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Registration Decision

RD2015-14

Pasteuria nishizawae

Pn1

(publié aussi en français)

30 July 2015

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2015-14E (print version)
H113-25/2015-14E-PDF (PDF version)

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Registration Decision for *Pasteuria nishizawae* Pn1

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 *Pasteuria nishizawae* Technical and Clariva pn, containing the technical grade active ingredient *Pasteuria nishizawae* Pn1, to suppress soybean cyst nematode in soybean.

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 PRD2015-11, *Pasteuria nishizawae* Pn1. This Registration Decision² describes this stage of the PMRA's regulatory process for *Pasteuria nishizawae* Pn1 and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2015-11.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-11, *Pasteuria nishizawae* Pn1 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 humans (for example, children) as well as organisms in the environment. 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

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".

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 *Pasteuria nishizawae* Pn1?

Pasteuria nishizawae Pn1 is a mycelial and endospore-forming bacterium, naturally found in North American soils, which parasitizes the adult females of cyst-forming nematodes, such as the soybean cyst nematode (SCN - *Heterodera glycines*).

Health Considerations

Can Approved Uses of *Pasteuria nishizawae* Pn1 Affect Human Health?

***Pasteuria nishizawae* Pn1 is unlikely to affect your health when Clariva pn is used according to the label directions.**

People could be exposed to *P. nishizawae* Pn1 when handling and applying Clariva pn. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, infectivity cycle);
- 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 *Pasteuria nishizawae* Technical and Clariva pn 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 specified 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 specifies science-based MRLs to ensure that the food Canadians eat is safe.

Residues of *P. nishizawae* Pn1 are not expected on crops at the time of harvest following seed treatment. When *Pasteuria nishizawae* Technical and Clariva pn, which contain spores of *P. nishizawae* Pn1 as the active ingredient, were administered orally to rats, no signs of toxicity

or disease were observed. Dietary exposure is expected to be negligible and the likelihood of residues contaminating drinking water supplies is also considered to be negligible. Consequently, dietary risks are not of concern. Therefore, the PMRA has determined that the specification of an MRL under the *Pest Control Products Act* is not required for *P. nishizawae* Pn1.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

Clariva pn is used as a seed treatment on soybeans. Consequently, it is unlikely that adults, youths and toddlers will be exposed to *P. nishizawae* Pn1. Even in the event of exposure, risk to the general population is not of concern since there were no signs of disease or toxicity noted in mammalian toxicological studies conducted with the technical and end-use product.

Occupational Risks From Handling Clariva pn

Occupational risks are not of concern when Clariva pn is used according to label directions, which include protective measures

Workers handling Clariva pn can come into direct contact with *P. nishizawae* Pn1 on the skin, eyes and lungs. For this reason, the product label will specify that workers exposed to Clariva pn must wear waterproof gloves, long-sleeved shirts, long pants, shoes plus socks, and a NIOSH approved mist filtering mask or respirator with any N-95, P-95, or R-95 filter. Eye goggles are not required as the eye irritation studies submitted indicated no 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 *Pasteuria nishizawae* Pn1 Is Introduced Into the Environment?

Environmental risks are not of concern

Pasteuria nishizawae Pn1 is a spore producing bacterium that is ubiquitous in terrestrial soils, as are other members of the genus. The spores are expected to be stable in a wide range of environmental conditions and are host specific; they will only parasitize soybean cyst nematode.

Clariva pn is not intended for aquatic uses and exposure to aquatic environments is expected to be minimal.

Although non-target testing was not conducted, acceptable scientific rationales were used to determine that no significant adverse effects to non-target organisms are expected.

Value Considerations

What Is the Value of Clariva pn?

Clariva pn, containing *Pasteuria nishizawae* Pn1, is a soybean seed treatment product used for the suppression of soybean cyst nematode.

This microbial product provides an additional tool to be used in conjunction with existing integrated pest management strategies such as using soybean cyst nematode resistant varieties and rotation with other crops such as corn. Clariva pn is compatible with certain other chemical seed treatments and with *Rhizobium* spp. based inoculants.

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 Clariva pn to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

In individuals exposed repeatedly to potentially large quantities of Clariva pn, respiratory and dermal sensitivity may possibly develop. All microorganisms, including *P. nishizawae* Pn1, contain substances that are potential sensitizers. Therefore, anyone handling or applying Clariva pn must wear appropriate waterproof gloves, a long-sleeved shirt, long pants, shoes plus socks, and a NIOSH approved mist filtering mask or respirator with any N-95, P-95 or R-95 filter. Also, the signal words, "POTENTIAL SENSITIZER" on the principal display panel and precautionary statements, "May cause sensitization" are required on the secondary display panel of the label for Clariva pn.

Environment

The end-use product label includes environmental precaution statements that prevent the contamination of aquatic systems from the use of Clariva pn.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-11, *Pasteuria nishizawae* Pn1) 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) or contact the PMRA's Pest Management Information Service.

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

Appendix I Comments and Responses

1. The commenter noted two instances where typographical errors were made:

- a) In Section 3.3.4 of PRD2015-11, a sentence incorrectly included the word 'few' when the word used should have been 'no'. The corrected sentence is as follows:

“Furthermore, no adverse effects from exposure to other isolates of *P. nishizawae* encountered in the environment have been reported.”

- b) In Appendix I, Table 1 of PRD2015-11, in the first row of page 20 (study reference 2113169), the study was incorrectly identified as an 'Acute Intraperitoneal Infectivity (21-Day study)' when it should have been listed as an 'Acute Intravenous Infectivity (21-Day study)'.