Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
CONTAINMENT

Application Form: HS3 Import or Manufacture any Hazardous Substance in Containment

under section 31 of the Hazardous Substances and New Organisms Act 1996

To submit an application, please send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140
OR email to: HSApplications@epa.govt.nz

Payment must accompany application: see our fees and charges schedule for details. Please allow 10 working days for processing.

Applicant:

Biotelliga Ltd

Name of substance:

SF7489

APPLICANT CHECKLIST

Mandatory sections filled out	☒	Appendices enclosed	☒
Initial fees enclosed	☒	Signed and dated	☒
Electronic copy of application emailed to EPA	☒		

Office use only

Application code:

Date received:

EPA contact:

Initial fees paid: $

Application version no.:

Important

1. You can talk to an applications advisor at the EPA, who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
2. This application form may be used to seek approvals for more than one hazardous substance where the substances are related – for example, a concentrated compound (active ingredient) and its related formulations, or a range of substances for similar purposes to be tested in a field trial.
3. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an appendix to the application form.
4. Commercially sensitive information must be collated in a separate appendix.
5. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
6. You can get more information at any time by contacting us. One of our staff members will be able to help you.

   Environmental Protection Authority
   Private Bag 63002
   Wellington
   New Zealand
   Telephone: 64 4 916 2426
   Facsimile: 64 4 914 0433
   Email: HSApplications@epa.govt.nz
   http://www.epa.govt.nz

Section 1 – Applicant details

1.1 Name and postal address in New Zealand of the organisation making the application:

Name: Biotelliga Ltd

Address: [redacted]

Phone: [redacted]

Fax:

1.2 The applicant's location address in New Zealand (if different from above):

Address: [redacted]

[redacted]

1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions that relate to processing the application on behalf of the applicant, or have the ability to go to the appropriate authority.

Name: [redacted]

Position: [redacted]

Address: [redacted]

Phone: [redacted]

Fax:

Email: [redacted]

Section 2 – Application type and related approvals required

This form is only for an application to import a hazardous substance into containment, or manufacture a hazardous substance in containment.

2.1 Is this application to manufacture or import a hazardous substance in containment for any of the following purposes?

Containment applications can only be made for a limited range of purposes. In particular, the substance must not be intended for commercial manufacture or sale.

Small amounts of any hazardous substance for use as an analytical standard, where approval to import or manufacture that substance has been declined?	☐ Yes	☒ No
Research on any hazardous substance to acquire information for use in assessing that substance for a HSNO approval?	☒ Yes	☐ No
Research and development on any hazardous substance?	☒ Yes	☐ No
Use in an emergency?	☐ Yes	☒ No
Formulating, relabelling, repackaging, or storing any hazardous substance for export to a destination outside New Zealand?	☒ Yes	☐ No
Other purposes?	☐ Yes	☒ No

2.2 If you answered 'yes' to one of the purposes listed above, please provide some supporting detail. If you answered 'yes' to 'other purpose', describe the purpose and explain why this purpose is appropriate to a containment application.

SF7489 is a biological fungicidal under development for commercial application to crops. It is a Microbial Agricultural Chemical. The active substance, SF7489 MAI, is defined as: non-viable *Epiccocum italicum* strain SVB-F1 and spent fermentation media. The formulation contains inert co-formulants and is formulated as a water dispersible granule (WG).

A permit for manufacture under containment is currently in place for this substance which expires on 1/05/2022 (HSC100200). Biotelliga Ltd wishes to renew this permit in order to complete research and development activities for product registration as an agricultural chemical in New Zealand under the ACVM Act 1997. This requires further studies to be completed on both the active substance and the formulated product.

The majority of studies will be conducted at laboratories and at third-party formulation and manufacturing facilities. Greenhouse and field trials will be conducted in containment.

Overseas third parties may perform some of the studies required and may also undertake tests on SF7489 which would require shipment of materials outside of New Zealand. These shipped materials may be re-imported into New Zealand.

2.3 Is the information in this application relevant to import, manufacture or both?

Import the substance(s) only?	☐ Yes	☒ No
Manufacture the substance(s) only?	☐ Yes	☒ No
Import and manufacture the substance(s)?	☒ Yes	☐ No
If import only, indicate whether or not manufacture is likely in New Zealand:	☐ Yes	☒ No

2.4 If the information in the application relates to manufacture of the substance(s) in New Zealand, provide information on the proposed manufacturing process and any alternatives.

Refer Confidential Appendix Section 2.2

2.5 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?
(Optional)

Name of approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	☒ Yes ☐ No ☐ NA Note: provisional registration granted 9542
Food Act 1981	☐ Yes ☐ No ☒ NA
Medicines Act 1981	☐ Yes ☐ No ☒ NA
Chemical Weapons (Prohibition) Act 1996	☐ Yes ☐ No ☒ NA
Radiation Protection Act 1965	☐ Yes ☐ No ☒ NA
Biosecurity Act 1993	☐ Yes ☐ No ☒ NA
Resource Management Act 1991	☐ Yes ☐ No ☒ NA

Other (please specify):

Section 3 – Information on the substance(s)

Note that all information that is commercially sensitive must be attached as an appendix. The application form should be cross-referenced to the appendix but should be able to be read as a stand-alone document (which will be publicly available).

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

3.1 State the unequivocal identification of the substance(s).

This section should include all information necessary to unequivocally identify the substance(s) and may include:

- Chemical name (Chemical Abstracts Preferred Index name or IUPAC name)
- Common name
- Synonyms
- Trade names
- CAS Registry number
- Molecular formula
- Structural formula
- Impurities.

For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture – ie, the chemical name, CAS number, function (eg, active ingredient, emulsifier, surfactant, filler) and percentages of ALL components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

If there are commercial reasons for not providing full information in the main part of the form, alternative approaches must be discussed with and agreed by the EPA. These must include the provision of a unique identifier of some kind.

- **Common name**: SF7489; SF7489 Microbial active ingredient (MAI)
- **Synonyms**: Refer to Confidential Appendix Section 2.1
- **Trade names**: Sylas™
- **CAS Registry number**: Not assigned
- **Molecular formula**: Refer to Confidential Appendix Section 2.1
- **Structural formula:** Refer to Confidential Appendix Section 2.1
- **Impurities**: not known

Formulation: Refer Confidential Appendix Section 1

3.2 Provide information on the chemical and physical properties of the substance(s).

Provide as much information as possible on the chemical and physical properties of the substance(s) [at 20°C and 1 atmosphere unless otherwise stated] – eg:

- Appearance (colour, odour, physical state or form)
- pH
- Density
- Vapour pressure
- Boiling/melting point
- Solubility in water
- Water/octanol partitioning co-efficient.

For mixtures, information is required on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture.

Refer to section 1.1 of the confidential dossier

3.3 Provide information on the hazardous properties of the substance(s).

Information should be provided on the hazardous properties of the substance(s) known to the applicant. You should consider each of the six hazardous properties below and provide information on those hazardous properties. This information is needed in order to assess risks and determine whether or not, and how, the substance can be adequately contained.

- Explosiveness
- Flammability
- Oxidising properties
- Corrosiveness
- Toxicity
- Ecotoxicity.

If your substance is a mixture and you cannot provide direct information on its hazardous properties, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings.

Hazardous properties for SF7489

- **Explosiveness**: there is no evidence that this substance has any explosive properties.
- **Flammability**: there is no evidence that this substance has any flammable properties
- **Oxidising properties**: there is no evidence that this substance has any oxidising properties

Corrosiveness: there is no evidence that this substance exhibits corrosiveness of metals.

Toxicity: Studies with SF7489 MAI, undertaken in accordance with OECD guidelines, show SF7489 is of low acute oral or dermal toxicity in rats (LD_50 >2,000mg/kg body weight). Studies in accordance with OECD guidance, show SF7489 MAI does not require classification for skin or eye. The formulated product contains inert ingredients which require, under mixture rules, a Category 2 eye irritation and Category 1 skin sensitisation classification.

Ecotoxicity: The active ingredient is a non-viable strain of *Epicoccum italicum* and spent fermentation media. The strain is widely found in nature and indigenous to NZ. There are no risks associated directly to the environmental microbiome resulting from any release of the microbial into the environment as it cannot proliferate in the environment. Contact and oral bee studies undertaken with SF7489 MAI, in accordance with OECD guidelines, show low toxicity to bees. A study in quails undertaken with the formulated product showed no endpoints of concern (LD_{50}>2,000mg/kg). Under GHS mixture rules, no classifications would be required.

3.4 Provide information on what will happen to the substance throughout its whole life, from its introduction into New Zealand, its uses, through to disposal.

The information provided needs to reflect the containment character of the application. It will be used in the development of exposure scenarios and the assessment of risks, and hence the specification of the containment conditions.

The steps in the life cycle of SF7489 during product testing and development is as follows:

1. Manufacture of the active substance is undertaken in controlled environments with SOPs reflecting containment requirements
2. Final processing steps may be undertaken by third parties, also using SOPs
3. The active ingredient SF7489 MAI and formulated product will be used for further R&D studies and field and greenhouse trials under containment
4. Product that is applied in field trials will degrade due to photo decomposition and crops will be disposed of post-trial
5. Product disposal is in a licenced landfill.

3.5 Provide information on the quantity of the substance proposed to be imported or manufactured.

This information is used in the development of exposure scenarios and the assessment of risks.

105 kg/year of the active substance SF7489 MAI over the 3 year permit period (to be used for, or formulated for, further R&D and field trials).

Section 4 – Information on the proposed containment system

4.1 Provide information on the proposed containment system.

It is essential that good information is provided on the containment system because the adequacy of containment, in conjunction with the hazardous properties of the substance, will have a major impact on whether or not approval is given.

You will need to provide a description of the containment proposed AND information on how you intend to address the following issues (proposed controls):

- Methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility
- Methods for excluding unwanted organisms from the facility or to control organisms within the facility
- Methods for excluding unauthorised people from the facility
- Methods for preventing unintended release of the substance by experimenters
- Methods for controlling the effects of any accidental release of the substance
- Inspection and monitoring requirements of the containment facility.

A management plan may be attached as an appendix. This plan should specify the procedures for implementing the above methods for containing the substance(s), and provide details of the qualifications of the person responsible for implementing those controls.

Laboratory/Manufacturing

1. Laboratories and manufacturing facilities follow accepted best practises for laboratories.
2. Authorised access by qualified personnel only
3. Personnel training on containment requirements including spillage response, disposal
4. SDS and product label include spillage and disposal requirements

Storage, Transport and Distribution

It is expected that SF7489 will be transported between laboratories and to and from field trial sites.

1. Storage. The substance will be held in locked storage when not in use

2. Appropriate packaging to be used at all times, to avoid any leaks or incidental product release. When in transport, at least two levels of containment should be used. Storage in accordance with the latest version of NZS 8409 Management of Agrichemicals.

3. Labelling and documentation. All containers labelled in accordance with the Hazardous Substances (Identification) Regulations 2001. Documentation accompanying shipments includes SDS and labelling with product name and description, Manufacturer’s contact details, destination name and address.

Field Trials

Trials will be conducted as per the guidelines below:

1. Field trial sites shall be chosen so as to prevent the substance entering any surface water or ground water system.
2. Field application sites to be identified and notified to EPA NZ.
3. Field application plots to be clearly defined and identified. Warning signs for public to stay out should be used at each site. Signs should clearly state: unauthorised access to the site is not permitted and that the site is subject to a trial
4. Evaluation protocols to be prepared and cover the following areas:
    a. Efficacy of product with respect to disease control. To determine spray rates and or intervals between spraying
    b. Examination of any phyto-toxicity to the crop being treated
    c. Any visible environmental effects on local flora and fauna should be recorded and reported.
5. Field trials to be monitored throughout the trial
6. Application equipment should be fit for purpose and safely contain all products prior, during and after use. Application equipment is required to be cleaned prior to and after use.
7. PPE to be used during application
8. Application of SF7489 is to be with handheld spray equipment. Spraying should not be conducted with any member of the public present within 100 meters of the trial site
9. All crops in the trials will be disposed of when the trial is completed
10. Field application to be conducted by trained authorised personnel only
11. Any accidental spillage of the substance shall be contained and placed in an appropriate container and appropriately disposed.

Section 5 – Identification and assessment of risks

In completing this section, it is important that you take account of the proposed containment system you described in Section 4. We are particularly interested in knowing about risks that may still remain with the containment system in place. You will need to consider the effects on the environment and public health, including any social effects. You should also take account of the quantity of material involved and the number of different locations that may be involved.

Complete this section as far as you can.

5.1 Identify all of the risks of the substance(s).

Include information on potentially significant, possible risks of the substance and whether or not these risks are *likely* to be significant. It is important to think about the source of the risk – ie, the way in which the risk is created (the exposure pathway) and then the consequences of exposure. Risks should be considered in relationship to:

- the sustainability of native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health (including occupational exposure)
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga
- the economic and related benefits to be derived from the use of the hazardous substance
- New Zealand's international obligations.

Introduction

SF7489 is a biofungicide based on a ubiquitous naturally-occurring fungus, *Epicoccum italicum* and hence there are no biosecurity concerns. SF7489 MAI contains non-viable microorganisms and spent fermentation materials all of which are rapidly degraded. An assessment of the SF7489 MAI and the inert co-formulants indicate no ecotoxic concerns from an ingredient assessment under mixture rules.

Risks to the sustainability of native and valued introduced flora and fauna

Due to the widespread occurrence of *Epicoccum italicum* in the New Zealand environment, the application of *SF7489* to field crops presents no new risks to native and introduced flora and fauna.

Risks to the intrinsic value of ecosystems

Due to the widespread occurrence of *Epicoccum italicum* in the New Zealand environment the application of *SF7489* to field crops presents no new risks to the intrinsic values of ecosystems.

Risks to public health

Risk of contact during manufacture and application is considered very unlikely with under good manufacturing practice standard operating procedures and trial control procedures.

It is very unlikely children and bystanders will come into contact with the product under containment due to trial protocols and procedures. Spray drift is minimised through ground based targeted application. SF7489 MAI is of low toxicity (oral, dermal, skin, eye). The formulated product is also diluted for application.

Occupational risk is considered low as PPE is required to be used during dispersion and spraying to ensure there is no skin or eye contact with the formulated product. Information on PPE requirements during mixing and application are included on the label and safety data sheet eg gloves, eye protection.

There is overseas evidence that *Epicoccum* spores can be responsible for either dermal or inhalation sensitisation, however there is no evidence to suggest that such sensitisation can be attributed to SF7489 and there have been no reports of sensitisation with people working with SF7489. The product also does not contain viable spores

Risks to the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other toanga.

The *Epiccocum* species has existing prevalence in the New Zealand environment and there is rapid degradation of fermentation materials. Toxicology studies conducted with the active substance have shown no human health, environmental or ecotoxicity endpoints of concern.

SF7489 is therefore not expected to impact the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga

Consultation on this biofungicide has been undertaken with Iwi and Maori interest groups in relation to a registration application for this product, with no concerns raised.

Benefits and Risks through the use of this hazardous substance

SF7489 is biological fungicide of low toxicity which will reduce the use of synthetic chemical fungicides which have a higher toxicity profile. This will meet growing consumer demand for healthier food, improve environmental health and address gaps in the crop protection market as a result of regulatory authorities removing harmful toxic chemicals from the market. SF7489 has efficacy and consistency necessary for a meaningful impact on crop productivity. The microbial nature of the active substance and its limited environmental persistence mean that Sylas can be applied close to grape harvest, and the withholding period is expected to be the default ACVM standard of 24 hours for products with no Maximum Residue Level (MRL).

International Obligations

There are no foreseen risks with respect to New Zealand's international obligations to trade.
Internationally, regulatory authorities are banning or phasing out the use of toxic, persistent synthetic chemical pesticides which are harmful to humans and ecosystems.

5.2 Provide an assessment of the potential risks identified in Section 5.1.

An explicit risk assessment only needs to be provided for those risks which might be significant. The assessment should consider whether the identified risks can be adequately managed by the proposed containment system, and the substance(s) itself adequately contained.

The assessment should include the nature, probability of occurrence, and magnitude of each adverse effect. The uncertainty bounds of the information contained in the assessment should also be discussed.

(Optional)

Based on the above analysis (5.1) two significant areas are of risk are considered.

Risks to the natural environment

These are considered minimal for the following reasons:

SF7489 is a biofungicide based on a ubiquitous naturally-occurring fungus, *Epicoccum italicum*. The active ingredient of Sylas, SF7489 MAI contains non-viable microorganisms and spent fermentation materials (there is no living material in the product). SF7489 MAI is of low acute mammalian toxicity and is of low toxicity to beneficial insects. It is biodegradable. The formulated product is not persistent or bioaccumulative in the environment and has a low toxicological footprint (Cat 1 skin sensitivity and Cat 2 eye irritation classifications relating to some co-formulants).

Due to degradability and lack of bioaccumulation it is considered there is no unacceptable environmental exposure in soil or water and no unacceptable exposure for non-target soil organisms, following the principles of the OECD guidance for environmental risk assessment for microorganisms.

Risks to Public Health

Risk of public exposure to SF7489 could occur through overspray and or drift from crop spraying; and consumption of crops treated with SF7489. Appropriate and manageable controls are in place to minimise public exposure to SF7489 throughout the lifecycle of the substance with access restrictions to authorised persons only, clearly marked trial sites and crops destroyed post trial.

Section 6 – International considerations

6.1 The EPA is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand, or by any other country. If you are aware of this, please provide details of the results of such consideration.
(Optional)

To date the applicant is not aware that SF7489 has been considered for use as fungicide by any overseas regulatory authorities

Section 7 – Miscellaneous

7.1 Provide a glossary of scientific and technical terms used in the application.

ACVM	Agricultural Compounds and Veterinary Medicines
EPA	Environmental Protection Agency
LD50	Lethal dose 50%
MAI	Microbial active ingredient
MRL	Maximum residue limits
OECD	Organisation for Economic Co-operation and Development
SF7489	Code name for biological fungicide
WG	Water dispersible granule

7.2 Provide here any other information you consider relevant to this application that is not already included.

Section 8 – Summary of public information

The information provided in this section may be used in the EPA's public register of substances, required under Section 20 of the HSNO Act.

This summary information will be used to provide information for the people and agencies (eg, Ministry for the Environment, Department of Conservation, Regional Councils etc) that will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

8.1 Name of the substance(s) for the public register:
Please use a maximum of 80 characters.

SF7489 (fungicide)

8.2 Purpose of the application for the public register:

This should include an abstract (in a maximum of 255 characters) giving information on the intended use of the substance and why an application is needed, based on its hazardous properties.

This application is seeking approval to continue R&D on SF7489 for use as a fungicide for crop protection in order to achieve product registration and commercial development.

8.3 Use categories of the substance(s):

The EPA has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk, and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

1. Main category: There are four main categories.
2. Industry category: There are 16 industry categories.
3. Function/Use category: There are 55 function/use categories.

(Optional)

4 - wide dispersive use

1 - agricultural

38 - pesticide

8.4 Executive summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties, intended uses and disposal
- an assessment of the adverse effects of the substance
- information on the proposed containment.

SF7489 is a biological fungicide and has efficacy and consistency necessary for a meaningful impact on crop productivity.

The active substance, SF7489 MAI, is defined as a specific non-viable *Epiccocum italicum* strain and spent fermentation media. The strain is ubiquitous in nature and found in NZ.

The formulation contains inert co-formulants and is formulated as a water dispersible granule (WG).

The applicant wishes to undertake R&D to develop SF7489 for NZ registration and commercial use. This includes the requirement for greenhouse and field trials; and manufacture of SF7489 MAI and formulated product.

SF7489 is of low toxicity, readily biodegradable and lacks bioaccumulation. Based on toxicology studies for SF7489 MAI, no classifications are required. Under mixture rules, the formulated product has Cat 1 skin sensitisation and Cat 2 eye irritation classifications under GHS mixture rules due to some of the inert ingredients.

SF7489 is considered to present a low risk to existing flora and fauna and human health.

[redacted] 01/12/2021

Signature **Date**

Appendix 1 – Commercially sensitive information

Refer to SF7489 confidential appendix