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Proposed Registration Decision

PRD2019-02

BLAD Polypeptide Problad Technical Fungicide and Problad Plus Fungicide

(publié aussi en français)

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Overview

Proposed Registration Decision for BLAD polypeptide, Problad Technical Fungicide and Problad Plus Fungicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of Problad Technical Fungicide and Problad Plus Fungicide, containing the technical grade active ingredient BLAD polypeptide, to control grey mould on certain fruiting vegetables (field and greenhouse eggplant, peppers, tomato and pepino), suppression of powdery mildew and control of grey mould on greenhouse strawberry, and control of grey mould on greenhouse ornamentals and on lowbush blueberry.

BLAD polypeptide is currently registered to suppress or control powdery mildew and grey mould on grape, field strawberry, field tomato, stone fruit, almond and ornamental plants. For details, see the Proposed Registration Decision PRD2015-01, *BLAD polypeptide* and the Registration Decision RD2015-18, *BLAD polypeptide*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of BLAD polypeptide, Problad Technical Fungicide, and Problad Plus Fungicide.

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 acceptable¹ 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 proposed conditions of registration. The *Pest Control Products Act* also requires that products have value² when used according to the 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.

¹ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

² "Value" as defined by subsection 2(1) of the *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."

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of Canada.ca.

Before making a final registration decision on BLAD polypeptide, Problad Technical Fungicide, and Problad Plus Fungicide, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.³ Health Canada will then publish a Registration Decision⁴ on BLAD polypeptide, Problad Technical Fungicide, and Problad Plus Fungicide, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is BLAD polypeptide?

BLAD polypeptide is a protein fragment from sweet lupine (*Lupinus albus*) that inhibits the growth of fungi by damaging their cell walls. BLAD stands for "Banda de *Lupinus albus* doce".

Health Considerations

Can Approved Uses of BLAD Polypeptide Affect Human Health?

BLAD polypeptide is unlikely to affect human health when it is used according to label directions.

Potential exposure to BLAD polypeptide may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed.

In laboratory animals, the acute toxicity of the end-use product, Problad Plus Fungicide, containing BLAD polypeptide, was low via the oral, dermal, and inhalation routes of exposure. Problad Plus Fungicide is mildly irritating to the skin and eyes, but is not a dermal sensitizer.

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁴ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

A request to bridge acute toxicity data from the end-use product to the technical grade active ingredient was considered to be acceptable. The active ingredient, BLAD polypeptide, was considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. BLAD polypeptide was mildly irritating to the skin and eyes, but not a dermal sensitizer.

BLAD polypeptide is not expected to cause effects in developing young or to cause damage to genetic material when used according to the label instructions.

BLAD polypeptide is not expected to elicit an allergic response in individuals who are sensitive to allergens present in lupine seeds and/or other legumes.

The risk assessment protects against the effects of BLAD polypeptide by ensuring that the level of human exposure is well below the lowest dose at which effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are acceptable.

Dietary risks from food and drinking water are expected to be negligible given the low toxicity, the lack of quantifiable residues from the supplemental residue information, and the likelihood (most likely negligible) that exposure of individuals to Problad Plus Fungicide with lupine and/or other legume (for example peanut) sensitivities will result in an allergic reaction.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational exposure is acceptable.

Risk from residential exposure to individuals coming in contact with Problad Plus Fungicide, containing the active ingredient BLAD polypeptide, during application is acceptable when Problad Plus Fungicide is used according to label directions.

Occupational Risks From Handling Problad Plus Fungicide

Occupational risks are acceptable when Problad Plus Fungicide is used according to the label directions, which include protective measures.

An assessment conducted for individuals handling and applying Problad Plus Fungicide indicated that the risk is acceptable when the product is used according to label directions.

Environmental Considerations

What Happens When BLAD Polypeptide Is Introduced Into the Environment?

Problad Plus Fungicide, containing the active ingredient BLAD polypeptide, is not expected to pose risks of concern to the environment when used according to label instructions.

BLAD polypeptide may enter the environment when applied as Problad Plus Fungicide to field and greenhouse fruit, vegetables, and ornamentals. Banda de *Lupinus albus doce* (BLAD) is a naturally-occurring seed storage protein which is expected to be broken down by microorganisms in soil and water.

Problad Technical Fungicide is expected to be non-toxic to all non-target terrestrial and aquatic organisms tested. Therefore, risk of concern to the aquatic and terrestrial environments is not expected when Problad Plus Fungicide is used according to the label directions.

Value Considerations

What Is the Value of Problad Plus Fungicide?

Problad Plus Fungicide is a broad spectrum biological fungicide with a unique mode of action that will contribute to an integrated disease management program.

Problad Plus Fungicide is effective when applied to plant foliage and has activity against powdery mildew and grey mould on greenhouse strawberry, certain fruiting vegetables, lowbush blueberry as well as greenhouse ornamental crops.

The active ingredient in Problad Plus Fungicide has a multi-site mode of action and the risk of resistance development is low.

Measures to Minimize Risk

Labels of registered pesticide products 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 being proposed on the label of Problad Technical Fungicide and Problad Plus Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Both Problad Technical Fungicide and Problad Plus Fungicide labels must include the statement, “CAUTION – SKIN AND EYE IRRITANT” on the principal display panel and “May irritate skin and eyes” and “Avoid contact with the skin and eyes” on the secondary display panel.

To avoid direct contact with Problad Plus Fungicide on the skin and eyes, workers involved in the mixing, loading, application, cleaning, and maintenance of machinery must wear long-sleeved shirts, long pants, chemical-resistant gloves, shoes, socks, and protective eyewear.

To avoid inadvertent bystander exposure during application on field crops, the Problad Plus Fungicide label must include the statement, “Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools, and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature, application equipment, and sprayer settings.”

Environment

No further mitigation measures are required at this time.

Next Steps

Before making a final registration decision on BLAD polypeptide, Problad Technical Fungicide and Problad Plus Fungicide, Health Canada’s PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada’s response to these comments.

Other Information

When the Health Canada makes its registration decision, it will publish a Registration Decision on BLAD polypeptide, Problad Technical Fungicide, and Problad Plus Fungicide (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA’s Reading Room (located in Ottawa).

Science Evaluation

BLAD polypeptide

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Problad Technical Fungicide

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

End-Use Product—Problad Plus Fungicide

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

1.3 Directions for Use

Problad Plus Fungicide is applied preventatively to plant foliage at rates of 1.5–3.3 L/ha. The product may be re-applied on 7–10 day intervals or according to phenological stages of growth. Higher rates and shorter intervals are to be used with high disease pressure. Up to five applications may be made per crop cycle or season up to and including the day of harvest.

1.4 Mode of Action

BLAD polypeptide inhibits fungal growth by binding to and degrading chitin, a major component of the fungal cell wall.

2.0 Method of Analysis

2.1 Methods for Analysis of the Active Ingredient

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

2.2 Method for Formulation Analysis

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

2.3 Methods for Residue Analysis

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

2.4 Methods for Determination of Relevant Impurities in the Manufactured Material

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

Incident Reports

As of 7 November 2018, no human or domestic animal incident reports involving BLAD polypeptide were submitted to the PMRA.

3.2 Occupational, Residential and Bystander Exposure and Risk Assessment

3.2.1 Dermal Absorption

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

3.2.2 Use Description

Problad Plus Fungicide is proposed for foliar application. The method in the field is by spray equipment commonly used for making ground applications (groundboom, airblast, and handheld equipment). Greenhouse application is limited to handheld devices, such as backpack, boom, or sprinkler equipment (in other words, chemigation). The maximum amount of the active ingredient handled is calculated to be 0.83 kg/day for handheld devices, 16.57 kg/day for airblast equipment, 21.54 kg/day for groundboom farmer applications, 298.19 kg/day for groundboom custom applications, and 115.96 kg/day for chemigation equipment (mixing and loading only). Problad Plus Fungicide has an application interval of 7–10 days and a maximum of five applications per season. The postapplication activities are expected to be typical for agricultural crops (for example, scouting of treated areas).

Problad Plus Fungicide is currently registered for field use on grapes, strawberries, tomatoes, stone fruit, and outdoor ornamentals. The method of application is by spray equipment commonly used for making ground applications (groundboom, airblast, and handheld equipment). The maximum amount of the active ingredient handled is calculated to be 298.19 kg/day by custom groundboom. Problad Plus Fungicide has an application interval of 7–10 days and a maximum of five applications per season. The postapplication activities are expected to be typical for agricultural crops (for example, scouting of treated areas).

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

3.2.4 Postapplication Exposure and Risk

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

3.2.5 Residential and Bystander Exposure and Risk

The proposed field crop uses of Problad Plus Fungicide may result in bystander exposure due to drift. The risk due to bystander exposure will be mitigated by observing the buffer statement currently on the label, advising against application to areas of human habitation unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

Bystanders are not expected to be impacted by the proposed greenhouse uses of Problad Plus Fungicide when access is limited to workers involved with mixing, loading, application, and postapplication activities. As such, a bystander risk assessment was not necessary.

Residential uses of Problad Plus Fungicide have not been proposed, therefore, this assessment was not required.

3.3 Food Residue Exposure Assessment

3.3.1 Food

There is reasonable certainty that no harmful effects will result from dietary exposure to residues of BLAD polypeptide from the proposed use on greenhouse strawberries, field and greenhouse eggplant, field ground cherry, field and greenhouse pepino, field and greenhouse pepper (including bell, chili, pimento, and sweet), field and greenhouse tomatillo, greenhouse tomatoes, lowbush blueberries, and greenhouse grown ornamentals in the general population and potentially sensitive subpopulations, including infants and children.

3.3.2 Drinking Water

Although the end-use product will not be applied near or directly to water, some drinking water exposure may be possible through run-off when Problad Plus Fungicide is applied outdoors. Exposure to Problad Plus Fungicide in drinking water is expected to be minimal. In addition, toxicity to Problad Plus Fungicide is low. Consequently, the risk due to exposure from drinking water is acceptable.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Calculations of acute reference doses and acceptable daily intakes are not required for BLAD polypeptide. Based on all the available information and hazard data, this active ingredient is considered to be of low toxicity. Thus there are no threshold effects of concern. As a result, there is no need to apply uncertainty factors to account for intra- and interspecies variability, or have a margin of exposure required. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of BLAD polypeptide including developmental effects from pre- or postnatal exposures, and cumulative effects on

infants and children of this active ingredient and other registered products containing it, does not apply to this active ingredient. As a result, the PMRA has not used a margin of exposure approach to assess the risks of BLAD polypeptide to human health.

3.3.4 Aggregate Exposure and Risk

Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of BLAD polypeptide to the general Canadian population, including infants and children, when the end-use product is used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.3.5 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative effects of pest control products with a common mechanism of toxicity. For the current evaluation, the PMRA did not identify information indicating that BLAD polypeptide shares a common mechanism of toxicity with other pest control products. Therefore there is no requirement for a cumulative health risk assessment at this time.

3.3.6 Maximum Residue Limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that 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 adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

For the initial registration, the dietary risks from food and drinking water were expected to be negligible given the low toxicity, the lack of quantifiable residues from the previously assessed supplemental residue information, and the likelihood (most likely negligible) that exposure of individuals to Problad Plus Fungicide with lupine and/or other legume (for example, peanut) sensitivities will result in an allergic reaction. Consequently, the specification of an MRL under the *Pest Control Products Act* was not required nor is it necessary for the proposed new uses.

4.0 Impact on the Environment

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

5.0 Value

Scientific rationales were provided to support the use on greenhouse strawberry, field and greenhouse fruiting vegetables, and greenhouse ornamentals for the control of grey mould caused by *Botrytis cinerea*. The following extrapolations were supported: greenhouse strawberry from field strawberry; greenhouse tomato from field tomato; eggplant, ground cherry and pepino

from field tomato; and greenhouse ornamentals from outdoor ornamentals. The extrapolation of the use on lowbush blueberry was also supported based on the currently registered use of BLAD polypeptide to control *Botrytis cinerea* on field strawberries and grapes. The rationales were acceptable because: (1) the control of *Botrytis cinerea* on field strawberry, field tomato, grape, stone fruits, and outdoor ornamentals are already registered on the current Problad Plus Fungicide label at the same rates, (2) the plant pathogen causing the diseases (*Botrytis cinerea*) is the same on these crops and (3) disease cycles are similar across crops.

The results of efficacy trials were also provided to support the use on greenhouse peppers, which demonstrated control of the botrytis grey mould.

There is no concern regarding phytotoxicity since these crops were already included on the registered label. A research trial on lowbush blueberry indicated that phytotoxicity would not be expected with the use of Problad Plus Fungicide on this crop.

In consideration of the currently registered use pattern as well as scientific rationales, results of research trials, and benefits information, the application to add use of Problad Plus Fungicide on greenhouse ornamentals, fruiting vegetables (field and greenhouse eggplant, peppers, tomato and pepino), greenhouse strawberry, and lowbush blueberry is supported.

The expansion of the registration of Problad Plus Fungicide to include these new uses will provide another option for disease management in these crops.

The target fungi causing grey mould and powdery mildew have a high risk for developing resistance to conventional fungicides. The active ingredient in Problad Plus Fungicide, BLAD polypeptide, has a unique mode of action for which resistance is unknown and the risk of resistance is considered low. Therefore, the use of Problad Plus Fungicide in an integrated disease management program will contribute to sustainable crop production practices.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

6.2 Formulants and Contaminants of Health or Environmental Concern

Refer to PRD2015-01, *BLAD Polypeptide*, for details.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for the initial registration of BLAD polypeptide is adequate to define the majority of toxic effects that may result from exposure to BLAD polypeptide. The active ingredient, BLAD polypeptide, is of low acute toxicity by oral, dermal, and inhalation routes. There was evidence of mild irritation to the skin and eyes of rabbits after acute dosing.

BLAD polypeptide is not a dermal sensitizer. Waivers were granted for short-term toxicity, prenatal developmental toxicity, and genotoxicity on the basis of minimal exposure to individuals coming in contact with BLAD polypeptide.

Loaders, mixers, applicators, and workers are not expected to be exposed to levels of BLAD polypeptide that will result in an unacceptable risk due to exposure when Problad Plus Fungicide is used according to label directions.

Inadvertent bystander exposure during application of Problad Plus Fungicide may be minimized when the end-use product is only applied when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools, and recreational areas is minimal. Applicators should take into consideration wind speed, wind direction, temperature, application equipment, and sprayer settings.

The dietary risks from food and drinking water are expected to be negligible. Consequently, the specification of an MRL under the *Pest Control Products Act* was not required for the initial registration nor is it necessary for the proposed uses.

7.2 Environmental Risk

The proposed new uses on greenhouse vegetables and ornamentals, in addition to new uses on certain field crops, do not pose additional risks of concern to the environment when used according to the label directions. The labels for Problad products were updated to reflect current labelling standards.

7.3 Value

Problad Plus Fungicide is effective against grey mould of greenhouse strawberries, certain fruiting vegetables, greenhouse ornamentals, and lowbush blueberry as well as against powdery mildew of greenhouse strawberry. It offers growers a non-conventional option for rotation with currently registered fungicide products as part of an integrated disease management program. Use of this product potentially reduces the number of applications of conventional fungicides, thereby contributing to resistance management and sustainability.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of Problad Technical Fungicide and Problad Plus Fungicide, containing the technical grade active ingredient BLAD polypeptide, to control grey mould on certain fruiting vegetables (field and greenhouse eggplant, peppers, tomato and pepino), suppression of powdery mildew and control of grey mould on greenhouse strawberry, and control of grey mould on greenhouse ornamentals and on lowbush blueberry.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

List of Abbreviations

BLAD	banda de <i>Lupinus albus</i> doce
FDA	<i>Food and Drug Act</i>
kg	kilogram(s)
kg/day	kilogram(s) per day
MRL	maximum residue limit
PMRA	Pest Management Regulatory Agency
PRD	proposed registration decision

Appendix I Tables and Figures

Table 1 List of Supported Uses

Supported Uses
Strawberry (greenhouse) -Control of Botrytis grey mould (<i>Botrytis cinerea</i>) -Suppression of Powdery mildew (<i>Sphaerotheca aphanis</i> syn <i>S. macularis</i>)
Fruiting vegetables: eggplant (field and greenhouse); ground cherry (field), pepino (field and greenhouse), pepper including bell, chili, cooking, pimento and sweet (field and greenhouse), tomatillo (field and greenhouse), tomato (greenhouse) -Control of Botrytis grey mould (<i>Botrytis cinerea</i>)
Greenhouse grown ornamentals -Control of Botrytis grey mould (<i>Botrytis cinerea</i>)
Lowbush blueberry -Control of Botrytis grey mould (<i>Botrytis cinerea</i>)

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

None.

2.0 Human and Animal Health

None.

3.0 Environment

None.

4.0 Value

PMRA

Document

Number Reference

2800337	2017, Value Summary for Problad Plus Fungicide (PCP No. 31782) and Fracture (PCP No. 32139), DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3(D), 10.3.1, 10.4, 10.5
2800339	2014, Evaluation of Problad Plus for the Management of Gray Mold (<i>Botrytis cinerea</i>) in Greenhouse Peppers - BPR14-052 - , DACO: 10.2.3.3(D), 10.3.2(B)
2800341	2014, Problad Plus (Problad BL178) For Botrytis of Greenhouse Pepper, DACO: 10.2.3.3(D), 10.3.2(B)
2840459	2017, Value-clarification-10jan2017, DACO: 10.3.1
2840461	2016, Fracture (BLAD Protein) for Greenhouse Tomato Integrated Disease Management, DACO: 10.3.2(B)
2840462	2016, Monilinia and Botrytis Blight Suppression Technologies for Wild Blueberry Production, DACO: 10.3.2(B)
2857375	2018, Monilinia and Botrytis Blight Suppression Technologies for Wild Blueberry Production, DACO: 10.2.3.3(D), 10.3.2(B)

B. Additional Information Considered

None.