Australian Government

Australian Pesticides and Veterinary Medicines Authority

Public Release Summary

on the evaluation of the new active Flg22-Bt Peptide in the product Vismax Specialty Fungicide

APVMA product number 95076

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This publication is available from the APVMA website.

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator responsible for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia. Before approving an active constituent and/or registering a product, the APVMA must be satisfied that the statutory criteria, including the safety, efficacy, trade, and labelling criteria, have been met. The information and technical data required by the APVMA to assess the statutory criteria 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.

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. 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 advisory agencies, including other Australian Government agencies and State departments of primary industries. 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 Public Release Summary 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 registration of Vismax Specialty Fungicide 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 application. 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 21 April 2026 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:

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

Please note: submissions will be published on the APVMA website unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Case Management Team – Pesticides
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Phone: +61 2 6770 2300
Email: casemanagement@apvma.gov.au.

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.

Introduction

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of Vismax Specialty Fungicide, and approval of the new active constituent, Flg22-Bt Peptide.

Applicant

ELEMENTAL ENZYMES AUSTRALIA PTY LTD.

Purpose of application

ELEMENTAL ENZYMES AUSTRALIA PTY LTD has applied to the APVMA for registration of the new product Vismax Specialty Fungicide, containing 0.12 g/L, as a Soluble Concentrate (SL) formulation of the new active constituent Flg22-Bt Peptide.

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of the product Vismax Specialty Fungicide, and approval of the new active constituent Flg22-Bt Peptide.

Proposed claims and use pattern

For use on almonds to suppress shot hole disease caused by *Wilsonomyces carpophilus*.

Mode of action

FIg22-Bt Peptide works through a non-toxic mode of action via a natural mechanism to increase resistance to plant pathogens. It activates the plant's immune system through multiple plant defence mechanisms, to provide broad-spectrum prevention and suppression of a wide range of fungal and bacterial diseases.

Overseas registrations

The product is currently registered in the USA as Vismax®, for protecting against bacterial and fungal diseases in horticultural and field crops. The product is also registered in Brazil for use in citrus crops affected by Citrus Greening and Citrus Canker.

Chemistry and manufacture

Active constituent

The active constituent Flg22-Bt Peptide is manufactured overseas. Details of the chemical name, structure, and physicochemical properties of Flg22-Bt Peptide are listed below in Tables 1 to 2.

Table 1: Nomenclature and structural formula of Flg22-Bt Peptide

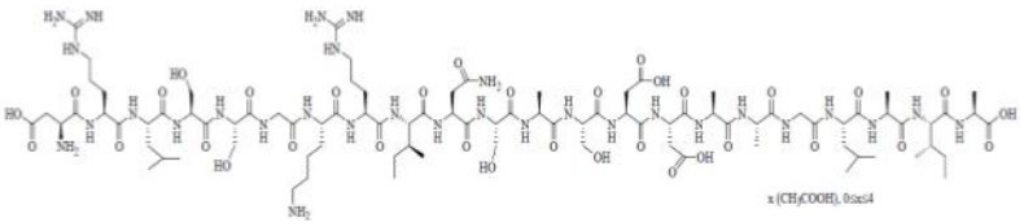
Common name (ISO):	Flg22-Bt Peptide
IUPAC name:	N/A
CAS registry number:	N/A
Molecular formula:	$C_{89}H_{154}N_{30}O_{34}$
Molecular weight:	2188.4 Da
Structural formula:	Amino acid sequence: H-Asp-Arg-Leu-Ser-Ser-Gly-Lys-Arg-Ile-Asn-Ser-Ala-Ser-Asp-Asp-Ala-Ala-Gly-Leu-Ala-Ile-Ala-OH (as acetate salt) 

Table 2: Key physicochemical properties of the active constituent Flg22-Bt Peptide

Physical form:	Powder
Colour:	White
Odour:	Odourless
Melting point:	There was no melting point observed when Flg22-Bt Peptide was heated from 30 ± 1 °C to 430 °C at a heating rate of 2 °C/minute in the presence of nitrogen at the normal atmospheric pressure (760 mm Hg).
Boiling point:	N/A
Bulk density	0.0404 g/mL
Stability:	Flg22-Bt Peptide Technical remains stable for at least 24 months when stored frozen (-20 °C) in commercial packaging and protected from light. Interactions with metals or metal ions is unknown and not required considering the manufacturing and the storage of the active constituent.
Safety properties:	Flg22-Bt Peptide is non-corrosive in nature. Flg22-Bt Peptide contains no chemical groups associated with flammability or explosive properties.
Solubility in water:	>100g/L
Organic solvent solubility:	Methanol: 0.00411 g/L *p*-xylene: 0.00156 g/L
Dissociation constant (PK_a):	Flg22-Bt Peptide has eight functional groups with acid-base behaviour. When Flg22-Bt Peptide dissolves in water, these groups ionize. At a pH value between 6.04 and 6.99, the net charge of the peptide is predicted to equal zero (the isoelectric point).
pH:	pH of 1.0% (w/V) aqueous solution is 4.85±0.01 at 20.2℃
Octanol/water partition coefficient (Log K_{ow}/K_{OW}):	The partition coefficient (Log_{10} Pow) of Flg22-Bt Peptide could not be determined as Flg22-Bt Peptide exhibited high tendency towards the hydrophilic solvent (water).
Vapour pressure:	Flg22-Bt Peptide Technical is a dry, solid peptide. Peptides have very low predicted vapor pressures (often below sensitivity of the measuring apparatus). Additionally, upon heating, biological materials such as peptides have a tendency to degrade before vaporizing.
Henry's law constant:	Flg22-Bt Peptide Technical is a dry, solid peptide, not a gas. Peptides have very low predicted vapor pressures. Therefore, Henry's law constant cannot be measured.
UV/VIS absorption spectra:	ε = 84933 L $mol^{-1}cm^{-1}$ at λ_{max} = 200 nm

Flg22-Bt Peptide is a naturally occurring peptide sequence containing 22 amino acids derived from flagellin protein from a ubiquitous soil bacteria, *Bacillus thuringiensis* strain BT013A. This small protein fragment is a highly conserved N-terminal epitope of bacterial flagellin that are required for bacterial motility. This linear

chain peptide does not have a well-defined two-dimensional or three-dimensional structure. The active constituent nominated for approval, Flg22-Bt Peptide, is not extracted from the bacteria, rather it is synthetically produced and purified.

Formulated product

The product Vismax Specialty Fungicide will be manufactured both overseas and in Australia. Tables 3 and 4 outline some key aspects of the formulation and physicochemical properties of the product.

Table 3: Key aspects of the formulation of the product Vismax Specialty Fungicide

Distinguishing name:	Vismax Specialty Fungicide
Formulation type:	Soluble Concentrate (SL)
Active constituent concentration/s:	Not less than 0.065 g/L

Table 4: Physicochemical properties of the product Vismax Specialty Fungicide

Physical form:	Liquid
pH:	Undiluted product pH: 5.74±0.01 at 20℃ 1% (w/v) Aqueous Solution of product pH: 6.46 ± 0.03 at 20 ℃
Specific gravity/density:	0.99567
Kinematic viscosity:	1.11 ± 0.01 cP (mPa s) at 20 °C 0.69 ± 0.01 cP (mPa s) at 40 °C
Persistent foam	No foam produced
Safety properties:	Not flammable, not explosive and do not pose corrosive hazard
Solubility in water	Fully miscible
Storage stability:	The product should remain within specifications for at least 2 years when stored under normal conditions.

Recommendations

The APVMA has evaluated the chemistry and manufacturing of the active constituent Flg22-Bt Peptide and associated product Vismax Specialty Fungicide, including the manufacturing process, quality control procedures, stability, batch analysis results and analytical methods, and found them to be acceptable. Storage stability and efficacy data support stability at ambient temperature over two years, with efficacy maintained throughout the storage period. Therefore, a condition of registration is imposed to include an

expiry date of two (2) years from date of manufacture on the product label. It is also recommended that the active constituent Flg22-Bt Peptide be included in the list of date-controlled agricultural chemical products in Schedule 1 of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Code Regulations). Overall, the formulated product is expected to remain stable (providing adequate efficacy) for at least 2 years when stored under normal conditions.

Based on a review of the chemistry and manufacturing details, the registration of Vismax Specialty Fungicide, and approval of the active constituent Flg22-Bt Peptide, are supported from a chemistry perspective.

Toxicological assessment

A limited toxicological data package (acute toxicity studies, *in vitro* assay and *in silico* analysis) for Flg22-Bt peptide was submitted by the applicant, which was sufficient to assess the toxicity of Flg22-Bt peptide.

Evaluation of toxicology

Chemical class

Flg22-Bt peptide is a naturally occurring 22-amino acid peptide derived from flagellin protein (fliC) from Bacillus thuringiensis BT013A. The synthetically derived peptide is identical to the naturally occurring peptide produced by *Bacillus thuringiensis*. Flg22-Bt peptide is a broad-spectrum activator of multiple plant defence mechanisms for the suppression of bacterial and fungal diseases in various crops. Flg22-Bt peptide produces an immune response within the plant to act against various pathogens.

Pharmacokinetics

A non-guideline *in vitro* digestion assay was performed to determine the fate of Flg22-Bt peptide in simulated gastric fluid. The study revealed that after 30 seconds exposure, none of the parent peptide was detectible, suggesting that the peptide is rapidly degraded upon exposure to a simulated digestive environment. This indicates that systemic exposure to the peptide is likely to be negligible and repeat dose toxicity studies are not warranted.

Acute toxicity (active constituent)

Flg22-Bt peptide was considered to have low toxicity via the oral, dermal and inhalation routes of exposure. It was slightly irritating to the eyes of rabbits; however, it was not irritating to the skin of rabbits, and it was not a skin sensitiser in a mouse local lymph node assay (LLNA) study.

Acute toxicity (product)

Vismax Specialty Fungicide has low toxicity by the oral, dermal and inhalation routes of exposure, it has slight eye irritation potential but is neither a skin irritant nor a skin sensitiser in the mouse (LLNA).

Repeat-dose toxicity

No repeat dose toxicity studies were submitted by the applicant.

Chronic toxicity and carcinogenicity

No chronic toxicity and carcinogenicity studies were submitted by the applicant.

Reproductive and developmental toxicity

No reproductive and developmental toxicity studies were submitted by the applicant.

Genotoxicity

Based on an adequate array of genotoxicity studies that all produced negative results, it can be concluded that Flg22-Bt peptide is unlikely to have any genotoxic potential.

Neurotoxicity/immunotoxicity

No neurotoxicity/immunotoxicity studies were submitted by the applicant.

Mode of action (toxicology)

No mode of action or investigative studies on Flg22-Bt peptide were provided by the applicant. However, the applicant proposed that Flg22-Bt Peptide works through a non-toxic mode of action via a natural mechanism to increase resistance to plant pathogens. It activates the plant's immune system through multiple plant defence mechanisms to provide broad-spectrum prevention and suppression of a wide range of fungal and bacterial diseases.

Toxicity of metabolites and/or impurities

None identified.

Reports related to human toxicity

No specific data have been provided by the applicant. The existing toxicology database on Flg22-Bt peptide was considered adequate by the APVMA to characterize the potential hazards to the general population. In addition, search of the scientific literature was conducted by the APVMA using the United States National Library of Medicine (https://www.ncbi.nlm.nih.gov/pubmed) on the potential of Flg22-Bt peptide for adverse effects (e.g., allergy and immunology) arising from occupational exposure. No relevant literature or studies were found. It should be noted, however that there are historical reports of allergenicity in farm workers exposed to early preparations of Bt formulations, which are not the same as the purified Flg22-Bt peptide.

Microbiological properties

Not applicable.

Infectivity/pathogenicity

Not applicable.

Sensitisation potential

Neither Flg22-Bt peptide nor the product demonstrated skin sensitisation potential in animal studies.

Health-based guidance values and poisons scheduling

Poisons Standard

Flg22-Bt peptide does not require control by scheduling due to low acute toxicity and lack of developmental toxicity and neurotoxicity effects and therefore, it was considered not to meet the scheduling factors as stipulated in the Scheduling Policy Framework (AHMAC, 2018[1]).

Health-based guidance values

Acceptable daily intake

No Acceptable Daily Intake (ADI) is proposed for Flg22-Bt peptide. The peptide is rapidly digested in simulated gastric fluid. The Flg22-Bt peptide is also expected to be rapidly degraded in the environment and human-relevant food/feed residues are unlikely to occur. Accordingly human systemic exposure is expected to be negligible and thus an ADI is not considered necessary.

Acute reference dose

No Acute Reference Dose (ARfD) is proposed for Flg22-Bt peptide.

Recommendations

There are no objections on human health grounds to the approval of the new active constituent Flg22-Bt peptide.

Based on a review of the human health details, the registration of the product Vismax Specialty Fungicide, containing 0.12 g/L of Flg22-Bt peptide is supported from health perspective when the product is used as directed on the label safety directions and appropriate PPE are worn.

[1] AHMAC, 2018 https://www.tga.gov.au/products/regulations-all-products/ingredients-and-scheduling-medicines-and-chemicals/scheduling-national-classification-system/scheduling-basics-medicines-and-chemicals-australia/ahmac-scheduling-policy-framework-medicines-and-chemicals

Residues assessment

No metabolism data have been provided for Flg22-Bt Peptide. Flg22-Bt Peptide is identical to a fragment of a naturally occurring protein from the flagellum of the bacterium Bacillus thuringiensis BT013A, which is ubiquitous within the environment. The Applicant indicated that it is rapidly degraded by plants and leaves no detectable residues. On this basis, metabolism data were not required, and a residues definition has not been established.

Analytical methods and storage stability

No analytical methods for the determination of Flg22-Bt Peptide in crops have been provided or are required for this naturally occurring material.

Residues in food and animal feeds

The Applicant has indicated that synthetically produced Flg22-Bt Peptide is identical to a naturally occurring 22-amino acid peptide sequence derived from the flagellin protein from the flagellum of the ubiquitous bacterium Bacillus thuringiensis BT013A. Therefore, this peptide sequence already exists and is prolific in nature. The Applicant indicated that it is rapidly degraded by plants and leaves no detectable residues. Given the nature and properties of Flg22-Bt Peptide, residue studies are not considered relevant nor necessary.

Noting that Flg22-Bt Peptide is a simple peptide, standard protein and amino acid metabolism in mammals applies. An in vitro digestive enzyme assay was presented to demonstrate the rapid degradation of Flg22-Bt Peptide in a simulated mammalian gastric fluid with pepsin for up to 60 minutes (pH 3; 37°C). The degradation products (amino acids) will be taken up in the intestines, transported across the membrane, released at the basal surface of the mucosal cells and transferred into the bloodstream to be transported to the liver and various cells for protein synthesis. Therefore, exposure to Flg22-Bt Peptide is not different to any other source of amino acids.

The Applicant has also indicated that Flg22-Bt Peptide works through a non-toxic mode of action via a natural mechanism to increase resistance to plant pathogens. It activates the plant's immune system through multiple plant defence mechanisms, thereby providing broad-spectrum prevention and suppression of a wide range of fungal and bacterial diseases. Based on the available data for Flg22-Bt Peptide, there are no indications of mammalian toxicological effects. Due to its rapid digestibility, lack of toxicity and allergenicity, Flg22-Bt Peptide dietary exposure is not anticipated to pose any human health hazards.

Table 5 lists uses of substances where MRLs are not necessary. MRLs are not necessary in situations where residues do not or should not occur in foods or animal feeds; or where the residues are identical to or indistinguishable from natural food components; or otherwise, are of no toxicological significance. A Table 5 entry in the MRL Standard for Residues of Chemical Products is appropriate to cover the proposed use of Flg22-Bt Peptide as its residues are indistinguishable from natural sources and are not of toxicological significance.

Residues in animal commodities

The active constituent of the product is a peptide sequence copied from a naturally occurring protein from the flagellum of Bacillus thuringiensis, which is ubiquitous in the environment. Flg22-Bt Peptide is non-toxic, rapidly digested and not metabolised in mammals. It is not necessary to establish animal commodity MRLs for Flg22-Bt Peptide.

Dietary risk assessment

Health-based guidance values are considered unnecessary for Flg22-Bt Peptide. For this reason and because expected residues are indistinguishable from natural sources, the use of this compound on food crops does not introduce a hazard to consumers of food crops treated with the proposed use and it is not necessary to undertake a dietary exposure assessment.

Recommendations

Table 5: The following amendment is required to be made to the APVMA MRL Standard (Table 5).

Amendment to Table 5	
Substance	**Use**
Add:	
Flg22-Bt Peptide	When used on food producing crops

Assessment of overseas trade aspects of residues in food

Whilst almonds are not considered to be major export commodities, commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed almond hulls produced from treated almonds, are considered to be major export commodities.

It is recommended that a Table 5 entry be established to cover the proposed use in Australia as MRLs are not considered necessary.

Noting that Flg22-Bt Peptide residues are indistinguishable from natural sources and are not of toxicological significance, it is deemed that the proposed use is not expected to present a risk to international trade.

Work health and safety assessment

Health hazards

Vismax Specialty Fungicide has low toxicity by the oral, dermal and inhalation routes of exposure, it has slight eye irritation potential but is neither a skin irritant nor a skin sensitiser in the mouse (LLNA).

Occupational exposure

Exposure during use

Vismax Specialty Fungicide, containing 0.12 g/L Flg22-Bt peptide is intended to be used for the control or suppression of shot hole in almonds. The product is applied as a foliar application to almonds, during flowering and up to harvest. Vismax Specialty Fungicide will be applied at a rate of 100 mL product per 100 L water with a maximum of 3 applications per season with a minimum interval of 7 days. Therefore, worker exposure during use is likely to result from mixing, loading and application (M/L/A) of the product.

The concentration of the active constituent in the proposed product is very low (0.12 g/L) and the application rates for foliar application of the product results in less than 1 g of the active constituent applied per hectare of crop.

As the active constituent is rapidly degraded, and is relatively insoluble in organic solvents, systemic exposure is anticipated to be negligible. The applicant has not identified any mammalian receptor for Flg22-Bt peptide, and as such the substance is not predicted to induce a physiological response outside of plants. While inhalation exposure is anticipated as a result of spray operations involving the use of this product, respiratory sensitisation is not expected to occur.

Quantitative exposure assessment is not considered necessary for users of the product, members of the public and bystanders, nor for post-application exposure to foliar residues upon re-entry to treated areas.

Exposure during re-entry or rehandling

Post-application exposure to foliar residues upon re-entry to treated areas is expected to be negligible.

Public exposure

The product is intended for professional use and is not expected to be handled by members of the public.

Recommendations

The following first aid instructions, safety directions and precautionary (warning) statements are recommended for the product label.

First aid instructions

First aid is not generally required. If in doubt, contact a Poisons Information Centre (phone *Australia 13 11 26*; *New Zealand 0800 764 766*) or a doctor.

Safety directions

May irritate the eyes. Avoid contact with eyes. Wash hands after use

Precautionary (warning) statements

Not required.

Environmental assessment

Fate and behaviour in the environment

Flg22-Bt peptide is identical to a naturally occurring 22-amino acid peptide derived from the *Bacillus thuringiensis* flagellin protein (fliC). Flagellin and flagellin fragments are ubiquitous in the soil environment. The flagellin protein is the most abundant *Bacillus* protein: one vegetative cell contains an estimated 150,000 to 400,000 monomers of flagellin.

Flg22-Bt peptide is highly soluble in water and is expected to remain in the water phase. It is susceptible to hydrolysis (DT_{50} 71 d at pH 4, DT_{50} 11 d at pH 7; DT_{50} 30 d at pH 9), and expected to break down into its component amino acids.

High molecular weight polypeptides such as Flg22-Bt peptide are not expected to be volatile and hence are not expected to undergo long-range transport through the air.

Effects and associated risks to non-target species

Terrestrial vertebrates

Flg22-Bt peptide has low toxicity to mammals (LD_{50} >5000 mg ac/kg bw, *Rattus norvegicus*) and birds (LD_{50} >2257 mg ac/kg bw, *Colinus virginianus*). It is rapidly digested in simulated gastric fluid of mammals and is expected to be rapidly degraded into its component amino acids upon oral consumption. Additionally, flg22-Bt peptide does not activate the vertebrate flagellin receptor, Toll-like receptor 5 (TLR5), which recognize a different domain of bacterial flagellin that does not include flg22. Therefore, adverse effects from long term exposure are not expected. Acceptable risks to terrestrial vertebrates were concluded assuming they feed on food items (e.g. vegetation and invertebrates) within the treatment area that are directly over-sprayed. No protection measures are therefore considered necessary for terrestrial vertebrates.

Aquatic species

Flg22-Bt peptide has low toxicity to fish (LC_{50} >90 mg ac/L, *Oncorhynchus mykiss*), aquatic invertebrates (EC_{50} >110 mg ac/L, *Daphnia magna*) and algae (E_rC_{10} >74 mg ac/L, *Raphidocelis subcapitata*). No adverse effects were observed at the maximum concentrations tested in any of the aquatic toxicity studies. Acceptable risks to aquatic species were concluded assuming a direct overspray of a shallow aquatic habitat. No protection measures are therefore considered necessary for aquatic species.

Bees and other non-target arthropods

Flg22-Bt peptide has low toxicity to bees by oral exposure (LD_{50} >110 µg ac/bee, *Apis mellifera*) and contact exposure (LD_{50} >110 µg ac/bee, *Apis mellifera*). No adverse effects were observed at the highest doses tested in either study. Acceptable risks were concluded assuming a direct overspray of blooming plants that are frequented by bees. No protection measures are therefore considered necessary for bees.

Based on a non-toxic mode of action and natural occurrence of flagellins in the soil environment, adverse effects due to flg22-Bt peptide on other arthropod species are not expected. Risks to other arthropods are therefore also expected to be low and no protection measures are considered necessary.

Soil organisms

Flagellin protein (fliC) occurs naturally in the soil environment. Following chronic exposure to Flg22-Bt peptide, reduced reproduction of earthworms was observed in a dose-dependent manner (EC_{10} 26 mg ac/kg dry soil, *Eisenia fetida*). No adverse effects were observed at the highest concentrations tested in two other species of soil macro-organisms (EC_{10} >1000 mg ac/kg dry soil, *Folsomia candida* and *Hypoaspis aculeifer*). A representative SL formulation of Flg22-Bt peptide had no direct effect on soil bacteria or fungi. Acceptable risks to organisms were concluded assuming a direct overspray of soil without interception. No protection measures are therefore considered necessary for soil organisms.

Non-target terrestrial plants

A representative SL formulation of flg22-Bt peptide caused no adverse effects on ten species of non-target terrestrial plants at the highest rate tested following pre-emergent exposure (ER_{25} >1.9 g ac/ha). In addition, no phytotoxicity was observed in submitted crop safety trials following foliar exposure of six plant species to field relevant rates (0.012 g ac/ha in *Brassica napus* to 0.36 g ac/ha in *Prunus dulcis*). Flg22-Bt peptide does not have a toxic mode of action but is used to stimulate an immune response in treated plants. It has not been shown to change the morphology or growth characteristics of the plants. Therefore, adverse effects due to flg22-Bt peptide on non-target terrestrial plants are not expected.

Recommendations

No protection measures are considered necessary for non-target species under the proposed conditions of use.

Efficacy and safety assessment

Elemental Enzymes Australia Pty Ltd has submitted efficacy and crop safety data seeking approval of a new active constituent, Flagellin 22 Bacillus thuringiensis Peptide (Flg22-Bt Peptide), and the registration of a formulated product Vismax Specialty Fungicide containing not less than 0.065 g/L Flg22-Bt Peptide.

Flg22-Bt Peptide triggers early, innate immune responses in plants and elicits broad-spectrum systemic and local resistance, inhibiting fungal and bacterial pathogen growth but does not cause plant cell death. Foliar application of the peptide can induce defence reactions in roots, stems and other plant parts.

Proposed product use pattern

For use on almonds to suppress shot hole disease caused by *Wilsonomyces carpophilus.*

Efficacy and target crop safety

Efficacy

The applicant submitted data from eight field efficacy trials conducted in Australia and three trials in California, USA to support the proposed label claims for Vismax Specialty Fungicide. The growing conditions in California are similar to those in some parts of Australia for almonds and the trials involved the use of the same almond varieties. The results of trials on three varieties of sweet almond under low to moderate disease pressures demonstrated that Vismax Specialty Fungicide suppresses shot hole in almond. The results from the trials showed Vismax Specialty Fungicide provided around 60% control of shot hole in almonds, which is consistent with the suppression claims. The reduction in incidence and severity of the disease was equivalent to that of industry standard fungicides in most trials.

The proposed label directions recommend that the product should be used in conjunction with a registered non-ionic surfactant. In the Australian trials, Vismax mixed with surfactants at the proposed label rate or applied in a sequence with other fungicides provided pathogen suppression. Half label rate (50 mL/100 L) was tested as an approximation of the product near the end of its two year-shelf life (providing minimum protein activity expected of not less than 0.065 g/L) and the efficacy observed did not differ from that of fresh product or accelerated aged product.

Crop safety

Crop safety was demonstrated with twice the proposed label rate and up to three applications applied throughout flowering and growing season of almond. Kernel yields and harvests were also determined in five trials which showed that Vismax Specialty Fungicide did not negatively impact yield or quality, with some trials showing improvement in yield.

Recommendations

Based on the trials, Vismax Specialty Fungicide is efficacious and safe for the suppression of shot hole in almonds.

Spray drift assessment

Regulatory Acceptable Levels (RALs) were established using the APVMA Spray Drift Assessment Tool (SDRAT), or Spray Drift Management Tool (SDMT), by each risk area, in order to calculate the appropriate spray drift buffer zones for Vismax Specialty Fungicide.

Human health

Risks to bystanders from spraying activities is not expected to occur.

Residues and trade

Risks to livestock from spraying activities is not expected to occur.

Environment

The RAL 9000 µg ac/L for the protection of natural aquatic areas is based on the LC_{10} 90,000 µg ac/L for toxicity of flg22-Bt peptide to *Oncorhynchus mykiss* and an assessment factor of 10.

The RAL 18,333 g ac/ha for the protection of pollinator areas is based on the contact LD_{50} >110 µg ac/bee for toxicity of flg22-Bt peptide to *Apis mellifera*, an assessment factor of 2.5, and a conversion factor of 1000 / ExpE 2.4 to account for the surface area of a bee.

The RAL 0.95 g ac/ha for the protection of vegetation areas is based on the pre-emergent ER_{25} >1.9 g ac/ha for ten plant species and an assessment factor of 2.

Table 6: Summary of RALs for Vismax Specialty Fungicide

Sensitive area	Regulatory Acceptable Level	
	Level of active	Units
Bystander		g/ha
Livestock		ppm
Aquatic	9000	µg/L
Pollinator	18,333	g/ha
Vegetation	0.95	g/ha

Buffer zones calculated by the SDRAT or SDMT, using the above RALs, were incorporated into the Vismax Specialty Fungicide label spray drift instructions. Results from the calculations showed no buffer zones are required for all sensitive areas. (see *Labelling requirements* below).

Labelling requirements

Company Name: ELEMENTAL ENZYMES AUSTRALIA PTY LTD
Product Name: Vismax Specialty
APVMA Approval No: Fungicide 95076 / 144596

Label Name:	Vismax Specialty Fungicide

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

Constituent Statements:	0.12 g/L Flg22-Bt Peptide

Mode of Action:	

Statement of Claims:	Vismax Specialty Fungicide is a broad-spectrum activator of multiple plant defence mechanisms for the suppression of bacterial and fungal diseases in various crops.

Net Contents:	1-1000L

Restraints:	DO NOT use with unblended crop oils.

Directions for Use:	This section contains file attachment. File Name: 6a. DIRECTIONS FOR USE.pdf File Size: 45069 bytes

Other Limitations:	

Withholding Periods:	Withholding Periods: Harvest: Nil Grazing: Nil

Trade Advice:	

General Instructions:	This section contains file attachment. File Name: 6b. GENERAL INSTRUCTIONS.pdf File Size: 43766 bytes

Resistance Warning:	Vismax® Specialty exhibits a mode of action uniquely different from currently available fungicides and bactericides. Since Vismax® Specialty has no direct activity on plant pathogens, the likelihood that resistance (insensitivity) will develop in the pathogens is low. However, plant pathogens are known to develop tolerance to host plant resistance and to products used repeatedly for control. As resistance development cannot be fully predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotating and/or tank mixing with products with different modes of action, as well as the use of good cultural practices. For further information contact your local supplier, Elemental Enzymes representative or local agricultural department agronomist.

Precautions:	

Protections:	PROTECTION OF WILDLIFE, FISH CRUSTACEA AND ENVIRONMENT DO NOT contaminate streams, rivers or watercourses with the chemical or used containers.

Storage and Disposal:	STORAGE AND DISPOSAL Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight. Protect from frost and do not allow Vismax® Specialty to freeze. This container can be recycled if it is clean, dry, free of visible residues and has the drumMUSTER logo visible. Triple-rinse container for disposal. Dispose of rinsate by adding it to the spray tank. Do not dispose of undiluted chemical on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management program site. The cap should not be replaced but may be taken separately.

Safety Directions:	SAFETY DIRECTIONS May irritate eyes. Avoid contact with eyes. Wash hands after use.

First Aid Instructions:	FIRST AID First aid is not generally required. If in doubt, contact a Poisons Information Centre (phone Australia 13 11 26) or a doctor.

First Aid Warnings:	

SPRAY DRIFT RESTRAINTS

Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.

DO NOT apply by a vertical sprayer unless the following requirements are met:

- spray is not directed above the target canopy

- the outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site.

DIRECTIONS FOR USE

Crop	Target Diseases	Application Method	Rate	Application Instructions
Almonds	Shot-Hole (*Wilsonomyces carpophilus*)	Foliar	100 ml/100L + non-ionic surfactant*	Apply during flowering until prior to harvest. Apply up to 3 times throughout the growing season, with a minimum interval of 7 days. For dilute spraying ensure thorough crop coverage and apply to the point of runoff. Apply enough water to the point of runoff using a medium spray quality according to the ASABE S572 standard. For concentrate spraying apply in a minimum volume of 800L/ha equivalent * Add a registered non-ionic surfactant as per label instructions.

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

GENERAL INSTRUCTIONS

INTEGRATED PEST MANAGEMENT

Vismax® Specialty should be integrated into an overall disease and pest management strategy whenever pesticide is required. Cultural practices known to reduce disease development should be followed. Consult your local agricultural authorities for IPM strategies established in your areas.

MIXING INSUTRCTIONS

Mixing Procedure for Tank Mixes

Step 1: Add 1/2 to 2/3 of the required amount of clean water to the spray or mixing tank.
Step 2: With the agitator running, add tank-mix partner(s) in the following order: wettable powders, wettable granules, liquid flowables, emulsifiable concentrates, soluble concentrates (Vismax® Specialty) and surfactants.
Step 3: Allow material(s) to completely dissolve and disperse into the mix water.
Step 4: Fill the spray tank with balance of water needed.
Step 5: Maintain agitation until the mixture has been applied.

Note: Do not allow spray mixture to stand overnight or for prolonged periods. No label dosage rate may be exceeded, and the most restrictive label precautions and limitations must be followed. This product may not be mixed with any product which prohibits such mixing.

Surfactants

This product does not contain a surfactant. For thorough coverage of foliage, Vismax® Specialty must be applied with a non-ionic surfactant at the indicated label rate.

Use only non-ionic or non-ionic blend adjuvants approved for use on growing crops. Reference adjuvant label for rate recommendations and mixing instructions. DO NOT use with unblended crop oils.

Crop Tolerance/Phytotoxicity: Although plant tolerance has been found to be acceptable for all crops on the label, not all possible tank-mix combinations have been tested under all conditions. When possible, it is recommended to test the combinations on a small portion of the crop to ensure that phytotoxic response will not occur as a result of application.

Acronyms and abbreviations

Shortened term	Full term
ac	Active constituent
ADI	Acceptable daily intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	Active ingredient
ARfD	Acute reference dose
bw	Bodyweight
d	Day
DT_{50}	Time taken for 50% of the concentration to dissipate
EC_{50}	Concentration at which 50% of the test population are immobilised
EEC	Estimated environmental concentration
E_rC_{50}	Concentration at which the rate of growth of 50% of the test population is impacted
g	Gram
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
h	Hour
ha	Hectare
IPM	Integrated pest management
in vitro	Outside the living body and in an artificial environment
kg	Kilogram
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
Log K_{OW}	Log to base 10 of octanol water partitioning co-efficient, synonym P_{OW}
LOQ	Limit of quantitation – level at which residues can be quantified
mg	Milligram

Shortened term	Full term
mL	Millilitre
MRL	Maximum Residue Limit
SDS	Safety Data Sheet
po	Oral
ppb	Parts per billion
PPE	Personal protective equipment
ppm	Parts per million
RAL	Regulatory Acceptable Level
REI	Re-entry interval
s	Second
SDMT	Spray Drift Management Tool
SDRAT	Spray Drift Risk Assessment Tool
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TGAC	Technical grade active constituent
µg	Microgram
vmd	Volume median diameter
WG	Water dispersible granule
WHP	Withholding period

Glossary

Term	Description
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
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
Metabolism	The chemical processes that maintain living organisms
Subcutaneous	Under the skin
Toxicology	The study of the nature and effects of poisons

References

APVMA (2025a). Acceptable Daily intakes for Agricultural and Veterinary Chemicals https://apvma.gov.au/node/26596.

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APVMA (2025c). FAISD Handbook. https://apvma.gov.au/node/26586.

Australian Pesticides and Veterinary Medicines Authority, Data guidelines – Residues (Part 5A), APVMA website, 04 April 2022, accessed: 04 February 2025

Bernstein, IL et al (1999). Immune Responses in Farm Workers after Exposure to *Bacillus thuringiensis* Pesticides. Environmental Health Perspectives 107(7): 575-582, July 1999.

Health (2023). Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Legislative Instrument - The Poisons Standard. Australian Federal Government Department of Health and Aged Care. (https://www.tga.gov.au/publication/poisons-standard-susmp)

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