Australian Government

Australian Pesticides and Veterinary Medicines Authority

# PUBLIC RELEASE SUMMARY

on the evaluation of the new active *Beauveria bassiana* strain PPRI 5339 in the product Broadband OD Insecticide

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# PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Environment and State Departments of Primary Industries.

The APVMA has a policy of encouraging transparency in its activities and seeking community involvement in decision making. Part of that process is the publication of Public Release Summaries for products containing new active constituents.

The information and technical data required by the APVMA to assess the safety of new chemical products, and the methods of assessment, must be consistent with accepted scientific principles and processes. Details are outlined on the APVMA website.

This Public Release Summary is intended as a brief overview of the assessment that has been conducted by the APVMA and of the specialist advice received from its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience to encourage public comment.

## About this document

This is a Public Release Summary.

It indicates that the APVMA is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's assessment, which may include details of:

- the toxicology of both the active constituent and product
- the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety

Comment is sought from interested stakeholders on the information contained within this document.

## Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of the new active constituent and registration of the product Broadband OD Insecticide should be granted. Submissions should relate only to matters that the APVMA is required, by legislation, to take into account in deciding whether to grant the applications. These matters include aspects of public health, occupational health and safety, chemistry and manufacture, residues in food, environmental safety, trade, and efficacy and target crop or animal safety. Submissions should state the grounds on which they are based. Comments received that address issues outside the relevant matters cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on Tuesday 3 October 2017 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address (if available)
- the date you made the submission.

All personal information, and confidential information judged by the APVMA to be confidential commercial information (CCI)[1] contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

[1] A full definition of "confidential commercial information" is contained in the Agvet Code.

## Further information

Further information can be obtained via the contact details provided above.

Further information on Public Release Summaries can be found on the APVMA website: http://www.apvma.gov.au.

# 1 INTRODUCTION

## 1.1 Applicant

BASF Australia Ltd.

## 1.2 Purpose of application

BASF Australia Ltd is seeking approval and registration of the oil dispersible product Broadband OD Insecticide, containing >4.0 × $10^9$ colony forming units (CFU) per mL of the new active constituent *Beauveria bassiana* PPRI 5339.

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of Broadband OD Insecticide, and approval of the new active constituent, *Beauveria bassiana,* PPRI 5339.

## 1.3 Product claims and use pattern

Broadband OD Insecticide, is a biological insecticide intended for use for the suppression of thrips (*Thrips tabaci* and *Frankliniella occidentalis*), whitefly (*Bemisia tabaci. B. argentifolii* and *Trialeurodes vaporariorum*), aphids (*Myzus persicae, Macrosiphum rosae* and *Macrosiphoniella sanborni*) and mites (*Tetranychus urticae*) in protected horticulture.

The product is applied at a rate of 100 mL/100 L for thrips and whitefly and 180 ml/100 L for aphids and mites when pests are first detected or are above economic thresholds. Broadband OD Insecticide is to be applied as a foliar spray to the point of good coverage, but not to the point of run off.

Broadband OD Insecticide should be applied in a water volume ranging from 500 to 2500 L/ha. Repeat applications of the product are to be made as necessary at intervals of 3-14 days. The last application can be made up to harvest, with a withholding period not required when used as directed.

In higher pest situations, the product is best used within an integrated pest management program in conjunction with a chemical insecticide.

## 1.4 Mode of action

*Beauveria bassiana* is a naturally occurring soil fungus found throughout the world acting as a parasite on various arthropod species causing white muscardine disease. Different strains of *Beauveria bassiana* vary in their host range and specificity.

The Insecticide Resistance Action Committee (IRAC) does not currently have any Mode of Action Classifications for biological insecticides. IRAC guidelines recommend integration of other control methods (chemical, cultural, biological) into insect control programs. The use of additional control measures is also important to minimise the risk of resistance developing with repeated, ongoing use.

## 1.5 Overseas registrations

The product is currently registered in South Africa as BroadBand, a fungal contact insecticide, for the population reduction of target pests: diamond back moth, false codling moth, red scale, red spider mite, potato tuber moth, stinkbug, thrips and whitefly in horticultural crops.

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# 2 CHEMISTRY AND MANUFACTURE

## 2.1 Active constituent

The active constituent *Beauveria bassiana* strain PPRI 5339 is a fungal spore used as a contact insecticide, for the population reduction of target pests on crops. *Beauveria bassiana* strain PPRI 5339 is not listed in Food and Agriculture Organisation of the United Nations (FAO) specifications.

### *Beauveria bassiana* strain PPRI 5339 has the following characteristics of identification:

| | |
|---|---|
| COMMON NAME (ISO): | Beauveria bassiana strain PPRI 5339 |
| SPECIES NAME (BINOMIAL): | Beauveria bassiana (Balsamo) Vuillemin |
| STRAIN: | PPRI 5539 |
| GENUS NAME: | Beauveria |
| FAMILY NAME: | Various names given by different authorities, including *Cordycipitaceae* and *Clavicipitaceae* |
| DESCRIPTION: | Strain PPRI 5339 was originally isolated by Dr Schalk Schoeman from the larva of a tortoise beetle, *Conchyloctenia punctate* (*Coleoptera: Cassidinae*) collected in Escombe, Queensburgh, KwaZulu Natal, South Africa |

Biological properties of *Beauveria bassiana* (Balsamo) Vuillemin including its history, natural occurrence and geographical distribution, host range, mode of action and production of metabolites/toxins have been reviewed, confirming the identity of *Beauveria bassiana* strain PPRI 5339.

The APVMA has evaluated the chemistry aspects of *Beauveria bassiana* strain PPRI 5339 (identification, fermentation process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for *Beauveria bassiana* strain PPRI 5339 active constituent:

| CONSTITUENT | SPECIFICATION | LEVEL |
|---|---|---|
| *Beauveria bassiana* strain PPRI 5339 | *Beauveria bassiana* strain PPRI 5339 | $\times 10^{11}$ cfu/g minimum |
| | *Beauvericin* | 0.5 µg/g maximum |

The active constituent *Beauveria bassiana* strain PPRI 5339 will be manufactured overseas.

Based on a review of the data provided by the applicant, the APVMA is satisfied that the chemistry and manufacturing (fermentation) details of *Beauveria bassiana* strain PPRI 5339 are acceptable

## 2.2 Formulated product

The formulated product Broadband OD Insecticide will be manufactured overseas and in Australia in high density polyethylene containers with pack sizes of 0.25 L to 1000 L.

The APVMA has reviewed the chemistry and manufacturing aspects of the product and found them to be acceptable.

### BROADBAND OD INSECTICIDE

| | |
|---|---|
| **DISTINGUISHING NAME:** | Broadband OD Insecticide |
| **FORMULATION TYPE:** | Oil-based suspension concentrate (OD) |
| **ACTIVE CONSTITUENT CONCENTRATION:** | *Beauveria bassiana* strain PPRI 5339 (40 g/L, >4 × $10^9$ colony-forming units per mL) |

### PHYSICAL AND CHEMICAL PROPERTIES OF THE FORMULATED PRODUCT

| | |
|---|---|
| **APPEARANCE:** | Yellow oil with light cream sediment that re-suspends with shaking |
| **PH VALUE:** | Neat test item: 6.1<br>1% dilution of test item: 6.7 |
| **SURFACE TENSION:** | 33.47 mN/m at 20 ºC |
| **VISCOSITY** | When subjected to changes in shear rate;<br>average viscosity [mPa·s] at 20 ºC: 85.6<br>average viscosity [mPa·s] at 45 ºC: 39.0 |
| **EXPLOSIVE PROPERTIES:** | No explosive properties |
| **OXIDISING PROPERTIES:** | No oxidizing properties |
| **FLAMMABILITY:** | Not flammable |
| **CORROSIVE HAZARD:** | Not corrosive hazard |
| **PACK SIZES:** | 0.25 L, 0.5 L, 1 L, 5 L, 1000 L |
| **PACKAGING MATERIAL:** | High density polyethylene (HDPE) |
| **PRODUCT STABILITY:** | As a product containing organisms, Broadband OD Insecticide is a date-controlled agricultural chemical product.<br><br>The available stability data supports a shelf life of 6 months, with storage below 25 ºC (air conditioning) |

## 2.3 Recommendations

Based on a review of the chemistry and manufacturing details provided by the applicant, the registration of Broadband OD Insecticide is supported from a chemistry perspective.

# 3 TOXICOLOGICAL ASSESSMENT

## 3.1 Evaluation of toxicology

The following summary focuses on the toxicity of the active as well as that of the Broadband product.

The submitted data package included acute toxicity studies on *Beauveria bassiana* PPRI 5339, pathogenicity studies, and published human case studies on *Beauveria bassiana* generally. The acute toxicology studies were conducted in accordance with relevant test guidelines and were considered adequate for the assessment of the product toxicology profile.

In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified.

Findings of adverse effects in any one species do not necessarily indicate such effects might be generated in humans. From a conservative risk assessment perspective, however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available.

Where possible, considerations of the species specific mechanisms of adverse reactions weigh heavily in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels compared with those, usually many times higher, which produce effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur.

### Microbiological properties

*Beauveria bassiana* is a naturally occurring soil fungus that acts as a parasite on various arthropod species causing white muscardine disease. Target pests include red spider mites, white flies, aphids, thrips, fleahoppers, boll weevil and turf insects. Different strains of *Beauveria bassiana* vary in their host range and specificity. *Beauveria bassiana* (various strains) is used as a biological insecticide overseas to control various pests. In Australia, *Beauveria bassiana* (strain ATCC 74040) was first approved as an active constituent by the APVMA in 1998 (APVMA approval number 44066), however there are no associated product registrations for that strain.

### Toxicity of *Beauveria Bassiana* Strain PPRI 5339

*Beauveria bassiana* PPRI 5339 has low acute oral (LD50 >5000 mg/kg bw) and acute dermal (LD50 >5050 mg/kg bw) toxicity, and low to moderate acute inhalational toxicity (LC50 <2590 mg/m3, 4-hour exposure). It is a not a skin irritant, but is a moderate eye irritant and a skin sensitiser (Guinea Pig Maximisation Test method).

The optimum temperature for growth of *Beauveria bassiana* PPRI 5339 is from 22°C to 28°C. *Beauveria bassiana* PPRI 5339 does not grow at mammalian body temperature (37°C). *Beauveria bassiana* PPRI 5339

is not pathogenic when administered *via* the intraperitoneal or tracheal routes. Similar to other *Beauveria bassiana* isolates, *Beauveria bassiana* PPRI 5339 is unlikely to be pathogenic *via* the oral and dermal routes. It is unlikely to be pathogenic to humans but may be capable of causing keratitis in eyes of immunocompromised humans. Based on all the available information, it was considered that the acute toxicity and infectivity data for *Beauveria bassiana* PPRI 5339 were similar to other investigated strains of *Beauveria bassiana.*

No dermal absorption studies or repeat dose toxicity studies were available for *Beauveria bassiana* or strain PPRI 5339. No infectivity or pathogenicity was reportedly observed in rats after 21 days exposure to $1.8 \times 10^9$ CFU /kg *Beauveria bassiana* ATCC 74040. The genotoxic potential of *Beauveria bassiana* PPRI 5339 was tested in an Ames test using four strains of *S. typhimurium,* which gave negative results both with and without metabolic activation.

The level of beauvericin (a toxicologically significant secondary metabolite produced by *Beauveria bassiana*) is set at a maximum level of 0.5 µg/g in the proposed APVMA Active Constituent Standard for *Beauveria bassiana* strain PPRI 5339.

There are no objections on human health grounds to the approval of the biological active constituent, *Beauveria bassiana* PPRI 5339.

### Toxicity of Broadband OD Insecticide

No acute toxicity data were submitted for the formulated product. The acute toxicity of the product was estimated based on the toxicity of the individual constituents. The product is expected to have low acute oral, dermal and inhalational toxicity, is likely to be a slight skin and eye irritant, and is likely to be a skin sensitiser.

## 3.2 Public Health Standards

### Poisons scheduling

*Beauveria bassiana* is in Schedule 6 of the SUSMP, except in preparations containing $1 \times 10^8$ CFU /mL or less, when it is in Schedule 5. Broadband OD Insecticide contains 4% w/w (>$4.0 \times 10^9$ CFU/mL) *Beauveria bassiana* PPRI 5339 and its toxicological profile is considered appropriate as a Schedule 6 product.

### Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD)

The Acceptable Daily Intake (ADI) is that quantity of a chemical compound that can safely be consumed on a daily basis for a lifetime.

The Acute Reference Dose (ARfD) is the maximum quantity of a chemical that can safely be consumed as a single, isolated event.

The establishment of an ADI and an ARfD for *Beauveria bassiana* PPRI 5339 was not considered to be necessary due to its low oral toxicity, apparent non-pathogenicity/non-infectivity to mammals, and because residues in the food are unlikely to be above normal background levels.

# 4 RESIDUES ASSESSMENT

## 4.1 Metabolism

No metabolism studies were supplied for *Beauveria bassiana* PPRI 5339. However, the active constituent is a soil borne fungus, which parasitises various insect species and is already present in the environment. As a Table 5 entry is proposed for the Maximum Residue Limit (MRL) Standard (see below), a residue definition is not required.

## 4.2 Crop residues and MRLs

As *Beauveria bassiana* is a soil borne fungus, the proposed use pattern of Broadband OD Insecticide is not likely to result in residues of the fungus on crops that are distinguishable from naturally occurring background levels.

The establishment of an ADI and an ARfD were not considered to be required for *Beauveria bassiana* PPRI 5339 due to its low oral toxicity and apparent non-pathogenicity/non-infectivity to mammals.

The toxicological significance of any residues of *Beauveria bassiana* resulting in crops from the proposed use of *Broadband OD Insecticide* is therefore expected to be low.

A Table 5 entry (uses of substances where MRLs are not neccessary) for *Beauveria bassiana* strain PPRI 5339 covering the use pattern is proposed for inclusion in the MRL Standard.

## 4.3 Residues in animal commodities

The proposed use pattern for Broadband OD Insecticide is in vegetable crops grown in protected systems, and ornamentals. There is a potential for some vegetable crops or crop by-products, e.g. tomato pomace to be fed to livestock.

Given that the proposed use pattern is not likely to give rise to residues in crops distinguishable from those resulting from the natural presence of the *Beauveria bassiana* fungus in soil, feeding of crops treated with Broadband OD Insecticide is not of concern from a residues perspective.

## 4.4 Dietary risk assessment

An Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) have not been established for *Beauveria bassiana* strain PPRI 5339 due to its low oral toxicity and apparent lack of pathogenicity or infectivity to mammals. Therefore, the National Estimated Daily Intake (NEDI) and National Estimated Short term Intake (NESTI) calculations cannot be performed and are not required. The chronic and acute dietary risks associated with *Beauveria bassiana* strain PPRI 5339 are expected to be low.

## 4.5 Recommendations

The following amendments to the MRL Standard are recommended in relation to the proposed use of Broadband OD Insecticide:

**Table 5**

| SUBSTANCE | USE |
|---|---|
| ADD: | |
| Beauveria bassiana strain PPRI 5339 | For use as an insecticide |

The following withholding period statement is proposed in conjunction with the above MRL Standard entry:

**WITHHOLDING PERIODS:**

NOT REQUIRED WHEN USED AS DIRECTED.

# 5 ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

The proposed use pattern is not likely to give rise to residues in crops distinguishable from those resulting from the natural presence of the *Beauveria bassiana* fungus in soil.

Furthermore, the proposed use patterns for Broadband OD Insecticide are in vegetable crops and ornamentals and do not involve major trade commodities.

The risk to trade resulting from the proposed use pattern of Broadband OD Insecticide is expected to be low.

# 6 OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

## 6.1 Use pattern

Broadband OD Insecticide will be used in protected vegetables and ornamentals for the suppression of thrips, whitefly, aphids and mites. Workers will dilute the product with water and apply the product at 3 to 14 day intervals, as necessary. Generally, three consecutive weekly applications are required for adequate pest suppression.

## 6.2 Occupational exposure

A qualitative assessment was undertaken based on the acute toxicity profile of the product and likely exposure to workers during use. The product is expected to have low acute oral, dermal and inhalational toxicity, is likely to be a slight skin and eye irritant, and is likely to be a skin sensitiser. Worker exposure to *Beauveria bassiana* PPRI 5339 could occur while opening the container, mixing/loading operations, application, cleaning up spills, maintaining equipment and entering treated areas. The main routes of exposure to the product will be dermal, inhalation and ocular.

## 6.3 Public exposure

Broadband OD Insecticide is for professional use only in protected horticultural environments and therefore the risk to general public or bystanders from spray drift is unlikely. As the product is estimated to be a slight skin irritant and a skin sensitiser, workers should wear overalls and gloves to protect against dermal exposure and safety glasses or goggles to protect the eyes. Similarly Personal Protective Equipment (PPE) should be used when entering treated areas following application.

## 6.4 Recommendations for safe use

Taking into consideration the potential toxicological hazard, use pattern and likelihood of handler exposure, the following first aid instructions, safety directions, re-entry statements are recommended for inclusion on the product label:

### First aid instructions

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

### Safety directions

May irritate the eyes. May irritate the skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. When opening the container, preparing the spray and using the prepared spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves

and goggles or safety glasses. Wash hands after use. After each day’s use wash gloves, goggles or safety glasses, and contaminated clothing.

### Re-entry interval

Do not enter treated areas until spray has dried or dissipated and enclosed area has been thoroughly ventilated, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves and goggles or safety glasses. Clothing must be laundered after each day's use.

### Precautions

Not for domestic use.

# 7 ENVIRONMENTAL ASSESSMENT

## 7.1 Introduction

Broadband OD Insecticide is an oil dispersible liquid for the biological control of mites, whitefly, aphids and thrips. The maximum label rate is 1.8 x $10^{14}$ CFU/ha, with a minimum interval of 3 days between consecutive treatments.

*Beauveria bassiana* is a fungus that occurs across all continents. It has been found in a diverse range of habitats, including alpine soils, peat bogs, savannah, vegetation, forest and cultivated soils, sand blows and dunes. Strain PPRI 5339 was isolated in southern Africa, and its presence in Australia has not been established. Pesticide products based on other strains of *Beauveria bassiana* have been used for many years in North and South America, Europe and Asia without any significant adverse effects on non-target organisms.

## 7.2 Environment Fate and Behaviour

The fate and behaviour of any microorganism in the environment is dependent upon a range of factors, including competition with other microorganisms (parasites/predators of fungi), soil parameters (pH, moisture, clay content) and agricultural practices such as tillage.

The $DT_{50}$ values (time taken for 50% of the concentration to dissipate) for soil and water are approximately five and three days respectively, indicating that the microorganism could accumulate to a small extent if applications occurred at 3 day intervals.

The predicted environmental concentrations of the strain in soil and water after a single foliar application were calculated to be 2.4 × $10^4$ CFU /kg soil and 1.2 × $10^7$ CFU /L, respectively, and with multiple applications at three day intervals, 7.1 x $10^7$ CFU /kg soil and 2.1 x $10^7$ CFU /L, respectively. These figures were calculated assuming that the fungal strain does not occur in the Australian environment.

## 7.3 Environmental Effects

The risk assessment evaluated the potential adverse effects of *Beauveria bassiana* PPRI 5339 to non-target organisms.

### Terrestrial arthropods

*Beauveria bassiana* PPRI 5339 has a broad host range and can cause pathogenic effects to various classes of arthropods. One published study found that *Beauveria bassiana* PPRI 5339 is pathogenic to the Australian native *Eucalyptus* snout beetle *Gonipterus scutellatus*. While this is not a threatened species at the Federal or State level in Australia, it does indicate that Australian native organisms are susceptible to the fungus.

The broad host range presents a risk of harm to non-target arthropods, including beneficial organisms (e.g. pollinators) and native Australian organisms.

Twelve studies were provided on potential effects to honeybees and bumblebees. Results of these studies were variable. Some susceptibility to infection by the fungus was noted in some trials, however this was inconsistent. A quantitative risk assessment found the risk to bees was acceptable based on the most reliable endpoints with oral and contact no observable effect concentration levels (NOECs) of 40 and 2 µg/bee, respectively.

Two studies were submitted directly addressing toxicity of the strain PPRI 5339 to beneficial non-target arthropods. These studies on *Aphidius rhopalosiphi* (a wasp) and *Orius laevigatus* (a predatory insect) showed endpoints of $LD_{50} > 3.7 \times 10^8$ CFU /mL and $LD_{50} > 4.1 \times 10^8$ CFU /mL, respectively. A quantitative risk assessment indicated acceptable risk to these organisms. However, studies with other strains of *Beauveria bassiana* indicate pathogenic effects to some arthropods, which may pose a risk to these organisms. Therefore an integrated pest management (IPM) warning is recommended where IPM is practised.

Considering use of the product is limited to protected horticulture (enclosed structures), significant exposure of non-target terrestrial arthropods to the product is not expected, hence, risks are considered to be acceptable. On the basis of pathogenicity observed in some non-target terrestrial arthropod species, hazard statements are recommended.

## Terrestrial vertebrates

Potential for pathogenicity or infectivity of *Beauveria bassiana* PPRI 5339 and its toxins to terrestrial vertebrates (e.g., birds, mammals, and reptiles) were considered.

The applicant provided data on the effects of the active constituent on mammals. Assessment of this data concluded that the active has low toxicity (LD50 > 5000 mg/kg) and is non-infectious to mammals. The body temperature of most mammals is around 37ºC and unsuitable for growth of the fungus, which does not grow above 35ºC. Consultation of the literature did not indicate any evidence that *Beauveria bassiana* is toxic or pathogenic to mammals.

Consultation of the literature failed to find information that specifically associated the fungus with toxicity or pathogenicity in birds. One avian study was submitted – a study on chickens (*Gallus domesticus*) using a different strain of *Beauveria bassiana*. This 28 day chicken study showed no effects following feeding with $1 \times 10^9$ CFU /g food. This study, and standard exposure scenarios for residues consumed by representative birds, indicates that with two or more applications, the RQ (risk quotient) value is only marginally greater than 1 and there are no reports in publicly available literature of *Beauveria bassiana* being toxic/pathogenic to birds.

Considering the available information on mammals and that the use of the product is limited to protected horticulture (enclosed structures), significant exposure of terrestrial vertebrates to the product is not expected, hence, risks are considered to be acceptable.

### Soil organisms

Soil macro-organisms such as earthworms are not known to be sensitive to microbial biocontrol agents; no adverse effects have been reported in the literature for this group of organisms. Earthworms appear to be extremely resistant to pathogens; no microbial pathogen of these organisms has been reported to have detrimental effects on their growth and survival.

It is expected that any introduced *Beauveria bassiana* strain will likely co-exist with existing strains of this microorganism in soil, but could have antagonistic effects on other microorganisms. However, any effect is expected to be transient and is unlikely to lead to a significant adverse effect upon other aspects of an ecosystem. Soils are characterised by a rich composition of microorganisms. Some of these play important roles in geochemical cycles that are associated with the soil. Although non-target effects of microbial pest control products on soil organisms have been observed, they have usually been small and transient, few extending beyond a single season.

Considering no more than minor and localised transient effects are expected, the risks to soil organisms are considered to be acceptable.

### Aquatic species

International assessments (European and US) from a closely related strain of *Beauveria bassiana* included a NOEC of 7.6 x $10^4$ CFU /mL in *Daphnia magna*. Increased mortality and decreased mean body weight was observed at 1.3 x $10^5$ CFU /mL. Assessment showed a low risk to crustaceans under real field conditions.

Risks to aquatic vertebrates (eg, fish) were determined to be acceptable. The fungus is not known to be toxic or pathogenic to fish and it is not expected to survive and accumulate in water. The mode of action of *Beauveria bassiana* PPRI 5339 is specific to invertebrates and affects chitin which is an important material in the cellular structure of arthropods, but not vertebrates. As a result, the risks to aquatic vertebrates are considered to be acceptable.

### Aquatic and terrestrial plants

No ecotoxicity studies were submitted on plants. *Beauveria bassiana* has not been recorded as a phytopathogen, and as an entomopathogen is not expected to have significant adverse effects on plants. The risk to plants is acceptable.

## 7.4 Risk Assessment

Broadband OD Insecticide is to be applied by ground spray at a maximum application rate of 180 g/ha (1.8 x $10^{14}$ CFU /ha) with a minimum interval of 3 days between consecutive treatments. Based on the submitted data, and consultation of the literature, the assessment showed that risk of the active constituent to birds, mammals, reptiles, amphibians, earthworms, soil microorganisms and aquatic vertebrates is acceptable from the proposed use in protected horticulture.

Considering that the product is a known pathogen of arthropods, there is a hazard to bees and other non-target arthropods (both terrestrial and aquatic). The quantitative assessment to bees and terrestrial non-target arthropods demonstrated RQ values indicative of an acceptable risk to these organisms when used in a protected cropping situation due to limited exposure. No endpoints for the effects of *Beauveria bassiana* PPRI 5339 on aquatic invertebrates were available, but endpoints for equivalent strains of the fungus were supplied; use of these latter endpoints enabled assessing the risks. Appropriate protection statements on the label are required to identify the hazard to bees, and other terrestrial and aquatic invertebrates.

### RESTRAINTS

DO NOT apply in open field situations. Applications may only be made under covered or protected situations such as glasshouses, greenhouses, shade houses or plastic tunnels.

### PROTECTION OF HONEY BEES AND OTHER INSECT POLLINATORS

Harmful to bees. DO NOT spray while bees are actively foraging.

### PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

DO NOT contaminate wetlands or watercourses with this product or used containers.

### GENERAL INSTRUCTIONS

INTERGRATED PEST MANAGEMENT

May not be compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Contact BASF for more information.

## 7.5 Conclusions

The APVMA is satisfied that use of the proposed product is unlikely to have an unintended effect that is harmful to plants or animals or things or the environment when used as directed.

# 8 EFFICACY AND SAFETY ASSESSMENT

## 8.1 Proposed product use pattern

The product Broadband OD Insecticide is to be used as a fungal contact insecticide for population reduction of target insect pests on crops, specifically on all protected vegetables and ornamentals for preventative suppression of thrips (*Thrips tabaci* and *Frankliniella occidentalis*), whitefly (*Bemisia tabaci. B. argentifolii* and *Trialeurodes vaporariorum*), aphids (*Myzus persicae, Macrosiphum rosae* and *Macrosiphoniella sanborni*) and mites (*Tetranychus urticae*).

Broadband OD Insecticide is applied as a foliar spray to the point of good coverage, but not to the point of run off, at a rate of 100 mL/100 L for thrips and whitefly and 180 ml/100 L for aphids and mites when pests are first detected. The product should be applied in a water volume ranging from 500 to 2500 L/ha. Repeat applications of the product are to be made as necessary at intervals of 3-14 days.

## 8.2 Summary of evaluation of efficacy and crop safety

### Efficacy

A total of 31 trials were conducted in 5 countries spanning 3 years (2011, 2012, 2013) to determine the efficacy and crop safety of the product in protected vegetable and ornamental crops. Multiple applications were made at regular intervals throughout a broad range of crops and growth development stages. Rates tested ranged from 0.05 mL/100 L to 720 mL/100 L. The trials showed varied levels of efficacy for each of the target pests proposed.

Broadband OD Insecticide was found to be effective in the population suppression of thrips and whitefly at the label rate of 100 mL/100 L after several applications at intervals of 3 to 14 days. Similarly, the product was effective in the population suppression of aphids and mites at the rate of 180 mL/100 L after several applications.

Data are sufficient to support population suppression thrips, whitefly, aphids and mites in protected horticulture. The use of additional control measures is also recommended to minimise the risk of resistance to the product developing with repeated, ongoing use.

### Crop Safety

Broadband OD Insecticide at proposed application rates was shown to be safe to a broad range of protected crops (cucumber, tomato, eggplant, capsicum, lettuce, dwarf French bean, lima bean, rose, gerbera, chrysanthemum, daisy, marigold, poinsettia and impatiens) when applied at a range of growth stages from the development of true leaves through to the end of flowering. The product at the proposed application rates is therefore considered safe for protected vegetables and ornamentals.

### Resistance management

Insecticide Resistance Action Committee (IRAC) does not currently have any Mode of Action classifications for biological insecticides. IRAC guidelines state: Integrate other control methods (chemical, cultural, biological) into insect control programs. Broadband OD Insecticide may be used with repeat applications at an interval of 3-14 days and the studies provided indicate that repeated use is needed to achieve an adequate level of pest suppression. However, it is expected that use will occur together with other measures to control the pest, including chemical insecticides. Broadband OD Insecticide is best used within an Integrated Pest Management Program in conjunction with a chemical insecticide.

## 8.3 Conclusions

Based on the available data submitted with the application the APVMA considers that the product will be effective for the population suppression of whitefly, thrips, aphids and mites.

# 9 LABELLING REQUIREMENTS

**Label Name:** Broadband OD Insecticide

**Signal Headings:** POISON
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING

**Active Constituent:** 40 g/L *Beauveria bassiana* strain PPRI 5339 (>4 × $10^9$ colony-forming units per mL)

**Statement of Claims:** For the population suppression of thrips, whitefly, aphids and mites in protected horticulture.

**Net Contents:** 0.25 L, 0.5 L, 1 L, 5 L, 1000 L

**Restraints**: DO NOT apply during or just before overhead irrigation.
DO NOT apply in open field situations. Applications may only be made under covered or protected situations such as glasshouses, greenhouses, shade houses or plastic tunnels.

**DIRECTIONS FOR USE**

| SITUATION | Pest | RATE | CRITICAL COMMENTS |
|---|---|---|---|
| Protected vegetables and ornamentals | Western Flower Thrips (*Frankliniella occidentalis)*<br>Onion Thrips (*Thrips tabaci*)<br>Greenhouse Whitefly (*Trialeurodes vaporarium*)<br>Silverleaf Whitefly (*Bemisia argentifolii)*<br>Sweet Potato Whitefly (*Bemisia tabaci*) | 100 ml/100 L | Apply when pests are first detected in the crop or above economic thresholds.<br><br>Repeat applications are to be made as necessary at an interval of 3-14 days. Use Shorter application intervals when insect pressure is higher. Generally 3 consecutive weekly applications are required for adequate pest suppression. Broadband should be applied in a water volume ranging from 500 to 2500 L/ha.<br><br>It is important to ensure coverage on the bottom side of the leaves where pests might be located.<br><br>In higher pest situations, Broadband is best used within an Integrated Pest Management program in conjunction with a chemical insecticide. |
| | Green Peach Aphid (*Myzus persicae*)<br>Rose Aphid (*Macrosiphum rosae*)<br>Chrysanthemum Aphid (*Macrosiphoniella sanborni*)<br>Two Spotted Spider Mite (*Tetranychus urticae)* | 180 ml/100 L | |

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

**Withholding Periods:** Not required when used as directed.

**General Instructions:**

Broadband is best used on low pest populations to maintain pressure below economic damage threshold. Although the efficacy of Broadband at 100 mL/100 L (0.1%) was generally not as high as that of chemical products, the efficacy is considered high enough for management of pest populations under normal conditions.
Spray sufficient Broadband/water mixture, to obtain full crop coverage, but not to the point of run off.

MIXING:

SHAKE WELL BEFORE USE
Before use ensure that all application equipment is clean. Half fill spray tank with water and start agitation. Before opening the bottle of Broadband, agitate the bottle by repeated inversions to re-suspend fungal spores that may have settled during transport and storage. Add the required quantity of Broadband. Fill the tank to the required volume whilst maintaining agitation. Continuous agitation must be maintained until spraying is complete. All application equipment should be cleaned thoroughly with water prior to storage.

COMPATIBILITY:

Contact BASF for more information.

INTERGRATED PEST MANAGEMENT
May not be compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Contact BASF for more information.
The use of additional control measures is important to minimise the risk of resistance to Broadband developing with repeated, ongoing use.

**Precautions** Not for domestic use.

**Re-entry or Rehandling**

Do not enter treated areas until spray has dried or dissipated and enclosed area has been thoroughly ventilated, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves and goggles or safety glasses. Clothing must be laundered after each day's use.

**Protections:** PROTECTION OF HONEY BEES AND OTHER INSECT POLLINATORS
Harmful to bees. DO NOT spray while bees are actively foraging.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT
DO NOT contaminate wetlands or watercourses with this product or used containers.

**Storage and Disposal:**

Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight. As Broadband OD Insecticide is a biological product, storage temperature is crucial to its stability. Broadband OD Insecticide has a shelf life of 6 months from the date of manufacture, with storage required below 25 ºC (air conditioning).

Triple-rinse containers before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. If not recycling, break, crush, or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, bury the empty packaging 500 mm

below the surface in a disposal pit specifically marked and set up for this purpose, clear of waterways, desirable vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

**Safety Directions:**

May irritate the eyes. May irritate the skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. When opening the container, preparing the spray and using the prepared spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves and goggles or safety glasses. Wash hands after use. After each day's use wash gloves, goggles or safety glasses, and contaminated clothing.

**First Aid Instructions:**

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

# ABBREVIATIONS

| | |
|---|---|
| ac | active constituent |
| ADI | Acceptable Daily Intake (for humans) |
| ai | active ingredient |
| ARfD | Acute Reference Dose |
| bw | bodyweight |
| ºC | Degrees Celsius |
| CFU | Colony Forming Units |
| d | day |
| DAT | Days After Treatment |
| DofE | Department of Environment |
| $DT_{50}$ | Time taken for 50% of the concentration to dissipate |
| $EC_{50}$ | concentration at which 50% of the test population are immobilised |
| EI | Export Interval |
| ESI | Export Slaughter Interval |
| EUP | End Use Product |
| Fo | original parent generation |
| g | gram |
| GAP | Good Agricultural Practice |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |
| GVP | Good Veterinary Practice |
| h | hour |
| ha | hectare |
| HDPE | High Density Polyethylene |
| HPLC | High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography |
| IRAC | Insecticide Resistance Action Committee |

| | |
|---|---|
| ip | intraperitoneal |
| IPM | Integrated Pest Management |
| in vitro | outside the living body and in an artificial environment |
| in vivo | inside the living body of a plant or animal |
| kg | kilogram |
| $K_{oc}$ | Organic carbon partitioning coefficient |
| L | Litre |
| $LC_{50}$ | concentration that kills 50% of the test population of organisms |
| $LD_{50}$ | dosage of chemical that kills 50% of the test population of organisms |
| LOD | Limit of Detection – level at which residues can be detected |
| LOQ | Limit of Quantitation – level at which residues can be quantified |
| mg | milligram |
| mL | millilitre |
| mPa·s | millipascal-second |
| MoA | Mode of Action |
| MRL | Maximum Residue Limit |
| MSDS | Material Safety Data Sheet |
| NDPSC | National Drugs and Poisons Schedule Committee |
| NEDI | National Estimated Daily Intake |
| NESTI | National Estimated Short Term Intake |
| ng | nanogram |
| NOEC/NOEL | No Observable Effect Concentration Level |
| OC | Organic Carbon |
| OM | Organic Matter |
| po | oral |
| ppb | parts per billion |
| PPE | Personal Protective Equipment |

| | |
|---|---|
| ppm | parts per million |
| RQ | Quotient-value |
| s | second |
| sc | subcutaneous |
| SDS | Safety Data Sheet |
| SUSMP | Standard for the Uniform Scheduling of Medicines and Poisons |
| TGA | Therapeutic Goods Administration |
| TGAC | Technical grade active constituent |
| T-Value | A value used to determine the First Aid Instructions for chemical products that contain two or more poisons |
| µg | microgram |
| WHP | Withholding Period |
| WP | Wettable Powder |

# GLOSSARY

| | |
|---|---|
| Active constituent | The substance that is primarily responsible for the effect produced by a chemical product |
| Acute | Having rapid onset and of short duration. |
| Carcinogenicity | The ability to cause cancer |
| Chronic | Of long duration |
| Codex MRL | Internationally published standard maximum residue limit |
| Desorption | Removal of a material from or through a surface |
| Efficacy | Production of the desired effect |
| Formulation | A combination of both active and inactive constituents to form the end use product |
| Genotoxicity | The ability to damage genetic material |
| Hydrophobic | repels water |
| Leaching | Removal of a compound by use of a solvent |
| Log Pow | Log to base 10 of octanol water partitioning co-efficient, synonym KOW |
| Metabolism | The chemical processes that maintain living organisms |
| Photodegradation | Breakdown of chemicals due to the action of light |
| Photolysis | Breakdown of chemicals due to the action of light |
| Subcutaneous | Under the skin |
| Toxicokinetics | The study of the movement of toxins through the body |
| Toxicology | The study of the nature and effects of poisons |
| Ubiquitous | Present, appearing or found everywhere |

# REFERENCES

US EPA (1998). United States Environmental Protection Agency (US EPA). *The Pesticide Handlers Exposure Database (PHED), version 1.1-PHED Surrogate Exposure Guide, Estimates of Worker Exposure.* US EPA, Washington DC, United States, 1998.