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:

Arxada NZ Limited

Name of substance:

TNL3753

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: Arxada NZ Limited

Address: [redacted]

Phone: [redacted]

Fax: [redacted]

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: [redacted]

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.

Approval is sought, pursuant to section 30(b) of the HSNO Act 1996, to import and manufacture an experimental pesticide for use in trials under containment. The intension is to conduct small scale contained field trials to provide information for development of this compound. We propose to conduct a number of small plot replicated field trials over a period of three years. The trial substance is a formulated product which contains both biologically active and non-biologically active ingredients. The compound will, in all probability be classified as hazardous under the Hazardous Substances (Minimum Degrees of Hazard) notice 2017.

The information for this substance is limited as it is an experimental substance, not yet classified fully through. Sufficient information will be available to acknowledge the hazards and risks involved with proposed experimental use of this plant protection product.

The volume of substance involved is only a few litres (up to 20L), and is prepared in either Arxada NZ Limited's Exempt Laboratory or Pilot Plant in New Plymouth.

It is proposed that the substances be used in containment throughout New Zealand and in compliance with the controls assigned to this approval. The proposed controls are included at section 4.

The substances will be applied to test plots by ground application methods or by direct plant treatment. The details being presented in the project plan/protocol submitted confidentially to EPA as Appendix 7a/b. The locations of the test sites will be provided to EPA as specified in the proposed controls.

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.

Manufacture in relation to this application refers to sample preparation in an exempt laboratory and/or supported pilot plant.

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
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):	N/A
	☐ Yes ☐ No
	☐ Yes ☐ No
	☐ Yes ☐ No

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.

The composition of this plant protection compound can be found in Appendix 5.

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.

This substance will be used for experimental research only and information is limited. The Safety Data Sheet for the formulated substances is provided in Appendix 6 in addition to the full composition of the product found in Appendix 5

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.

This substance will be used for experimental research only. The Safety Data Sheet for the formulated substance is provided in Appendix 6 in addition to the full compositions of the products found in Appendix 5.

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.

1 The proposed controls for these substances reflect what happens during the lifecycle from import or manufacture until applied to the test sites and including disposal of unused substance.

2 A typical life cycle is

a. Import substance or prepare in an exempt laboratory (or pilot plant if a scale up batch is required).

i. The Exempt Laboratory is in an isolated building – accessed via a closed door. It is identified as Laboratory with no access without permission. The Pilot Plant is located within the main manufacturing site and is secured in a specific building which is identified as such. No access is allowed without permission. Staff are aware of the requirements and controls imposed by EPA.

ii. Chemists using these facilities are required to wear the recommended PPE (Personal Protection Equipment), including: Lab Coat, enclosed shoes, safety glasses and gloves. Where necessary, dependant on the risks associated with the substance(s) being handled, a face shield, or respirator will be used.

Both the formulation and analytical labs are fitted with Fume Hoods, which are inspected by an independent third party, and covered under a 12A inspection schedule.

iii. Thorough wash down and disposal of any residue is collected on site in a dedicated catchment area, which is plumbed in, and housed with secondary containment.

b. Transport according to international or HSNO requirements between point of entry or laboratory and storage facility, then the sub-sample between storage and trial site.

i. On receipt of a sample, it is recorded in the sample register, labelled, and stored as per legislative requirements, including the current edition of the Health and Safety at Work Act (Hazardous Substances) Regulations, and relevent EPA notices.

ii. The sub-sample between storage and trial site, if a local Taranaki site, is transported in a Arxada NZ vehicle in a secure chemical container in the back of a covered ute. If the sample is being sent to off-site trials, then it is sent via an approved chemical carrier with the required placarding.

iii. Packaging; when received from overseas, the sample will be packed to meet legislative requirements, including IATA Dangerous Goods Regulations/GHS standards. To ship internally, quantities greater than 200ml of a formulated substance, packaging used meets the EPA packaging code, normally 1L HPDE containers. Smaller volumes of formulated product will be shipped in combination packaging, usually consisting of glass bottles with screw tops secured secondary packaging (plastic bag/container) containing absorbent material and shipped in a fibreboard box.

c. The required quantity of the sub-sample is applied to the trial plots with purpose designed equipment. The remainder returned to storage.

i. Any unused samples will either be returned to the New Plymouth site for storage or disposal in accordance with approved methods, or stored in a dedicated, secured, and compliant storage area.

ii. Disposal of unused samples is via 4 methods.

a. Used in the manner it was designed for. Empty container, triple rinsed and added to the final spray tank.

b. Stored in a secure chemical unit – identified and secured, on a Arxada regional base site.

c. Returned to Arxada Manufacturing site for disposal in an approved method e.g. disposal at approved facility once third-party leachate testing is conducted and clearance given. Or through an approved waste management company.

d. Stored in a secure chemical storage area at Arxada factory Manufacturing, which includes secondary containment.

The substance is labelled as : sample tnl XXX containing XXg/L of the active …… the formulation type is identified on the label. Along with a Hazardous Substance reference. All samples have basic precautionary warnings – ie Harmful, Keep out of reach of Children. Additional labelling including relevant GHS pictograms will be included dependant on the risks associated with the product and determined by the mini SDS created within Chemwatch. A copy of the Mini SDS will accompany the product at all life stages.

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.

Approval is sought to import or manufacture a maximum of 20 kilograms/litres of this test substance. The entire quantity imported or manufactured shall be used only in containment and according to the proposed controls.

Volumes used in particular trial work ranges from 10 to 100mL per trial over multiple applications therefore the amount of substance being applied in containment in small – however this application limits the total volume of the substance to 20 litres (kg) maximum.

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:**

  At all stages of the life cycle associated with hazardous substances, they are handled and stored in accordance with current legislative requirements. This includes secondary containment where applicable. Both the Manufacturing site and Laboratory have Spill Contingency Plans in place, (attached in Appendix 4a Exempt Laboratory and 4b Pilot Plant location) and all Arxada sites are secured, with alarm systems, locked perimeter fences and security fob access into the buildings.

  Within the Laboratory, Fume Hoods are installed and used, where the Manufacturing plant has dedicated air extraction installed, which has been verified by an independent third party, and operates under an existing resource consent, (discharge to air).

  All transportation of hazardous substances are in accordance with NZ Land Transport Rules, including use of approved containers.

  All trial sites must be: A sufficient distance from streams, drains and other waterways to ensure there is no contamination from spraying and harvesting operations. Located so that product cannot drain into water bodies in the event of heavy rainfall causing surface runoff.

- **Methods for excluding unwanted organisms from the facility or to control organisms within the facility.**

Unwanted organisms are not likely to be a problem. During trials, only small amounts of the substance will be applied to a small area. Most of these applications will be restricted to timings when bees and beneficial insects are unlikely to be present.

To avoid unauthorised access, over spraying, or harvesting of treated plant material all trial sites must: Be within an existing established fenced area where access is limited by the laws of trespass when sited in a commercial crop or private property and have sufficient signage to clearly mark the existence of the trial site. Sites should be fenced if stock are likely to be in adjacent areas.

- **Methods for excluding unauthorised people from the facility**

  Site access is restricted to Staff and all visitors and contractors are vetted before entering site. Once approved they are required to sign in and then are escorted to their place of business. Noting that visitors are in the company of Arxada employee at all times.

  The sites are alarmed and have a perimeter fence which is locked after hours. During operational hours, an approved electronic fob is required to access the buildings, and a log of all movements is kept.

  Once in the field trial site, the following controls are adhered to – site to be at least 20 metres from buildings where people live or work (commercial and research glasshouses being an exception). Located away from public roads and access ways. Communicate all identified risks and obligations such as stock exclusion and security to the land owner/co-operator.

- **Methods for preventing unintended release of the substance by experimenters**

  Measuring and pouring of the substance will be over a retaining vessel that any spills can be recovered. Equipment used in the trial shall be cleaned as far as practicable at the trial site utilising designated and recorded rinsing water disposal areas.

- **Methods for controlling the effects of any accidental release of the substance**

  Accidental release of the substance within the Arxada production/laboratory site will be controlled via the emergency valves that prevent any spillage on site from entering the waterways. Spillage (unlikely to be great amounts as we are talking about research samples) will be recovered via wet'n'dry vacuum and, if unable to be used, disposed of in the waste management system on site.

  If in the field, the area will be immediately isolated and secured. If practicable, the affected area will be removed from site and disposed of in an approved disposal facility.

- **Inspection and monitoring requirements of the containment facility.**

  Prior to trial commencement, Field Staff discuss the protocol (see Appendix 7) and any deviations with the Study Director to ensure both the site and the protocol are relevant for the situation. Once the trial

commences the Trial Status Sheet will be updated with the relevant information on location, crops, compounds etc.

During the trial, weekly trial reports are sent to Senior Research Staff to show current results, trial status and trial progress. Senior Research Staff provide feedback to the Field Staff to improve trial management if necessary.

At the completion of the trial, Field Staff will complete ARM files and incorporate a report within the file of all relevant information outlined earlier in the Operating Plan. These files are archived to Propel.

A random selection of trials from each Field Staff member responsible for trial management will be audited annually by the Research Manager, Field Science Manager, or the Technical Services and Development Manager. Such ARM files are noted as “Audited Complete” in the trial status section. Results and findings of the audit are reported to the full research team and senior management at the annual data review meeting.

Review of the Operating Plan and systems in place shall be carried out at the Trials Planning Meeting annually to ensure any new risks and pending risks can be mitigated. These systems and procedures are outlined in the current ACVM Approved Operating plan - Appendix 1.

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.

The containment system is designated by the proposed controls. These controls are designed to provide safeguards commensurate with the limited information available about the hazard of these substances.

The means of implementing these controls and the personnel responsible is described in the confidential Appendix 1 of this application. The Current ACVM approved Operation Plan (OP-0028-04) is provided as an in depth Management Plant for Field Trials and samples used.

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**

Given the level of containment proposed for the life of these substances it is highly improbable that this compound will pose any immediate risk to the environment, the intrinsic value of ecosystems, public health, native and valued introduced flora and fauna. The likelihood of accidental release is remote given the management practices used to implement the controls.

- **the intrinsic value of ecosystems**

The substances covered by this application is experimental and limited information is available about the hazards hence, commensurate controls have been proposed.

- **public health (including occupational exposure)**

The most significant risk is to personnel involved in the application of these substances. This risk is managed through training of personnel, using equipment designed for application of hazardous substances and using protective equipment appropriate to the level of information known about the substance.

It is concluded that the risk to public health (including occupational exposure) is very low and the risk to the environment negligible for the substance covered by this application.

- **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 risk to Maori culture and traditions is considered low; ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga are unlikely to be effected by the compounds as the risk for release is considered negligible. Furthermore the volume present in any one place in NZ is very small.

- **the economic and related benefits to be derived from the use of the hazardous substance**

The economic and related benefits of the approval of this application is significant. Arxada NZ Limited is an internationally owned company, their manufacturing and research operations are based in New Plymouth. The trials conducted in New Zealand provide critical data for commercialisation of new products to be registered in New Zealand, Australia, Asia and the Pacific Islands. These products have benefits to farmers in providing new tools to manage weeds in an environmentally aware manner and hence provide food cost efficiently. Arxada's research and development operation employs 15 –20 people both in the research laboratories and field.

- **New Zealand's international obligations.**

As an internationally owned company, Arxada NZ is aware of and controlled by the obligations of their international owner – Arxada, Switzerland.

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)

Please see risk identifiable and assessment table Appendix 2.

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)

All main active ingredients proposed in this formulation are currently registered in New Zealand for agricultural crops. This compound in particular – TNL3753 has previously been assessed and approved for research with Controls under APP203703 HSC100187. This research approval has expired however the company would like to continue with research on this compound in various crops therefore a new research approval is requested.

Section 7 – Miscellaneous

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

The following is a glossary of scientific and technical terms used in this application:

Active ingredient	The component in the substance that is biologically active as a pesticide.
Exempt Laboratory	Designated area for developing formulations.
Formulation	The form in which the pesticide is supplied by the manufacturer for use.
Herbicide	A substance used to kill or control weeds.
OSH	Occupational safety & Health.
Pesticide	A substance for destroying unwanted organisms, can be specifically a fungicide, herbicide, insecticide, miticide, nematicide, parasiticide or rodenticide.
Pilot plant	Contained space where a smaller version of production batches can be produced.
Plot	Plot - a single homogeneous unit, being plant(s) or area, used for an assessment of a substance at a specific rate or concentration.
Project	A series of individual trials to characterise experimental compounds from the same chemistry and which are conducted over one or more seasons. The results of the individual trials are formally reported at the completion of the project.
SDS	Safety data sheet.
Trial site	An area, being a group of separate but contiguous plots (either treated and/or untreated), with a specifically delineated and defined boundary.

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

No additional information is provided.

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.

Arxada NZ Limited: Experimental Plant Protection Compound identified by the code:

TNL3753

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.

To import or manufacture under containment for field testing an experimental substance for the purpose of fungicidal activity in various agricultural and horticultural crops.

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)

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.

This is a generic application to import or manufacture an experimental substance which contains a biologically active compound. This compound will be tested as a possible future crop protection product for use in New Zealand.

Approval is sought, pursuant to section 30(b) of the HSNO Act, to import or manufacture in containment no more than 20 litres (kg) of the substance. The purpose of importation or manufacture is to dilute the substance with adjuvants and water and spray it on to various crops to control a range of diseases. Spraying of small quantities (a few millilitres to a litre) of the substances will occur at various locations identified to EPA.

The proposed containment practices are described in Section 4 of the application form and are designed to contain the substances commensurate with having limited knowledge of their potential hazards.

[redacted]

23 September 2022

Signature **Date**

Appendix 1 – Commercially sensitive information

Appendix 1 – Arxada NZ Limited Operating Plan

Appendix 2 – Risk identification & assessment

Appendix 3 – Standard operating procedure

Appendix 4 – Spill contingency – Exempt Laboratory and Pilot Plant Locations

Appendix 5 – Substance compositions

Appendix 6 – SDS sheets

Appendix 7 – Protocols