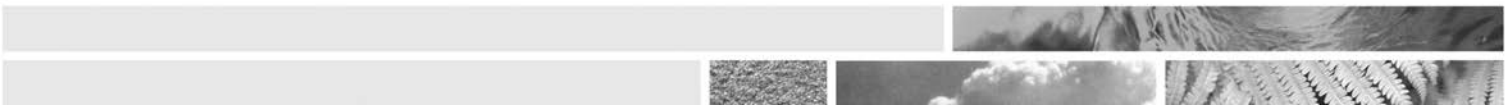
Environmental Protection Authority
Te Mana Rauhī Taiao

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:

Adama New Zealand Limited

Name of substance:

Adama Experimental Plant Protection Product

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: Adama New Zealand Limited

Address: [redacted]

Phone: [redacted]

Fax:

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

Address: [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.

Approval is sought, pursuant to section 30(b) of the HSNO Act 1996, to import an experimental plant protection product for evaluation in trials under containment.

The compound to be evaluated in New Zealand will contain biologically active ingredient(s) to control relevant plant pests. The substance will be trialled in New Zealand with the intention of obtaining EPA approval and ACVM registration.

Small scale field trials and laboratory testing are to be undertaken to determine the efficacy, safety and residue profile of the compound in New Zealand prior to regulatory approval. The experimental compound is also notified to the MPI under approval granted under section 28 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

For this compound, we have provided the SDS and the composition details in the confidential appendix to acknowledge the hazards and risks involved with the proposed experimental use of the product.

The volume of the compound will be determined by the scale of testing required as detailed in the project plan in the confidential appendix. Only the required amount for the project plan will be imported and the aim is that the entire quantity imported will used in containment.

The compound will be imported into New Zealand for use by qualified personnel in trials. The trials will be overseen by the Study Director.

For the compound imported, small plot replicated trials will be conducted in containment in various regions of New Zealand.The trials will be used to gererated data on the efficacy, crop safety and residue profile of the compound. The evaluation period for each substance may take up to 3 years.

The compound will be applied to trial sites and individual test plots/plants by ground application methods only. The details of the specific substance is provided in the confidential appendix.

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.

N/A

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):	
	☐ 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 the substance is supplied in confidence to the EPA in the confidential appendix.

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.

The known chemical and physical properties of the substance is provided in the SDS included in the confidential appendix.

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.

Known and expected hazardous properties for the plant protection compound is included in the SDS in confidential appendix.

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 life cycle of the substance in New Zealand is as follows:

1. Importation of samples
2. Transportation of samples to storage facility
3. Storage of samples
4. Dispensing of samples into trial quantities
5. Transportation of trial samples to trial contactors/trial sites
6. Preparation of spray treatment mixture
7. Application of spray mixture
8. Disposal of surplus spray mixture
9. Disposal of used containers
10. Disposal of treated produce
11. Site close off
12. Disposal of surplus samples

The substance will be packed in UN approved packaging or similar that is suitable for the shipment to and within New Zealand. Transport workers will only handle the fully packaged product, comprising the outer package, inner absorbent material and the inner package containing the substance. Exposure during transport, storage and handling is only possible through the breach of this packaging.

The amount of experimental compound will be limited and the aim is to have the entire quantity imported used in containment.
The empty containers will be triple rinsed and disposed of by return overseas, disposal at a licensed facility, or by burying at an approved 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.

The quantity of the experminental compound will be no more than 5L as detailed in the study plan.

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.

The proposed containment system for these field trials is as follows:

GENERAL CONTROLS

- All trials will be under the direction of the Study Director
- No substance which trigger any hazardous property threshold in classes 1, 2, 3.2, 4 or 5 will be imported.
- All applications will be made by ground based methods.
- No application of the compounds will be made onto or into water.
- Appropriate PPE (Personal Protective Equipment) will be used when handling the plant compounds at all stages of the life cycle. Information in regards to this will be found in the SDS (Safety Data Sheet).

TO LIMIT THE LIKELIHOOD OF ESCAPE OF ANY CONTAINED HAZARDOUS SUBSTANCE OR CONTAMINATION BY HAZARDOUS SUBSTANCE

(A) IMPORTATION AND TRANSPORT

- Product will be transported in accordance with good practice and where appropriate in compliance with any relevant requirements of the Land Transport Act 1998, the Civil Aviation Act 1990 and the Maritime Transport Act 1994.
- All product will be imported and transported in secure packaging, appropriate to the nature and hazard classifications of the particular compound
- The appropriate storage and segregation will be observed during transport.
- All containers will be clearly labelled according to relevant legislation, and will be accompanied by a Safety Data Sheet detailing the hazards of the product, and the appropriate response in the event of an accident. The label and SDS will contain the following directions for containment of spillages:
    - Wear suitable PPE such as face shield, impervious gloves and boots.
    - Prevent the product or spilled material from entering waterways.
    - Absorb liquid spills with inert material such as vermiculite, sand or other inert material and place in waste containers. Sweep or scoop up solid spills and place into waste containers.
    - Wash area with water and absorb with further inert material.
    - Dispose of waste material safely at an approved facility.

(B) STORAGE

- Product will be securely stored in its original packaging in a designated facility with appropriate security.
- The storage facility will have appropriate signage and segregation
- SDS's will be readily available.

(C) PRODUCT USE

- Trial personnel will have appropriate agrichemical training and hold a Certified Handler / Approved Handler Certificate if HSNO controls for the test substance require this certification.
- Personal protective equipment appropriate to the hazards of the compound will be worn.
- Applicators will be trained with respect to calibration, maintenance and use of application equipment.
- The substance will be used only under the supervision of the Study Director or Principal Investigator.
- Before commencement of the study, the Study Director ensures that copies of the Study Protocol are supplied to all personnel involved.
- The practical minimum amount of substance will be mixed for each application.
- Application shall be made by appropriate ground based methods. Additional approval will be sought from the EPA should there be a requirement for application by aerial means.
- Applications will be timed to minimise risks to non-target organisms, such as bees.
- Spraying must be in accordance with the *Code of Practice for the Management of Agrichemicals, NZS840:2004.*
- All requirements and restrictions pertaining to the use of agrichemicals in relevant regional council plans must be met.
- All equipment used should be cleaned in accordance with best practice to prevent any surplus substance leaving the site, and then more thoroughly as required where the equipment is stored.

(D) DISPOSAL OF SURPLUS PRODUCT OR WASTE

- Excess trial substance will be disposed of by return to Adama New Zealand Ltd study director, or by destruction through a commercial chemical processor, approved landfill or licensed incinerator
- If the plant compound is registered and approved for use in New Zealand under the HSNO act 1996 and the ACVM act 1997 the compound may be applied following the controls, conditions and use directions of that approval.
- Treated produce not used for the purposes of residue testing will be disposed of by either ploughing in, mulching, composting, desiccation, and other suitable means to render it inaccessible to people or animals or at an appropriate local authority operated landfill or other suitable facility. Treated plant material will not enter commercial composting operations.

(E) UNAUTHORISED ACCESS TO TRIAL SITES

- Trials will be located in dedicated research blocks or as clearly marked areas within commercial glasshouses, crops, farms or orchards on private properties to which public access is restricted
- Access to trial sites will be by permission of the Study Director or principal investigator
- The trial sites will have signage clearly identifying the trial site within the location and that unauthorised access is not allowed, that the site is subject to a trial, and that the crops should not be removed or disturbed.
- The land owner and all persons involved in the day-to-day management of the trial must be fully informed of the:
    - Location and purpose of the trial
    - General description of treatments
    - Safety information relevant to the trial
    - Instructions on normal management practices that are able to be applied in the trial area
    - Contact telephone numbers of trial personnel (including the Study Director)

(F) ACCESS BY ANIMALS

- Trial sites selected will be within areas that exclude grazing animals for the duration of the trial.

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.

Risks to human health and the environment are possible, but due to the small quantities imported and used in containment these are unlikely to be significant.

Risks could arise from the following pathways:

(1) Accidental Spillage

Spillage could occur at any stage of the product life cycle, however as the substances will be for experimental use only and of limited quantities the risks resulting from spills are likely to be minimal. A SDS detailing spill management procedures will accompany the product.

(2) The sustainability of native and valued introduced flora and fauna.

Native and valued introduced flora and fauna could be affected in the event of an accidental spillage during transportation or use of the product. Any such spill would be cleaned up as per the procedures given in the SDS. Any adverse effects on valued native and introduced flora and fauna is expected to be localised and minimal due to the small volumes involved in trials.

(3) The intrinsic value of ecosystems

The high level of containment will minimise any risk to the intrinsic value of ecosystems. Trial areas will be within commercial sites and no trials will be conducted in sensitive areas. Experimental compounds will not be applied into or onto water.

(4) Public Health (including occupational exposure)

- **Transport** will be by trained personnel. In the unlikely event of an accident during transportation, the accompanying SDS will have directions for immediate action to minimise any risks.

- **General public** are not expected to be at risk as the product will be stored and used at sites with no direct public access. Appropriate personal protection will be worn by spray applicators and those accessing the trial site.

(5) Assessment of effects in relation to significance to Maori

No adverse effects to Maori, Maori culture, traditions and ancestral lands are anticipated by the use of these compounds as they will be used in restricted areas.
Accidental spillage is not expected to have any significant effect on Maori in relation to their culture and traditions due to the localised nature and small volumes.

(6) The economic and related benefits to be derived from the use of the hazardous substance.

Approval of this application will allow Adama New Zealand Ltd to undertake trials for the development of new plant protection compounds that may assist farmers and growers by providing new tools to control existing or emergent issues and may also provide the opportunity to identify less hazardous alternatives to existing products.

(7) New Zealand's international obligations

Adama New Zealand Ltd is not aware of any risks to international obligations which may impact on the application.

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)

While no risks were identified as significant, accidental spillage during importation, transport and use was assessed as being the most likely risk area. The small quantities of hazardous substances imported into containment minimises this risk, and it is futher reduced after decanting into trial quantities. The following controls are considered sufficient to manage the risks associated with accidental spillage:

- Product will be transported in accordance with good practice and in compliance with any relevant requirements of the Land Transport Act 1998, the Civil Aviation Act 1990 and the Maritime Transport Act 1994.
- All product will be imported and transported in secure packaging, suitable for the particular formulation.
- The appropriate storage and segregation will be observed during transport.
- All containers will be clearly labelled according to relevant legislation, and will be accompanied by a Safety Data Sheet detailing the hazards of the product, and the appropriate response in the event of an accident, including any information specific to the particular product. The SDS will contain the following directions for containment of spillages:
  - Wear suitable protective clothing including face shield, impervious gloves and boots.
  - Prevent the product or spilled material from entering water bodies.
  - Absorb liquid spills with inert material such as earth or sand and place in waste containers.

- Wash area with water and absorb with further inert material. Dispose of safely.
- In a transport emergency dial 111, Police or Fire Brigade.
- For specialist advice in an emergency only, call 0800 734 607 (24 hours)

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)

No international considerations have been identified with the compound identified in the confidential appendix for trial in containment.

Section 7 – Miscellaneous

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

Adama experimental plant protection product.

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

N/A

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.

Adama experimental plant protection product.

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 into containment an experimental plant protection product for field trials in containment to allow assessment and development under local conditions for the control of plant pests in relevant 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.

The purpose of this application is to import into containment an experimental plant protection product that contains biologically active ingredient(s) for small scale field and laboratory testing. This will allow assessment and development of this compound under local conditions for the control of plant pests in relevant crops.

Approval is sought to import small quanties of the compound sufficient to conduct relevant tests over the approval period. The trials will involve applying the compound to defined plots within the trial areas. Applications in field trials will only involve small quantities of the compound which will occur at various locations in containment.

The trial sites will be selected based on the probability of the presence of the target pest. The trial areas will be representative of crop plants of the target species.

The containment practices proposed with this application are designed to contain the compound and manage any hazards and risk by covering the management of the substance throughout the life cycle particularly during storage, transport, use, and disposal.

[redacted]

10 June 2020

Signature **Date**

Appendix 1 – Commercially sensitive information

Project Plan, Composition details and SDS are included in the confidential appendix.