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:

BELCHIM Crop Protection NV/SA

Name of substance:

Lentagran 45 WP

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: **AgriNova NZ Ltd** (nominated agent for **BELCHIM Crop Protection NV/SA**)

Address: [redacted]

Phone: [redacted]

Fax:

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

Address:

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.

Samples are required to generate extra data for the registration of the product Lentagran 45 WP under the ACVM Act: residues, efficacy and selectivity trials.

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.

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).

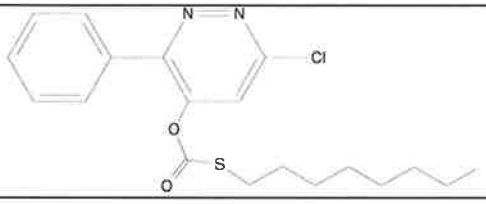
This section should include all information necessary to unequivocally identify the substance(s) and may include:

- 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.

Lentagran 45 WP is a wettable powder containing 450 g/Kg of pyridate for the use as herbicide. Here below you can find more detailed information on the active substance :

End-Point	**Active Substance - Pyridate**
	EU Agreed endpoints (7576/VI/97– 22/03/2001)
Common name (ISO)	Pyridate
Chemical name (IUPAC)	6-chloro-3-phenylpyridazin-4-yl S-octyl carbonothioate
Chemical name (CA)	O-(6-chloro-3-phenyl-4-pyridazinyl) S-octyl carbonothioate
CIPAC No	0447
CAS No	55512-33-9
EEC No	259-686-7
FAO SPECIFICATION	Not available.
Molecular formula	$C_{19}H_{23}ClN_2O_2S$
Molecular mass	378.91
Structural formula	

Information on impurities is considered as confidential data, and is therefore reported in the appendix 1 – commmercially sensitive information.

Detailed information on the composition of the plant protection product Lentagran 45 WP, including identity and content of all the inert ingredients, is given in the appendix 1 – commmercially sensitive information.

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.

- Appearance of the formulation Lentagran 45 WP: White powder with persistent characteristic odour
- pH of 1% aqueous dilution of Lentagran 45 WP in deionised water: pH = 4.67
- Bulk density (CIPAC MT 169) of the formulation: 0.36 g/ml
- Vapour pressure of the a.i. pyridate: 4.8 x 10^{-7} Pa at 20°C (purity: 98.9%)
- Melting point of the a.i. pyridate: 26.5°C-27.8°C (purity: 98.9%)
- Boiling point of the a.i. pyridate: decomposition at 250°C without boiling (purity: 98.9%)
- Solubility of pyridate in water, pH 3: 0.33 ± 0.05 mg/L at 20 ± 0.2°C 0.328 g/L at 20°C
- Water/octanol partitioning co-efficient of Pyridate: Log Po/w = 4.01 ± 0.16 at room temperature.(purity: 98.9%)

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 of the formulation:

- Explosive properties: not explosive
- Oxidizing properties: not oxidising
- Flash point: not required for solid formulations
- Auto-flammability: No self-ignition until 220 °C

Toxicity

General: **Skin Sens. 1A : May cause allergic skin reaction**

Acute Oral Toxicity LD50	LD50 (rat): 2330 mg/kg [OECD 401]
Acute Dermal Toxicity LD50	LD50 (rat): > 4000 mg/kg [OECD 402]
Acute Inhalation Toxicity LC50	LC50 (rat): > 2.14 mg/l [OECD 403]
Skin Irritation	Not irritant (rabbit)
Eye Irritation	Not irritant (rabbit)
Skin sensitization	Sensitizing (Guinea pig maximization test)

Ecotoxicity:

General: **very toxic to aquatic organisms, may cause long-term adverse effects.**

LC50 (*Salmo gairdneri* /96h): 118 mg/l
LC50 (*Cyprinus carpio*/96h): 187.1 mg/l [OECD 203]
EC50 (*Daphnia magna*/48h) 2.13 mg/l [OECD test medium]
EC50 (*Scenedesmus subspicatus*/72h): 4.59 mg/l [OECD 201]

NOEC (*Daphnia magma*/22 d): 0.031 mg/l

Please refer also to the SOS letter n ° SOS1003462, with proposed classification;

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.

Field trials under an ACVM Research Approval to produce data suitable for registration in New Zealand. Trial providers all experienced, suitable qualified persons, conducting small plot replicated trials to ACVM standards.

Once released from the border, the product must be shipped to 15 Sunlight Grove, Porirua. Then samples will be shipped to different trial sites, located at: Pukekohe, Hawkes Bay, Canterbury. The personnel involved in the trials will be responsible of establishement of the trial, application of the product, collection of samples and destruction of

the residue crop. At completion of trial program any remaining product will ethier be return to manufacturer or disposed via Transpacific – approved waste management service for the diposal of chemistry in New Zealand.

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.

Additional data required for ACVM registration

- Other crops
- Weed Spectrumn trials – more data required on key weeds to expand label claim
- Residue data – additional data required, more information needed to reduce withholding period.

Only sufficient product, clearly labelled, will be provided to each trial provider for the seasons trial they are to conduct :

- **Total amount of product: 4 kg**
- Justification:

  Maximum of 31 small plot replicated trials to obtain required data to meet ACVM standards for Residues, Crop Safety and Efficacy under New Zealand conditions.

  31 trials – 8 replicates x 18 m^2 per trial, single and double application per trial.

  = 13392 m^2 to be treated or 1.4 ha.

  Maximum dose rate: 2 kg product/ha

  Total product needed: 1.4 ha x 2 kg/ha = 2.8 kg

  Taking into account 20% spray tank waste: 3.36 kg

  Packaging in 1 kg lots: 4 x 1kg = 4 kg

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.

- Methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility:
    - Trial providers will be issued with proposed NZ or European label details and SDS sheets. Transport to site by approved suitable transport.
    - Written conditions of product use and return of unused product to study director will be required. Unused product will be stored at Agrinova NZ, containment facility, any remaining product will be disposed of by commercial approved incinerator or upon registration by approved commercial use.
    - Treatment and decontamination – substance will be applied by hand held or operator worn, hydraulic pressure or compressed CO_2 pressurised applicators onto the plots, this will limit drift.
    - Buffer zones will isolates the treated plots from other commercial crops.
    - Spraying will be conducted by qualified, Grosafe certified applicators in accordance with NZS8409: code of practice for the management of agrichemicals.
    - No water source, stream, or other body of water will be within the trial site. Site will be selected away from housing or other occupation.
    - Trial sites will be fenced to prevent stock access. Within a commercial existing farm. Boundaries will be clearly labelled and mapped, and remain visible until the end of the trial, and identifiable at later dates.

- Treated crop will be ploughed, mulched and incorporated, or disposed of at approved landfill, to avoid any change of entering the animal or human food chain.
- The trial area will be of a very limited area only sufficiently large enough to obtain the regulator information required. Located on a large commercial property.
- Access limited to persons authorised by the trial director, sites secured and sign posted.

- Methods for excluding unauthorised people and organisms from the facility:
  - Location and access – on private land away from road, housing or public access, with co-operating grower. Landowner, entrance only via privately owned property, trial site fence off or segregate crop from commercial area and stock, entrance to trial area clearly marked and sign posted to the fact access is restricted without permission off the trial director or the property owner/manager.
  - Access limited via- location, signage – "no entry without permission of trial provider land owner/manager, not for animal or human consumption" including contact details fencing – stock proof fencing. Entrance restricted and security provided by the normal commercial activities of property as determined by the land owner/manager. Minimising or preventing incidental or accidental trespass of unauthorised persons of animals.
  - Fencing and location selection away from stock. Co-operation with land owners. Buffer areas of sprayed of or cultivated soil around each trial greater than 2m width.

- Methods for preventing unintended release of the substance by experiments:
  - Only sufficient product, clearly labelled and properly packaged as per the proposed controls with appropriate safety precautions and first aid statements, will be provided to each trial provider for the season's trials they are to conduct. Product will be held and dispensed by our chemist at Agrinova laboratory at our approved containment facility. Any remaining unused materials will be returned to our chemist for storage or disposal.
  - Only sufficient material shall be prepared by the trial provider to conduct each treatment.
  - Rinsate from the application equipment and diluted product remaining will be disposed of within the fenced trial site area in an unused waste area.
  - At completion of trial program any remaining product will either be returned to manufacturer or disposed via Transpacific – approved waste management service for the disposal of chemistry in New Zealand.
  - Crop destruction – no crop is to be feed to animals. All treated crop will be sprayed off at completion of the trial and then residue rotary cultivated. Site will then be replanted in another crop type.
  - Samples taken for GLP residue analysis will be incinerated by testing laboratory (Hills or Eurofins).
  - Accidental spillage – shall be contained, prevented from entering water ways, and absorbed with earth, sand or clay. Material will then be packaged in labels containers for suitable disposal as per the SDS.

- Methods for controlling the effect of any accidental release of the substance:
    - First aid measures: see section 4 of the attached MSDS.
    - Firefighting measures: see section 5 of the attached MSDS.
    - Accidental release measures: see section 6 of the attached MSDS.
    - Exposure controls/personal protection: see section 8 of the attached MSDS.

- Inspection and monitoring requirements of the containment facility.
    - Product will be tracked as per HSNO act.
    - Only experience trial providers will be allowed access to the product.
    - Trial providers will be issued with proposed NZ or European label details and SDS sheets.
    - Written conditions of the product uses and return of unused product to study director will be required.
    - Records of volumes received, used and or returned will be kept by the trial providers and the director.

Approved handler and Grosafe certification will be required from each trials provider.

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.

Particular attention should be paid to the impact on aquatic organisms.

The preliminary hazard classification assigned by EPA during SOS process is:

Hazard Endpoint	Preliminary Classification
Skin Irritant	6.3
Contact Sensitiser	6.5B
Target Organ Systemic Toxicant	6.9
Aquatic Ecotoxicant	9.1
Vertebrate Ecotoxicant	9.3

The proposed registration trial program is to be conducted by experienced professionals on a very limited scale away from the public, on agricultural land, away from water ways, fenced and clearly identified. Product supplied will be limited to minimum requirement of the trial providers.

Product is internationally registered and treated crop will be destroyed, not feed to stock, so no risk to internationaly trade is posed. The use pattern, environmental and user safety guidelines will both adhere to the EU label and proposed controls identified under the SOS. Protecting those involved in the trials.

The limited scale and location of trials on agricultural land away from water ways, will limited any risk to native flora, funa and taonga. The trials will allow evaluation of costs and benefits to agriculture in New Zealand and assist with determining any potential positive or negative impact on Maori.

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)

The risk for operators, workers and bystanders is expected to be low:

- The trial program will be conducted by experienced educated professionals. The professionals will wear appropriate personal protective equipment. SDS and European label will provided, indicating all the hazard and precaution information.
- The trials will be conducted on a very limited scale away from the public (on agricultural land) and will be clearly identified.
- To avoid misuse, product supplied will be limited to minimum requirement of the trial providers.

The potential exposure to consumers can be neglected:

- To avoid that residues of Lentagran will enter the consumption market, the treated crop will be destroyed and not fed to livestock.

Risk for local fauna and flora is expected to be low:

- The small scale trials will be located away from waterways and on argricultural land.
- Applications will be performed during optimal weather conditions to limit the exposure to local fauna and flora:
    - In dry conditions, to avoid run-off
    - Low wind conditions, to avoid drift

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)

EU Commission published renewal of approval of the active substance pyridate on July 10th, 2015 for 10 years with entry into force date 1st January 2016. Belchim Crop Protection was the only applicant for EU renewal of pyridate after having upgraded the dossier according current EU requirements.

The plant protection product Lentagran 45 WP is registered in several countries in EU.

Section 7 – Miscellaneous

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

a.s.	Active substance
CAS number	Chemical Abstracts Registry Number
CIPAC	Collaborative International Pesticides Analytical Council
EINECS	European Inventory of Existing Chemical Substances
bw	Body weight
°C	Degree celsius (centigrade)
EC_{50}	Median effective concentration
ha	Hectare
LC_{50}	Median lethal concentration
LD_{50}	Median lethal dose
NOEL	No observed effect level
ER_{50}	Effective residue concentration to 50% of test organisms

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.

Lentagran 45 WP

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.

The formulated product, Lentagran 45 WP, is a contact herbicide to be applied as foliar spray on Vegetable Brassica`s, Forage Brassica`s, Onions, Asparagus, Leek.
Samples are required to generate extra data for the registration of the product Lentagran 45 WP under the ACVM Act: residues, efficacy and selectivity trials.

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 formulated product, Lentagran 45 WP, is a contact herbicide to be applied as foliar spray on Vegetable Brassica`s, Forage Brassica`s, Onions, Asparagus, Leek.
Lentagran 45 WP may cause allergic skin reaction and is very toxic to aquatic organisms. Please refer to the label for detailed instructions for use and information on protective gloves and clothing. Moreover, special care is required to avoid contamination of surface waters or ditches, as well as drift, in order to protect aquatic organisms and non-target plants.
Shipment and trials will be carried out by professionals only and experimental plots will be isolated from public. Only sufficient product, clearly labelled will be provided to trained staff. All of the unused material will be sent for incineration to an approved waste incineration facility.

[redacted] 22th of August 2019

Signature **Date**

[redacted]