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Registration Decision

RD2012-32

Aureobasidium pullulans
strain DSM 14940
and
Aureobasidium pullulans
strain DSM 14941

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

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

Canada 

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Registration Decision for *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Aureobasidium pullulans* DSM 14940, *Aureobasidium pullulans* DSM 14941 and Blossom Protect, containing the technical grade active ingredients *Aureobasidium pullulans* strain DSM 14940 and strain DSM 14941, to control fire blight in pome fruits and suppression of fire blight in woody Rosaceae ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2012-17, *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941. This Registration Decision² describes this stage of the PMRA's regulatory process for *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-17. This decision is consistent with the proposed registration decision stated in PRD2012-17.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-17, *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in

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*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941?

Aureobasidium pullulans strains DSM 14940 and DSM 14941 are the active ingredients in the end-use product (EP), Blossom Protect. These strains of fungi are used as microbial pest control agents (MPCA) against fire blight caused by *Erwinia amylovora* in pome fruits and woody Rosaceae ornamentals. Both strains DSM 14940 and DSM 14941 of *A. pullulans* were originally isolated from apple leaves of an untreated apple plantation in Germany.

The two *A. pullulans* strains are living yeasts that compete against the fire blight pathogen for space and nutrients under the low pH of the spray solution provided by the citric acid buffer. The fire blight pathogen is not adapted to grow under a low pH environment.

Health Considerations

Can Approved Uses of *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941 Affect Human Health?

***Aureobasidium pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941 are unlikely to affect your health when Blossom Protect is used according to the label directions.**

People could be exposed to *A. pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941 when handling and applying Blossom Protect. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When spores of *A. pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941 were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science based MRLs to ensure that the food Canadians eat is safe.

Aureobasidium pullulans is a ubiquitous yeast-like fungus that is commonly found in the phyllosphere. The level of *A. pullulans* on pome fruit is not expected to significantly increase due to the application of Blossom Protect, since it is found in the phyllosphere at concentrations comparable to the application rate. Any increase that may occur in the population of *A. pullulans* is expected to return to natural levels at the time of harvest since application of Blossom Protect is to be made during bloom. Furthermore, when *A. pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941 were administered orally to rats, no signs of toxicity or disease were observed, and no metabolites of toxicological significance have been shown to be produced by this or other strains of *A. pullulans*. Therefore, the establishment of a MRL is not required for *A. pullulans* strain DSM 14940 or *A. pullulans* strain DSM 14941. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling Blossom Protect

Occupational risks are not of concern when Blossom Protect is used according to label directions, which include protective measures.

Growers handling Blossom Protect can come into direct contact with *A. pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941 on the skin, in the eyes or by inhalation. For this reason, the product labels specify that growers exposed to Blossom Protect must wear waterproof gloves, coveralls, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941 are Introduced into the Environment?

Environmental risks are not of concern.

The active ingredients contained in Blossom Protect, *A. pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941, are individual isolates of the species *A. pullulans* which is a ubiquitous yeast-like organism. Following application, levels of *A. pullulans* DSM strain 14940 and *A. pullulans* strain DSM 14941 in the environment are comparable to observable levels of naturally occurring *A. pullulans*. Since naturally occurring background levels of *A. pullulans* vary, levels may temporarily increase after application, however, it is expected that the population of *A. pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941 would return to the site specific natural background levels over the course of the growing season.

Studies were conducted to determine the effects of *A. pullulans* DSM 14941 on birds and of Blossom Protect (containing *A. pullulans* strain DSM 14940 and *A. pullulans* strain DSM 14941) on fish, bees, terrestrial and aquatic arthropods, and aquatic plants. These studies showed that *A. pullulans* DSM 14941 was not toxic or pathogenic to birds, and that Blossom Protect was not toxic or pathogenic to fish, bees, terrestrial and aquatic arthropods, or aquatic plants.

Although terrestrial non-arthropod invertebrate, plant, and aquatic non-arthropod invertebrate, and microorganism toxicity/pathogenicity testing were not assessed in the review, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected. The level of exposure to these non-target organisms from the application of Blossom Protect are expected to be comparable to exposures that could occur from natural populations of *A. pullulans*. Furthermore, a search of published scientific literature did not result in any reports of adverse effects to non-target organism from *A. pullulans*.

Value Considerations

What Is the Value of Blossom Protect?

***Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941, the active ingredients in Blossom Protect, control fire blight in pome fruits (bearing and non-bearing) and suppress fire blight in woody Rosaceae ornamentals.**

Blossom Protect, containing 2.5×10^9 CFU/g *A. pullulans* strain DSM 14940 and 2.5×10^9 CFU/g *A. pullulans* strain DSM 14941, is a product formulated as a crown treatment against fire blight in pome fruits (bearing and non-bearing) and in woody Rosaceae ornamentals. A citric acid buffer is included in the formulation to ensure a consistent low pH value, which is essential for the initial growth of the *A. pullulans* strains.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Blossom Protect to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

In individuals exposed to large quantities of Blossom Protect, respiratory and dermal sensitivity could possibly develop upon repeated exposure to the product since the end-use product has been identified as a sensitizer. Therefore, anyone handling or applying Blossom Protect must wear waterproof gloves, coveralls, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential. An additional risk reduction measure is a restricted entry interval for early-entry workers immediately following product application until sprays have dried. Workers may re-enter before sprays have dried if wearing appropriate personal protective equipment (PPE), including water-proof gloves, long-sleeved shirt, long pants, and shoes plus socks.

Environment

The end-use product label will include environmental precaution statements that prevent the contamination of aquatic systems from the use of Blossom Protect.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-17 - *Aureobasidium pullulans* strain DSM 14940 and *Aureobasidium pullulans* strain DSM 14941) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.