a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter when handling, mixing, loading, or applying the product, and during all clean-up/repair activities.”
2. Under PRECAUTIONS section, add the label statement as follows:

“KEEP TREATED SEED OUT OF REACH OF CHILDREN AND ANIMALS”

References

PMRA No.	Reference
3374525	USEPA, 2009. Agrobacterium Radiobacter strains K84/Kerr-84 and K1026 Registration Review. Registration Review Case: 4101
3374543	USEPA, 2012. Agrobacterium Radiobacter strains K84/Kerr-84 and K1026 Final Registration Review Decision. Registration Review Case: 4101