Registration Decision RD2013-02

Garlic Powder

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Registration Decision for Garlic Powder

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 Garlic Powder Technical, Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use, containing the technical grade active ingredient garlic powder, to suppress powdery mildew on grape and scab on apple, crabapple, and pear.

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 document[1] Proposed Registration Decision PRD2012-22, *Garlic Powder*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for garlic powder and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-22. This decision is consistent with the proposed registration decision stated in PRD2012-22.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-22, *Garlic Powder* 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 acceptable[3] 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 value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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".

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 (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 Garlic Powder?

Garlic powder is the active ingredient in the commercial class end-use products Buran, AEF 11-04, and AEF 11-05. It is also found as the active ingredient in the domestic class end-use products Bioprotec Fruit Tree Fungicide Concentrate and Bioprotec Fruit Tree Fungicide Ready to Use. These products are used to suppress powdery mildew on grape and scab on apple, crabapple, and pear.

Health Considerations

Can Approved Uses of Garlic Powder Affect Human Health?

Garlic powder is unlikely to affect human health when used according to label directions.

Exposure to garlic powder may occur 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 dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, garlic powder, is of low acute toxicity by the oral and dermal routes and is slightly irritating to eyes and skin. Due to the irritative nature of garlic, inhalation exposure may cause throat irritation. There is potential for skin sensitization to occur when skin is repeatedly exposed to the garlic powder. Therefore, cautionary statements alerting users to this sensitization concern are required on product labels.

Inhalation and dermal exposures are likely for domestic users, occupational workers, and commercial applicators. Anyone entering the sprayed areas before the spray is dried may be exposed dermally. Therefore, appropriate precautionary statements and a restricted entry statement are required on the end-use product labels to mitigate such exposure concerns.

Based on garlic's long history of consumption as a food and in natural health products, there is little indication of short or long term toxic effects from exposure to garlic powder from the use of the commercial and domestic class end-use products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Garlic is used for culinary purposes world-wide and is also consumed for its medicinal values. Garlic powder is rapidly degraded in the environment, so exposure from residues in water and from treated food commodities is likely to be minimal. There is reasonable certainty that no harmful effects will occur from dietary exposure to garlic powder from the use of the end-use products.

Occupational Risks From Handling Garlic Powder

Occupational risks are not of concern when garlic powder end-use products are used according to label directions, which include protective measures.

As these new products are a liquid formulation, there is no concern from exposure to garlic powder dust during mixing/loading. Occupational exposure when applying the end-use products is not expected to result in unacceptable risk when the end-use product is used according to label directions.

Precautionary and hygiene statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Garlic Powder Is Introduced Into the Environment?

Garlic powder technical is not persistent and the proposed use is not expected to pose an unacceptable risk to non-target terrestrial or aquatic organisms.

Garlic powder technical is derived from a naturally-occurring food commodity (garlic bulb). The active components of garlic, allyl sulfides, applied as garlic powder will enter the environment through application by field and airblast sprayer to apple, crabapple, pear and grapes. Allyl sulfides are volatile and, as such, volatilization is expected to be an important route of dissipation for this technical active in the environment. Allyl sulfides are expected to degrade in air by reaction with hydroxyl radicals.

Garlic powder is non-toxic to honey bees and birds and is slightly toxic to fish and aquatic invertebrates on an acute basis. Garlic powder technical will not pose a risk to non-target terrestrial or aquatic organisms from this proposed use.

Value Considerations

What Is the Value of Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use?

Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use are garlic-based preventative fungicides with demonstrated efficacy against powdery mildew and scab.

Powdery mildew on grape and scab on apple, crabapple, and pear are important diseases that can lead to reductions in yield and fruit quality. These products represent valuable low-risk alternative options for disease management available to both commercial and domestic users. The risk of disease resistance development by the target pathogens is assumed to be very low given the general nature of the active ingredient's mode of action.

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 Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Buran and AEF 11-04:

In addition to the statement "Avoid breathing spray mists", the labels of the end-use products must include "May cause respiratory irritation." in the Precautions section.

As these products are a liquid formulation, there is no concern from exposure to garlic powder dust during mixing/loading. Therefore, these products have the statement "Applicators using a power sprayer must wear a bayonet-style cartridge respirator (for particulates) equipped with at least an N-95, R-95, P-95 or HE filter."

To avoid bystander exposure, the labels state "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 inversion, application equipment and sprayer settings."

In the precautions section, the following statements are included “Individuals who are sensitive or allergic to garlic should avoid handling the product. Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain.”

AEF11-05 and Bioprotec Fruit Tree Fungicide Concentrate

In the precautions section, the end-use product labels state “May cause eye irritation. May cause skin irritation. May cause skin sensitization. May cause respiratory irritation. Avoid breathing spray mists.”

In the precautions section, the following statements are included “Individuals who are sensitive or allergic to garlic should avoid handling the product. Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain.”

To avoid bystander exposure, the labels state “Apply only when the potential for drift is minimal.”

The statement “KEEP OUT OF REACH OF CHILDREN” is required on the principal display panel.

Bioprotec Fruit Tree Fungicide Ready To Use:

In the precautions section, the end-use product label states “Avoid breathing spray mists.”

The statement “KEEP OUT OF REACH OF CHILDREN” is required on the principal display panel.

In the precautions section, the following statements are included “Individuals who are sensitive or allergic to garlic should avoid handling the product. Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain.”

To avoid bystander exposure, the label states “Apply only when the potential for drift is minimal.”

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-22, *Garlic Powder)* 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.inforserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] 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.*