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Australian Pesticides and Veterinary Medicines Authority

Public Release Summary

on the evaluation of the new active sugar beet extract in the product Actavan® Bio Plant Defence Elicitor

APVMA product number 94052

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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 [Product Name(s)] 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 Tuesday 10 March 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

Australian Pesticides and Veterinary Medicines Authority

GPO Box 574
Canberra ACT 2601, Australia

Phone: +61 2 6770 2300
Email: casemanagement@apvma.gov.au.

Further information

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

Copies of technical evaluation reports covering chemistry, efficacy and safety, toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request.

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 Actavan® Bio Plant Defence Elicitor and approval of the new active constituent sugar beet extract.

Applicant

Adama Australia Pty Limited.

Purpose of application

Adama Australia Pty Limited has applied to the APVMA for registration of the new product Actavan® Bio Plant Defence Elicitor, containing 900 g/L of sugar beet extract as active constituent as a soluble concentrate (SL) formulation. Sugar beet extract is a new active.

Proposed claims and use pattern

Actavan® Bio Plant Defence Elicitor is for use in wine and table grapes and is intended for use as a natural elicitor purported to enhance the plant defences increasing their resistance to botrytis infection.

Mode of action

Sugar beet extract is a fungicide that acts through indirect modes of action including as an osmo-protectant and resistance inducer. Sugar beet extract has no direct fungicidal activity. The product's components function as a combination of an osmo-protectant and resistance inducer (systemic acquired resistance) which when activated in the plant upregulates the plants own defences against fungal infections.

This product has no curative activity and is to be used as part of a broader Botrytis management program in conjunction with fungicides from a different mode of action.

Overseas registrations

The product is currently registered in Peru as ACTAVAN®, to effectively prevent the occurrence of fruit rots in crops such as grapes, berries, and certain vegetables, while also improving their quality. In addition, ACTAVAN® increases the sugar content, peel firmness, size, and weight of the berries, also reducing fruit splitting.

Chemistry and manufacture

Active constituent

The active constituent sugar beet extract is manufactured overseas. Sugar beet extract is an aqueous extract of sugar beet roots and is a complex chemical mixture, with trimethylglycine (TMG), also known as betaine or glycine betaine, being selected as a marker compound and considered the leading chemical compound. The extract will contain a minimum of 280 g/kg TMG.

Details of the chemical name, structure, and physicochemical properties of sugar beet extract are listed below in Tables 1 to 2.

Table 1: Nomenclature of the active constituent sugar beet extract

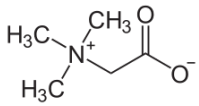
Common name:	Sugar beet extract (overall active constituent), (Trimethylammonio)acetate (major component)
IUPAC name (TMG):	Methanaminium, 1,1-dicarboxy-*N,N,N*-trimethyl-, inner salt.
CAS registry numbers:	Sugar beet extract: 89957-89-1 TMG: 107-43-7
Molecular formula (TMG):	$C_5H_{11}NO_2$
Molecular weight (TMG):	117.15
Structural formula (TMG):	

Table 2: Key physicochemical properties of the active constituent sugar beet extract

<table>
<tr><td>Appearance:</td><td>Dark brown liquid</td></tr>
<tr><td>Melting/boiling points:</td><td>The boiling point of the beet extract is estimated to be 100 °C, while the melting point of TMG is 293 °C.</td></tr>
<tr><td>Density</td><td>1.179 - 1.209 g/mL</td></tr>
<tr><td>Solubility of TMG in water:</td><td>611 g/L at 19.3 °C.</td></tr>
<tr><td>Solubility of sugar beet extract in organic solvents (at 25 °C):</td><td>n-Heptane: < 10 g/L
Toluene: < 10 g/L
Dichloromethane: < 10 g/L
Methanol: < 10 g/L
Acetone: < 10 g/L
Ethyl acetate: <10 g/L

The sugar beet extract was essentially immiscible with all the organic solvents tested.</td></tr>
<tr><td>Dissociation constant (PK_a) for TMG</td><td>1.832 with one protonated cation.</td></tr>
<tr><td>PH:</td><td>11 - 12</td></tr>
<tr><td>Octanol/water partition coefficient (Log K_{ow}):</td><td>The log K_{ow} of the lead component TMG is -2.93 at 25 °C, indicating TMG is very hydrophilic</td></tr>
<tr><td>Vapour pressure:</td><td>The vapour pressure of the lead component TMG is estimated to be 7.11 × 10^{-5} Pa at 25 °C.</td></tr>
<tr><td>Henry's law constant for TMG:</td><td>3.96</td></tr>
<tr><td>UV/VIS absorption spectra:</td><td>For sugar beet extract:
<table>
<tr><th></th><th>λ_{max}</th><th>ε
(L mol^{-1} cm^{-1})</th><th>log ε</th></tr>
<tr><td>pH 1.5</td><td>265 nm</td><td>4931</td><td>3.69</td></tr>
<tr><td>pH 6.8</td><td>263 nm</td><td>4097</td><td>3.61</td></tr>
<tr><td>pH 12.0</td><td>265 nm</td><td>5717</td><td>3.76</td></tr>
</table>
For TMG:
Maximum absorption at 200 nm, no detectable absorption between 240 nm and 800 nm.</td></tr>
<tr><td>Safety properties:</td><td>Not required, as the active has a high water content and is therefore not flammable or explosive</td></tr>
<tr><td>Storage stability:</td><td>The sugar beet extract active constituent was stable during storage at 54 °C for 2 weeks when stored in a 1 L HDPE container.</td></tr>
</table>

Formulated product

The product *Actavan® Bio Plant Defence Elicitor* will be manufactured overseas.

The proposed product is a soluble concentrate (SL) formulation. Prior to application to grapevines, it will be diluted in water.

The proposed SL product contains 900 g/L sugar beet extract.

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 *Actavan® Bio Plant Defence Elicitor*

Distinguishing name:	*Actavan® Bio Plant Defence Elicitor* (ADS-43)
Formulation type:	Soluble concentrate (SL)
Active constituent concentration:	900 g/L sugar beet extract, yielding least 252 g/L (or 218 g/kg) trimethylglycine (TMG) as the active constituent

Table 4: Physicochemical properties of the product *Actavan® Bio Plant Defence Elicitor*

Physical form:	Dark brown liquid
pH (neat):	8.5 at 20 °C
Relative density:	D_4^{20} = 1.160
Viscosity:	8.68 mPa·s at 20 °C; 5.03 mPa·s at 40 °C
Surface tension:	43.4 mN/m at 20.3 °C
Persistent foam:	0 mL foam after 1 min for water dilution (0.27 – 1% in CIPAC Standard Water D)
Safety properties:	The product has a high water content and therefore is not flammable or explosive
Storage stability:	The product was stable during storage at 54 °C for 2 weeks and at 0°C for 7 days

Recommendations

The APVMA Chemistry section has evaluated the chemistry and manufacturing aspects of the sugar beet extract active constituent, and associated product *Actavan® Bio Plant Defence Elicitor*, including the manufacturing process, quality control procedures, stability, batch analysis results and analytical methods, and found them to be acceptable.

The available storage stability data indicate that the formulated product is expected to remain stable for at least 2 years when stored under normal conditions.

Based on a review of the chemistry and manufacturing details, the registration of *Actavan® Bio Plant Defence Elicitor*, and approval of the active constituent *sugar beet extract*, are supported from a chemistry perspective.

Toxicological assessment

The applicant submitted sufficient supporting toxicity data and scientific argument for the approval of beet extract, along with international assessment reports that have been prepared by the European Medicines Agency, and the European Food Safety Authority[1] on the sugar beet extract leading chemical compound, betaine, which is approved in Europe as a medicine, and as a food and feed supplement. Taken together, these reports represent the expert interpretation of the toxicity dataset for the leading chemical compound of beet extract (betaine), and in effect, beet extract itself. The applicant has provided a satisfactory level of underlying literature reviewed by the EFSA assessments plus additional complementary literature. Notably, in Australia, betaine and betaine hydrochloride are active ingredients in human prescription medicines and may be used as an excipient ingredient in human listed medicines. Furthermore, it is commonly found in food supplements and cosmetics.

Evaluation of toxicology

Chemical class

The active constituent, beet extract, is manufactured from the roots of the common European sugar beet (*Beta vulgaris* L. ssp. *vulgaris*), a major source of sugar in the world. The leading chemical compound of beet extract is betaine. Other major identified components of beet extract include proteins, sugars, fats and water, which are not of toxicological concern.

Biochemical aspects

Betaine, considered toxicologically as the leading chemical compound of beet extract, is present in most organisms, including humans, and acts as a methyl group donor in transmethylation reactions in many biochemical reactions, including the formation of proteins, lipids and nucleic acids. Betaine also has a role as an osmolyte, ensuring osmo-protection. Sources of betaine include the diet, or it is synthesised from choline (also obtained from the diet) or formed via lipid (including phospholipid) metabolism.

Acute toxicity

Acute toxicity studies on beet extract were not provided by the applicant. However, acute toxicity studies were provided for Actavan® Bio Plant Defence Elicitor, which contains 900 g/L beet extract. The product has low acute oral, dermal, and inhalational toxicity, is not an eye or skin irritant, nor a skin sensitiser. It can be inferred that beet extract will have a similar acute toxicity profile.

Repeat-dose toxicity

It is considered that the repeat-dose toxicity of betaine (and by extension beet extract) is very low. This can be inferred by it being an endogenous molecule present in humans, and it being present at significant levels

[1] The EFSA Journal. 191: 1-17; The EFSA Journal. 11(5): 3211; The EFSA Journal 15(11):5057; The EFSA Journal. 16(7): 5335; The EFSA Journal. 17(4): 5658.

in the average diet. The need for the provision of animal toxicity studies or human clinical trials is not considered necessary to establish the repeat-dose toxicity of beet extract. Nonetheless, the literature provided by the applicant to support the safety of beet extract was reviewed, noting that the typical dosing used was more appropriate to support the use of betaine as a human food supplement. The literature did not raise concerns regarding the safe use of beet extract in the context of an agricultural product.

Toxicity of metabolites and/or impurities

No studies were submitted. The metabolites of the leading chemical compound betaine, and other beet extract components, are not anticipated to be different than from those that occur in the typical diet.

Sensitisation potential

No studies were submitted. Betaine and the product, Actavan® Bio Plant Defence Elicitor, are not considered sensitisers.

Health-based guidance values and poisons scheduling

Poisons Standard

Betaine is the leading chemical and toxicological compound of beet extract. Betaine hydrochloride (and therefore betaine by definition) is listed in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), for any use, because of its low toxicity. As beet is a common food, beet extract is not anticipated to contain other components at a level to be significant toxicological concern requiring scheduling consideration.

Health-based guidance values

No acceptable daily intake (ADI) or acute reference dose (ARfD) has been established for beet extract. As beet extract is derived from a food crop, and has low oral toxicity, health-based guidance values are not considered necessary. Furthermore, residues of the leading chemical compound betaine are unlikely to be distinguishable from naturally occurring background levels.

Recommendations

There are no objections on human health grounds to the approval of a new active constituent beet extract, and to the registration of the product Actavan® Bio Plant Defence Elicitor, containing 900 g/L sugar beet extract, when used in accordance with the directions for use and adhering to the recommended safety directions.

Residues assessment

As part of the residues assessment of sugar beet extract, analytical methodology and publicly available scientific information were considered.

Metabolism

No metabolism data have been provided for sugar beet extract. The leading chemical compound in the extract is betaine (also known as trimethylglycine or glycine betaine) which is a naturally occurring non-essential amino acid found in most foods with shellfish, whole grains, flour, and some vegetables such as beetroot, spinach and silverbeet being rich sources. Biosynthesis and metabolism of betaine in plants and animals is well understood as described in numerous publicly available sources[2]. On this basis, further metabolism data were not required and a residue definition is considered to be unnecessary.

Residues in food and animal feeds

The main source of betaine in the normal Western diet would be from flour products such as breads and pastas. Apart from direct food sources, betaine is also produced in the body through the oxidation of choline, which is found in various food sources.

Betaine is ubiquitous in the environment and is produced by bacteria, plants, invertebrates and mammals. It is used industrially as a moisturizer in the food and cosmetics industries and can also be found in dietary supplements. Furthermore, various betaine analogues are found in plants.

In the study of Zeisel et. al. (2003), it was found that the foods containing the highest betaine concentration (mg/100 g) were: wheat bran (1339), wheat germ (1241), spinach (645), pretzels (237), shrimp (218) and wheat bread (201).

Table 5 of the MRL Standard for Residues of Chemical Products 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; where the residues are identical to or indistinguishable from natural food components; or where the residues are otherwise 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 sugar beet extract as its residues are likely to be indistinguishable from naturally occurring background levels in food and it is considered to be of low toxicological significance.

[2] PubMed Central®. *Betaine as a Functional Ingredient: Metabolism, Health-Promoting Attributes, Food Sources, Applications and Analysis Methods.* PubMed Central® website, accessed January 2026.

Residues in animal commodities

Livestock are already exposed to comparable levels of betaine in untreated feeds. Betaine is highly water soluble and readily utilised or excreted by animals and is not bioaccumulative. It is not necessary to establish animal commodity MRLs for sugar beet extract.

Dietary risk assessment

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

Recommendations

The following amendments are required to be made to the APVMA MRL Standard for Residues of Chemical Products (Table 5).

Table 5: Amendments to the APVMA MRL Standard for Residues of Chemical Products

Amendments to Table 5	
Substance	**Use**
Add:	
Sugar beet extract	As a fungicide for food producing crops

Assessment of overseas trade aspects of residues in food

Grapes (including dried grapes) and wine are considered to be major export commodities, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated grapes.

MRLs are considered to be unnecessary for the proposed use and a Table 5 entry has been recommended. As betaine levels are likely to be indistinguishable from naturally occurring background levels in food, the use of sugar beet extract on grapes is not expected to present a risk to international trade.

Work health and safety assessment

Health hazards

Actavan® Bio Plant Defence Elicitor has low acute oral, dermal, and inhalational toxicity, is not an eye or skin irritant, nor a skin sensitiser.

Occupational exposure

Safety during use

Actavan® Bio Plant Defence Elicitor containing 900 g/L of beet extract in a soluble concentrate formulation, is intended for use as a plant activator to enhance the inherent defences of table and wine grapevines against *Botrytis cinerea* (Botrytis bunch rot/Grey mould).

The product is intended for professional use and will be applied mechanically by airblast equipment as a medium to coarse spray. According to the draft label, Actavan® Bio Plant Defence Elicitor is to be applied at a rate of 4 L/ha (3.6 kg beet extract/ha). The spray is prepared by mixing the product in 100 L of water and applied as a dilute spray to the point of run-off. Actavan® Bio Plant Defence Elicitor has been developed for dilute spray volume use rates of between 700 to 1500 L/ha. It is to be applied up to four applications per season from early fruit set through to 14 days prior to harvest. It may be applied at 14-to-21-day intervals. Therefore, the expected pattern of exposure is of short-term duration.

Sugar beet extract has been prepared from a common food crop. The leading toxicological compound of sugar beet extract is betaine, a substance that is endogenous in plants and animals. For example, resting concentrations of betaine in human serum is about 20 to 70 μmol/L and betaine content of some food may contain several hundred milligrams/100 g (e.g., quinoa may contain 630 mg/100 g).

No worker exposure studies for Actavan® Bio Plant Defence Elicitor were submitted for assessment. Occupational exposure arising from mixing/loading or spraying of most pesticides comes primarily through skin contact. Of note is that the skin absorption of betaine is negligible. Betaine is a zwitterion and as expected has a very low percutaneous absorption (<0.1%).

These factors indicate that a quantitative occupational risk assessment is not required as no systemic dose of beet extract would be achieved that would be of concern.

Based on the above information, the only factors necessary to consider when establishing the safety directions of Actavan® Bio Plant Defence Elicitor are its acute toxicity. The product has low acute oral, dermal, and inhalational toxicity, is not an eye or skin irritant, nor a skin sensitiser. Therefore, it is recommended that the safety directions require no hazard or precautionary statements or personal protective equipment for mixing and using, they only require a statement for good hygienic practice.

Safety during re-entry or rehandling

Workers performing post-application activities such as clean-up and maintenance activities in treated vineyards may be exposed to beet extract residues mainly via dermal route. It is recommended no precautionary re-handling statement is required for workers performing clean-up and maintenance activities in treated vineyards, particularly as the product has no hazards of concern. This is reflected in the recommended label statements.

Public exposure

The applicant has stated that the product is intended for professional use only. Therefore, risks from use are not relevant for the public.

Application of Actavan® Bio Plant Defence Elicitor by airblast equipment may lead to unintended bystander exposure via chemical spray drift. This may be in the form of a single random exposure or repeat exposures of residents who reside adjacent to areas being treated with the product. Risks from spraying activities will result in bystander exposures that will be no greater than that expected from a normal diet. Therefore, no buffer zones are required.

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 doctor or Poisons Information Centre (Phone Australia 13 11 26)

Safety directions

Wash hands after use.

Precautionary (warning) statements

Not required.

Environmental assessment

Fate and behaviour in the environment

Sugar beet extract and its leading chemical compound TMG are natural substances that are readily biodegradable. TMG is non-volatile and highly soluble with low potential for bioaccumulation (log Pow -2.9). TMG degrades rapidly in surface water (DT_{50} 0.22-1.4 days).

Effects and associated risks to non-target species

Terrestrial vertebrates

The formulated product Actavan® Bio Plant Defence Elicitor had no evident toxicity or mortality in mammals up to the highest dose tested following a single oral dose (NOEL 1560 mg ac/kg bw, *Rattus norvegicus*). Following 90-day repeat dose exposure to TMG, no ecologically relevant adverse effects were observed in mammals at the highest dose tested (NOAEL 1571 mg ac/kg bw/d).[3]

The acute assessment for terrestrial vertebrates assumes 100% of food items are obtained from the treatment area on the last day of application, while the chronic assessment assumes 50% of food items are obtained from the treatment area for the first 21 day after the last application. Acceptable risks could be concluded for wild mammals at the screening level. No toxicity data were available for birds; however, no concerns have been identified for mammals, and the components of the plant extract are expected to comprise a normal part of their diet. Therefore, risks to birds are also considered acceptable. No protection measures are considered necessary for terrestrial vertebrates.

Aquatic species

At the limit test concentrations, sugar beet extract and the formulated product have low toxicity to fish (LC_{50} >78 mg ac/L, *Oncorhynchus mykiss*), aquatic invertebrates (EC_{50} >100 mg ac/L, *Daphnia magna*) and algae (E_rC_{50} >100 mg ac/L, *Pseudokirchneriella subcapitata*). Although the product is not applied to water, a screening level risk assessment assumed the worst-case scenario of a direct overspray of shallow aquatic habitat in order to identify those substances and associated uses that do not pose a risk to aquatic species. Acceptable risks to aquatic species were concluded at the screening level. Accordingly, only standard protection statements are required for inclusion on the product label, and no non-standard protection measures are necessary.

[3] All ecotoxicity endpoints are expressed in terms of sugar beet extract equivalents

Bees and other non-target arthropods

The formulated product Actavan® Bio Plant Defence Elicitor has low toxicity to adult bees (contact and oral LD_{50} >527 µg ac/bee, *Apis mellifera*) and low toxicity to bee larvae (LD_{50} >240 µg ac/bee). Following chronic oral exposure, no adverse effects were observed at the highest doses tested in adults (NOEDD 796 µg ac/bee) and larvae (NOEDD 240 µg ac/bee). A screening level risk assessment assumed the worst-case scenario of a direct overspray of blooming plants that are frequented by bees in order to identify those substances and associated uses that do not pose a risk. Acceptable risks to bees could be concluded at the screening level, and no protection measures are therefore considered necessary.

In tier 1 (glass plate) laboratory studies, the formulated product had low toxicity to the indicator species of predatory arthropods (LR_{50} >10,800 g ac/ha, *Typhlodromus pyri*) and parasitic arthropods (LR_{50} >10,800 g ac/ha, *Aphidius rhopalosiphi*). A screening level risk assessment assumes non-target arthropods are exposed to fresh-dried residues within the treatment area immediately after the last application. Acceptable risks to other non-target arthropods could be concluded at the screening level, and no protection measures are therefore considered necessary.

Soil organisms

Following long-term exposure to the formulated product in soil, reproduction of earthworms was inhibited in a dose-dependent manner (EC_{10} 338 mg ac/kg dry soil, *Eisenia fetida*). No adverse effects were observed at the highest concentrations tested in springtails (NOEC 780 mg ac/kg dry soil, *Folsomia candida*) or soil mites (NOEC 780 mg ac/kg dry soil, *Hypoaspis aculeifer*). Actavan® Bio Plant Defence Elicitor similarly did not inhibit soil processes such as nitrogen transformation at the highest test concentration (NOEC 48 mg ac/kg dry soil).

A screening level risk assessment assumed the worst-case scenario of a direct overspray of soil without interception in order to identify those substances and associated uses that do not pose a risk to soil organisms. Acceptable risks to soil organisms could be concluded at the screening level, and no protection measures are therefore required.

Non-target terrestrial plants

Crop safety data on grapes suggest the formulated product will not be harmful to plants up to the highest tested rate of 7200 g ac/ha. Supporting information in the published literature show the leading chemical compound TMG does not adversely affect many species of plant following foliar application (lowest NOER 17,900 g ac/ha, *Avena sativa*); rather, TMG functions as an osmolyte to improve plant stress tolerance. Based on the available information, no protection measures are considered necessary for non-target terrestrial plants.

Recommendations

In considering the environmental safety of the proposed use of Actavan® Bio Plant Defence Elicitor, the APVMA had regard to the toxicity of the active constituent and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems. Based on the outcome of the risk assessment, it is recommended the APVMA can be satisfied under s14 of the Agricultural and Veterinary Chemicals Code Act 1994 that the proposed use of the product meets the safety criteria with respect to s5A(1)(c); and the proposed label meets the labelling criteria under s5D (1), with respect to environmental considerations.

The following standard protection statement is required on the label for the protection of aquatic environments:

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

Efficacy and safety assessment

Proposed product use pattern

Actavan® Bio Plant Defence Elicitor is a 900 g/L Beet extract containing a minimum of 280 g/kg trimethylglycine claimed to enhance natural plant defences, increasing their resistance to Botrytis infection. It contains trimethyl glycine (glycine betaine), seaweed extract + polyphenols and anthocyanins which claim to function as a combination of an osmo-protectant and resistance inducer. The resistance inducer mode of action is systemic acquired resistance (SAR) which when activated in the plant has no direct effect on fungal infections.

This product has no curative activity and is to be used as part of a broader Botrytis management program in conjunction with fungicides from a different mode of action.

Efficacy and target crop/animal safety

Efficacy and crop safety trials conducted both in Australia and overseas were provided to support a label claim of suppression of Botrytis bunch rot. The overseas trials were conducted in New Zealand and Italy, where conditions are favourable to botrytis development. Although the climates are not identical with Australia, there are similarities, specifically in the vagaries of incident rainfall and temperature maxima which resulted in a similar range of disease development from New Zealand trials compared to the Australian trials.

The trials were carried out according to acceptable scientific practices appropriate for measuring efficacy for the suppression of Botrytis by measuring disease plot severity or disease incidence and severity over time and crop safety as phytotoxicity or yield loss in grape.

In the trials, Actavan® Bio was applied according to label recommendations under light to high disease pressure of Botrytis. Application rates included the proposed label rate of 3.6 kg beet extract/ha with an adjuvant in a water volume of up to 1000 L/ha with a maximum of 4 applications, at 14- 21 days intervals. All trial work examined both efficacy and crop safety over time, using a replicated (n=4) RCB small plot trial design. Crop safety trials also included application at double label rate at 14-day intervals to determine potential negative crop safety effects.

Efficacy

A total of nine Australian, seven New Zealand and one Italian replicated efficacy trials were submitted to support the product's claims against Botrytis. Due to environmental constraints, some trials exhibited low or delayed disease pressure and were therefore only considered partially supportive. However, these trials were still of value for the assessment of the product's efficacy because treatment responses were comparable across all tested products, indicating that the proposed product performs equivalently to established industry standards. The rest of the trials demonstrated significant reduction in both the incidence and severity of Botrytis damage compared to untreated control. Collectively, the evidence is considered adequate to support the product's claims against Botrytis.

Crop safety

Crop safety assessment was included as part of all efficacy trials mentioned above. No crop damage was reported from any trial at rates up to and including 8 L/ha. Organoleptic tests were also provided, and confirmed the product has no sensory impact on the processed commodity. Crop safety, assessed on this basis, is therefore supported.

Recommendations

Based on the trials and evidence provided, a label claim for the suppression of Botrytis in grapes when applied according to the label recommendations using the proposed new product Actavan® Bio Plant Defence Elicitor is supported. The proposed label makes it clear that the product is for preventative use and is not intended as a post-infection curative spray.

The trial work also supported the crop safety of Actavan® Bio Plant Defence Elicitor in grapes.

Spray drift assessment

Appropriate spray drift buffer zones for Actavan® Bio Plant Defence Elicitor were calculated by the APVMA Spray Drift Assessment Tool (SDRAT), or Spray Drift Management Tool (SDMT) using Regulatory Acceptable Levels (RALs) for each risk area.

Human health

Risks from spraying activities will result in bystander exposures that will be no greater than that expected from a normal diet. Therefore, no buffer zones are required.

Residues and trade

Residues of sugar beet extract are indistinguishable from natural sources and are not of toxicological significance and therefore, a spray drift assessment is not required.

Environment

The RAL of 7800 µg ac/L for the protection of natural aquatic areas is based on the *Oncorhynchus mykiss* LC_{50} >78 mg ac/L and an assessment factor of 10.

The RAL of 87833 g ac/ha for the protection of pollinator areas is based on the *Apis mellifera* contact LD_{50} >527 g ac/ha and a conversion factor of LOC 0.4 / ExpE 2.4 × 1000.

The RAL of 7200 g ac/ha for the protection of vegetation areas is based on the *Vitis vinifera* NOER 7200 g ac/ha and an assessment factor of 1.

Table 6: Summary of RALs for Actavan® Bio Plant Defence Elicitor

Sensitive area	Regulatory Acceptable Level	
	Level of active	Units
Bystander	N/A	g/ha
Livestock	N/A	ppm
Aquatic	7800	µg/L
Pollinator	87833	g/ha
Vegetation	7200	g/ha

No buffer zones were found necessary for Actavan® Bio Plant Defence Elicitor.

Labelling requirements

Product Name: Actavan® Bio Plant Defence Elicitor

APVMA Approval No: 94052 / 141352

Label Name:	Actavan® Bio Plant Defence Elicitor

Signal Headings:	READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Constituent Statements:	ACTIVE CONSTITUENT: 900 g/L SUGAR BEET EXTRACT

Statement of Claims:	Elicitor that enhances natural plant defences increasing their resistance to Botrytis infection.

Net Contents:	1 - 1000 L

Restraints:	**RESTRAINTS** DO NOT apply if rain is expected prior to spray solution drying. DO NOT apply this product as a post-infection curative spray to control disease in crops. **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 inversion conditions.

Directions for Use:	This section contains file attachment.

Withholding Periods:	*Harvest:*	NOT REQUIRED WHEN USED AS DIRECTED.
	Grazing:	NOT REQUIRED WHEN USED AS DIRECTED.

Trade Advice:	

General Instructions:	**GENERAL INSTRUCTIONS** ACTAVAN® BIO is a natural elicitor that enhances natural plant defenses, stimulating systemic acquired resistance (SAR) to Botrytis infection of grapes. Shake container prior to opening. Half fill the spray tank with clean water and with the agitator operating, add the required quantity of ACTAVAN® BIO. Top up the spray tank to the required volume with clean water with the agitator running. Maintain agitation while spraying. **MIXING** When applying products in tank mixtures, wettable powders or dry flowable formulations (e.g. water dispersible/soluble granules) should be added to the spray tank first. Allow sufficient time for any granular products to sufficiently disperse before adding suspension concentrates, dispersible concentrates, suspo-emulsions or emulsifiable concentrates, water soluble salts or formulations (such as ACTAVAN® BIO) and then oil dispersions. Add any adjuvants last and at the end of tank filling. **APPLICATION** Thorough coverage of the canopy is essential. Dilute Spraying: Use a sprayer designed to apply high volumes of water up to the point of run-off and matched to the crop being sprayed. Set up and operate the sprayer to achieve even coverage throughout the crop canopy. Apply sufficient water to cover the crop to the point of run-off. Avoid excessive run-off. The required water volume may be determined by applying different test volumes, using different settings on the sprayer, from industry guidelines or expert advice. Add the amount of product specified in the Directions For Use Table for each 100 L of water. Spray to the point of run-off. The required dilute spray volume will change and the sprayer set up and operation may also need to be changed, as the crop grows. ACTAVAN® BIO has been developed using dilute spray volumes between 700-1500 L/ha. Concentrate Spraying (Grapes): Use a sprayer designed and set up for the concentrate spraying (that is a sprayer which applies water volumes less than those required to reach the point of run-off) and matched to the crop being sprayed. Set up and operate the sprayer to achieve even coverage throughout the crop canopy using your chosen water volume. Determine an appropriate dilute spray volume (See Dilute Spraying above) for the crop canopy. This is needed to calculate the concentrate mixing rate. The mixing rate for concentrate can then be calculated in the following way: *Example Only:* Dilute spray volume as determined above: for example, 1000 L/ha Your chosen concentrate spray volume: for example, 500 L/ha The concentration factor in this example is: 2 x (i.e., 1,000 L / 500 L = 2) If the dilute label rate is 400 mL/100 L, then the concentrate rate becomes 2 x 400, that is 800 mL/100 L of concentrate spray. The chosen spray volume, amount of product per 100 L of water, and the sprayer set up and operation may need to be changed as the crop grows. For further information on concentrate spraying, users are advised to consult relevant industry guidelines, undertake appropriate competency training and follow industry Best Practices. **USE OF ADJUVANTS** ACTAVAN® BIO is recommended to be applied with the following adjuvants.

Crop Type	Rate of Adjuvant[#]
Grapes	Apply with a non-ionic adjuvant (e.g. Viti-Wet[†]) at 0.01% v/v

[#] % rate is on v/v basis

General Instructions: *(cont.)*	**RAINFASTNESS** Avoid making spray applications if rain is expected before the spray can dry completely. ACTAVAN® BIO can be considered rainfast once the spray has dried completely. Where ACTAVAN® BIO is applied in tank mix, use the longer of the partner products rainfast periods to determine when to apply. **COMPATIBILITY** For information on compatibility, please contact ADAMA Australia.

Resistance Warning:	**FUNGICIDE RESISTANCE WARNING** ACTAVAN® BIO is a natural plant defence elicitor. The development of resistance to this mode of action is not expected. It is recommended that it is used in conjunction with complimentary disease management measures such as: • Use of effective pruning techniques to enhance air flow through the vine canopy. • Use of alternative products that promote overall vine health. • Use of other products that complement the activity of ACTAVAN® BIO. When applied in a tank mix with standard program sprays, observe CropLife resistance management strategies for those tank mix partners. The following recommendations also apply to the use of ACTAVAN® BIO: • Apply ACTAVAN® BIO as a protectant spray only. • Due to the physiological mechanism of activity, applications are recommended targeting the early fruit development stage. • ACTAVAN® BIO applications are to be made preventatively from early fruit set (E-L 27). • ACTAVAN® BIO can be used as part of a broader Botrytis management program in conjunction with fungicides from a different mode of action.

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

Storage and Disposal:	KEEP OUT OF REACH OF CHILREN Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight. Avoid storage at low temperatures. *DrumMUSTER Containers*: 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. 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

Storage and Disposal: (*cont.*)	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. *Refillable Containers:* Empty contents fully into application equipment. Close all valves and contact Schutz on 03 9360 9291 to arrange collection.

Safety Directions:	Wash hands after use.

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

Directions for Use:

CROP	DISEASE	RATE	CRITICAL COMMENTS
Table and wine grapes	Botrytis bunch rot/ Grey Mould (*Botrytis cinerea*) - Suppression	4 L/ha Apply with a non-ionic adjuvant at 0.01% v/v	Apply up to 4 applications from early fruit set (E-L 27) through to 14 days prior to harvest. Applications should ideally target early fruit development stages. Use 400 mL/100 L for spray volumes of up to 1000 L/ha water. If using higher application volumes, dilute accordingly. Do not exceed a total use rate of 4 L/ha per application. ACTAVAN® BIO does not have curative activity. Use as a preventative spray as part of a season long program for botrytis management, alternating with fungicides from a different mode of action group. Apply from E-L 27 on a 14-21 day interval to enhance the plants own defences and physiological structure as fruit develop. Apply by dilute or concentrated spraying equipment – refer to Application, Compatibilities and Use of Adjuvants section in the General Instructions for more details.

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

Acronyms and abbreviations

Shortened term	Full term
ac	Active constituent
ADI	Acceptable daily intake (for humans)
ai	Active ingredient
ARfD	Acute reference dose
bw	Bodyweight
CAS	Chemical Abstracts Service
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
EFSA	European Food Safety Authority
E_rC_{50}	Concentration at which the rate of growth of 50% of the test population is impacted
EUP	End use product
g	Gram
GAP	Good Agricultural Practice
h	Hour
ha	Hectare
IUPAC	International Union of Pure and Applied Chemistry
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
mL	Millilitre

Shortened term	Full term
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet
NESTI	National Estimated Short-Term Intake
ng	Nanogram
NOEC/NOEL	No observable effect concentration level
NOAEL	No observed adverse effect level
OC	Organic carbon
PPE	Personal protective equipment
ppm	Parts per million
RAL	Regulatory Acceptable Level
SC	Suspension concentrate
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
µmol	micromole
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
Chronic	Of long duration
Efficacy	Production of the desired effect
Formulation	A combination of both active and inactive constituents to form the end use product
Metabolism	The chemical processes that maintain living organisms
Toxicology	The study of the nature and effects of poisons

References

APVMA, 2023, Spray Drift Risk Assessment Tool (SDRAT), accessed January 2026 at https://www.apvma.gov.au/resources/using-chemicals/spray-drift/sdrat

EFSA, 2005, Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to an application concerning the use of betaine as a novel food in the EU. EFSA Journal. 191: 1-17. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2005.191

EFSA, 2013, Scientific Opinion on the safety and efficacy of betaine anhydrous as a feed additive for all animal species. EFSA Journal. 11(5): 3211. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2013.3211

EFSA, 2017, Safety of betaine as a novel food pursuant to Regulation (EC) No 258/97. EFSA Journal 15(11):5057. https://doi.org/10.2903/j.efsa.2017.5057

EFSA, 2019, Safety and efficacy of betaine anhydrous for food-producing animal species based on a dossier submitted by AB Vista. EFSA Journal. 16(7): 5335. https://doi.org/10.2903/j.efsa.2018.5335

EFSA, 2019, Safety of betaine as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal. 17(4): 5658. https://doi.org/10.2903/j.efsa.2019.5658