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:

Invasive Pest Control Limited

Name of substance:

Diphacinone and cholecalciferol gel

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: [redacted]
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.

The purpose of this application is to undertake efficacy field trials on possums (*Trichosurus vulpecula*) with a gel containing diphacinone and cholecalciferol contained within and dispensed from a toxin delivery device named The Possum Spitfire. The purpose of the trials is to generate efficacy data to support a registration package for this gel formulation. The gel will be trialed at up to nine field trial sites by researchers with a Controlled Substances License and extensive experience handling and trialing VTAs.

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.

The active ingredients cholecalciferol and diphacinone are currently imported to New Zealand to manufacture DoubleTap® baits (HSR101231 and ACVM V9649).

The diphacinone and cholecalciferol gel will be manufactured by Connovation Ltd at their premises with a total of 45.9 kg of gel manufactured. The ingredients (*Confidential Appendix 1*) will be weighed out and mixed together. Gel will be loaded into pouches that are to be contained inside the Possum Spitfire device. Each pouch will contain up to 120 g of gel and all pouches will be transported from Connovation Ltd to a secure research facility at Landcare Research, Lincoln, Canterbury by Dangerous Goods Courier. At the secure research facility pouches will be loaded into individual Possum Spitfire devices and the devices transported directly to field trial sites by vehicle with the research team. The details of the composition of the substances in the gel are provided in *Confidential Appendix 1*. Gel in pouches will be transported by vehicle to the field trial sites (*Confidential Appendix 1*) to undertake field trials on possums and these trials will be undertaken between 30th March 2021 and 30th December 2022.

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):	
Biocidal Products Regulation (EU)	☐ 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.

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

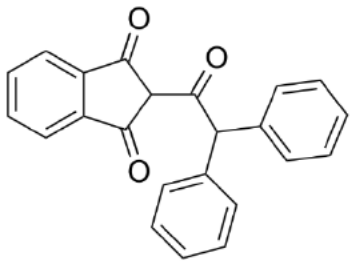
This section should include all information necessary to unequivocally identify the substance(s) and may include:
Diphacinone

Chemical name (IUPAC): 2-(2,2-diphenylacetyl)indene-1,3-dione

Chemical name (CA): 2-diphenylacetyl-1,3-indandione

Molecular formula: $C_{23}H_{16}O_3$

Structural formula:



Manufacturer development codes: Diphacinone active

CIPAC No: 131

CAS No: 82-66-6

EEC No (EINECS or ELINCS): 201-434-5

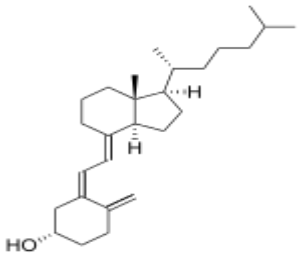
Cholecalciferol

Chemical name (IUPAC):(1S)-3-[2-[(1R,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidenecyclohexan-1-ol

Chemical name (CA): 9,10-Secocholestra-5,7,10 (19)-trien-3-betaol

Molecular formula: $C_{27}H_{44}O$

Structural formula:



Manufacturer development codes: Cholecalciferol active

CIPAC No: 8063

CAS No: 67-97-0

EEC No (EINECS or ELINCS): 200-673-2

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.

Please refer to *Confidential Appendix 1* for product composition.

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.

Chemical and Physical properties of the product – Gel bait containing diphacinone and cholecalciferol

- **Appearance** (colour, odour, physical state or form):
  Blue gel the consistency of toothpaste, containing oils and orange flavouring attractive to possums.
- **pH:** Not applicable.
- **Density:** Not available
- **Vapour pressure:** Not applicable, this bait is a gel.
- **Boiling/melting point:** Not applicable.
- **Solubility in water:** Not applicable – insoluble, but degrades over time
- **Water/octanol partitioning co-efficient**: Not applicable

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.

Diphacinone and cholecalciferol gel bait

- **Explosiveness:** This bait does not contain any components classified as explosive and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Flammability:** This bait does not contain any components classified as flammable and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Oxidising properties:** This bait does not contain any components classified as oxidising and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.
- **Corrosiveness:** This bait does not contain any components classified as corrosive and all the components are stable under normal conditions. Therefore, this property does not apply to this bait.

Diphacinone and cholecalciferol gel bait

- **Toxicity:**

• **Class 6: Toxicity** • Sub class 6.1 • Acute toxicity (oral) • Acute toxicity (dermal) • Acute toxicity (inhalation)	 • 6.1B • 6.1C • 6.1B
• **Sub class 6.3** • Skin irritation	• Not triggered
• **Sub class 6.4** • Eye irritation	• 6.4A
• **Sub class 6.5** • Sensitisation	• Not triggered
• **Sub class 6.6** • Mutagenicity	• Not triggered
• **Sub class 6.7** • Carcinogenicity	• Not triggered
• **Sub class 6.8** • Reproductive/Developmental Toxicity	• 6.8B
• **Sub class 6.9** • Target organs/systems	• 6.9A
• **Ecotoxicity:** • **Class 9: Ecotoxicity** • **Sub class 9.1 Aquatic**	• Not triggered
• **Sub class 9.2 Soil Environment**	• Not triggered
• **Sub class 9.3 Terrestrial Vertebrates**	• 9.3B
• **Sub class 9.4 Terrestrial Invertebrates**	• Not triggered

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.

Diphacinone and cholecalciferol gel bait

Importation

The active ingredients cholecalciferol and diphacinone will be imported into New Zealand and then will be transported by road to the manufacturing site.

Manufacture

The gel bait containing 9.9% cholecalciferol and 0.8% diphacinone will be manufactured by Connovation Limited. The pellet bait will be manufactured at Connovation Limited's [redacted], [redacted] under their existing ACVM approval to manufacture VTA products.

Identification

Packaging will be labelled with product information (*Confidential Appendix 2*) and a Material Safety Data Sheet (SDS) will be available (*Confidential Appendix 3*). The label and MSDS identifies the hazard statements, precaution phrases and provide advice for First Aid responses, storage, disposal and use of the product for possum control.

Transport

The active ingredients will be transported by Dangerous Goods Courier from Airport Customs to Connovation Ltd.

Storage

The active ingredients and then the gel containing 9.9% cholecalciferol and 0.8% diphacinone will be stored at a secure storage site at Connovation Limited. The storage for the actives and toxic bait is within a locked room that only members of the research team have access to, this room is within a building that requires pin code access and again is limited to company employees only.

Use

An Animal Ethics Application has been submitted to enable field trials of these baits on possums. The gel bait containing 9.9% cholecalciferol and 0.8% diphacinone is formulated as a ready-to-use bait (gel bait) that is to be dispensed by the Possum Spitfire device for use as a Vertebrate Toxic Agent (VTA) for possum control. When triggered the Possum Spitfire will spray between 0.8 g and 1.2 g of gel bait onto an individual possums abdomen that is then ingested through grooming. Each device will be loaded with a pouch containing up to 120 g of gel bait which is equivalent to 100 activations.

The research team for field trials will hold controlled substance licences and all other persons involved will be approved handlers.

Possum trials

Trial site 1

Possum Spitfire devices will be deployed at the field site placed within a grid of ten devices with each device 100 m apart. Each spitfire will be loaded with a pouch containing up to 120 g of gel bait containing 9.9% cholecalciferol and 0.8% diphacinone.

A maximum of 10 Possum Spitfires will be used at the field trial site with each device containing a maximum of 120 g of gel bait with a further 120 g of gel bait per device to enable a refill if needed and 100 g for analysis which results in a total of 2.5 kg of gel bait. Spitfires will be checked every two days. Bluetooth connectivity will provide a precise firing record which allows remaining toxin volume to be determined at each visit.

Trial sites 2, 3, 4 and 5

Possum Spitfire devices will be deployed at up to four field sites. At each site, five devices will be placed on a line at 50-100 m intervals. Three parallel lines will be laid out at 50-100 m distances to achieve 15 devices deployed at each site. Each spitfire will be loaded with a pouch containing up to 120 g of gel bait containing 9.9% cholecalciferol and 0.8% diphacinone.

A maximum of 15 Possum Spitfires will be used at each site with each device containing a maximum of up to 120 g with a further 120 g of gel bait per device available to enable a refill if needed and 100 g for analysis which results in a total of 14.5 kg of gel bait. Spitfires will initially be checked every 1-2 days for the first week and then every 4-6 days for the remainder of the trials.

Trial sites 6, 7, 8 and 9
Possum Spitfire devices will be deployed at up to four field sites. At each site, devices layout will be tailored to a geographic feature and placed in a grid most appropriate to ensure a core protection model (traps around a central area halting re-invasion) Each spitfire will be loaded with a pouch containing up to 120 g of gel bait containing 9.9% cholecalciferol and 0.8% diphacinone.
A maximum of 30 Possum Spitfires will be used at each site with each device containing a maximum of up to 120 g with a further 120 g of gel bait per device to enable a refill if needed and 100 g for analysis which results in a total of 28.9 kg of gel bait. Spitfires will be checked every 1-2 days for the first week and then every 7-14 days for the remainder of the trial.

Disposal
Any unused gel bait in pouches and all possum carcasses recovered from the field trial site will be disposed of 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.

Diphacinone and cholecalciferol gel bait

Up to 45.9 kg of gel bait containing 9.9% cholecalciferol and 0.8% diphacinone will be manufactured for field trials. A total of 45.6 kg of gel bait will be used in field trials on possums and the remaining 300 g will be used for analysis.

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

  Diphacinone and cholecalciferol actives will be transported from Auckland Airport Customs to Connovation Ltd by Dangerous Goods courier. Pouches with gel bait containing 9.9% cholecalciferol and 0.8% diphacinone will be transported to Landcare Research in Lincoln, Canterbury and stored in a dangerous goods secure lock up room within a research building that only has swipe card access for approved personnel. Signs will be on the door in compliance with EPA containment guidelines. The pouches will be loaded into the Possum Spitfire devices at the secure research facility and the devices then transported directly to the field trial sites by passenger vehicle with a lockable separate tray (Ute). The pouches storing gel bait containing cholecalciferol

and diphacinone will only be handled by the research team who hold a CSL (*See Confidential Appendix 1*). At the conclusion of the trials any unused gel bait or any possum carcasses retrieved will be disposed of at an approved landfill.

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

  The Spitfire devices have an operation time set so that they cannot function during daylight hours This will be tailored to the daylight hours specific to each field site at the time of deployment. The field trial sites are fenced to exclude livestock and there is no access to the public. Access is only to research personnel and landowners. The Possum Spitfire device containing 9.9% cholecalciferol and 0.8% diphacinone (Confidential Appendix 1) has species-selective triggers that are required to be activated for the device to spray the gel bait, further reducing the likelihood of any unwanted organisms accessing the gel bait during field trials.
- Methods for excluding unauthorised people from the facility

  The field trial sites will be fenced to exclude livestock and on private property so there is no access to the public. Access is only to research personnel. Signs will be placed at entry points warning people of the trial and that these field trial sites are not to be accessed.
- Methods for preventing unintended release of the substance by experimenters

  The substance is a gel bait stored inside a pouch that is housed within the Possum Spitfire device which will be loaded into each device at the secure research facility. Members of the research team will wear appropriate safety gear including disposable latex gloves during the trial. At the conclusion of the trials any unused gel bait, latex gloves and any possum carcasses located will be disposed of at an approved landfill.

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

  Possum Spitfire devices have several design features that have been included to exclude non-target species triggering the device – namely a weight activated trigger and a second trigger under the hood of the device. The device requires the possum to activate both for it to successfully trigger. At the conclusion of the trials any unused bait or possum carcasses recovered will be disposed of at an approved landfill.

  Pouches with gel bait containing 9.9% cholecalciferol and 0.8% diphacinone will be transported to Landcare Research in Lincoln, Canterbury and stored in a dangerous goods secure lock up room within a research building that only has swipe card access to approved personnel. The pouches will be loaded into the Possum Spitfire devices at the secure research facility and the devices then transported directly to the field trial sites by passenger vehicle with a locked ute tray.

  Field trial sites will be checked regularly, with a frequency of 1-2 days for the first week and then once every 4-6 days at trial sites 2,3 ,4 and 5 and once every seven days at sites 6, 7, 8 and 9. At the conclusion of the trials any uneaten baits, latex gloves and any possum carcasses located will be disposed of at an approved landfill.
- Inspection and monitoring requirements of the containment facility.

  Field trial sites will be checked regularly, with a frequency of 1-2 days for the first week and then once every 4-6 days at trial sites 2,3 ,4 and 5 and once every seven days at sites 6, 7, 8 and 9

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.

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.

Event	Risk pathway	Lifecycle stage
Spillage of bait	Packaging damage	T, S
	Traffic accident	T
	Handling bait	U
	Disposal of bait (unused or recovered bait)	T, S, U, D
Human contact with bait	Packaging damage	T, S, U
	Traffic accident	T
	Handling bait	U
	Disposal of bait (unused or recovered bait)	U, D

Non-target species (animals, birds) in contact with bait	Domestic animals, e.g. cats or dogs eating bait Birds eating bait	T T
Bait gets into water way	Packaging damage Traffic accident (spillage) Bait placement near waterway Disposal of bait Vandalism	T, S T D T, S, D
Secondary Poisoning	Non-target species, e.g. cats, dogs, birds, scavenge wallaby carcasses	D

T=Transport, S=Storage, U=Use, D=Disposal

The development of the Possum Spitfire containing diphacinone and cholecalciferol gel was linked to a Lincoln University MBIE programme. As part of the implementation strategy for this research programme and the pest control tools, a national Māori advisory and advocacy group known as Nga Matapopore “The Watchful Ones” was established and oversaw the research conducted within the programme. The development of the Possum Spitfire has been discussed with Maori at Nga Matapopore hui and at other Maori focused events.

The search for alternatives to 1080 and brodifacoum and the development of low residue more humane toxic baits and more targeted delivery systems has been supported by Nga Matapopore. It is hoped therefore that products that are alternatives to traditional vertebrate pest control tools (such as brodifacoum) will be supported by many Māori. Use of diphacinone with cholecalciferol has the potential to offer a new option for the control of possums for example and would have conservation, protection of taonga and disease control benefits without the undesirable effects associated with brodifacoum.

NZ has international obligations regarding animal welfare and also residues in meat. A VTA product containing Diphacinone and cholecalciferol has benefits for both and assists in our obligations with regard to international biodiversity.

With regard to residues, buffer zone specifications for wild animal procurement are cited here as an example of a risk and benefit for VTA use. Buffer zone specifications are intended to protect against concentrations of vertebrate toxic agents (VTAs) being above acceptable national and international limits in edible tissue (muscle/meat). Currently the New Zealand Food Safety Authority has set the buffer zones at 200 m for rabbits, 1 km for hares and wallabies, 2 km for pigs (except where second-generation anticoagulants are used where it is 5 km) and 2 km for all other wild animals.

There would be low risk of wild animal procurement of edible tissue, for human consumption above acceptable limits if only “low residue” vertebrate pesticides with comparatively rapid depletion times after sub-lethal exposure were employed for pest control. And, if this was the case there would be no or minimal need for buffer zones and caution periods. However, at this time there is still a need for the use of vertebrate pesticides with long retention times, such as brodifacoum, until alternatives tools such as diphacinone or cholecalciferol with lower risk are available.

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 diphacinone and cholecalciferol gel bait will have a low risk of exposure to the environment and the general public. Diphacinone and cholecalciferol actives will be transported from Auckland Airport Customs by Dangerous Goods courier to Connovation Ltd. Pouches with gel bait containing 9.9% cholecalciferol and 0.8% diphacinone will be transported to Landcare Research in Lincoln, Canterbury and stored in a dangerous goods secure lock up room within a research building that only has swipe card access for approved personnel. The toxin storeroom key is held by only one person at the facility. Signs will be on the door in compliance with EPA containment guidelines. The pouches will be loaded into the Possum Spitfire devices at the secure research facility and the devices then transported directly to the field trial sites by passenger vehicle with a lockable separate tray (Ute). At the conclusion of the trials any unused bait or possum carcasses recovered will be disposed of at an approved landfill.

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)

Diphacinone is registered in New Zealand as a VTA for use on rats (HSR001596). Cholecalciferol is registered in New Zealand as a VTA for use on possums and rats (HSR001598) and DoubleTap® which contains diphacinone and cholecalciferol is registered in NZ with the EPA (HSR101231) and ACVM (V9649) as a VTA for use on possums and rats. We are not aware of the diphacinone and cholecalciferol gel formulation being registered in any other country.

Section 7 – Miscellaneous

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

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.

Diphacinone and cholecalciferol gel

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 purpose of this application is to undertake field trials on possums (*Trichosurus vulpecula*) with a resettable toxin delivery device named The Possum Spitfire. When triggered by possums this device delivers between 0.8 - 1.2 g of a gel containing the Vertebrate Toxic Agents (VTA) diphacinone and cholecalciferol onto their abdomen that is then ingested through grooming. The purpose of the trial is to generate efficacy data to support the registration of this VTA for the control of possums.

8.3Use 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).

Main category: There are four main categories.

3 Non-dispersive use

Industry category: There are 16 industry categories.

0 Other

Function/Use category: There are 55 function/use categories.

39. Pesticides non-agricultural

Subcategory: Pest control products

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.

Gel bait containing 9.9% cholecalciferol and 0.8% diphacinone is to be trialled using the Possum Spitfire resettable toxin delivery device in field trials as a Vertebrate Toxic Agent (VTA) for controlling possums. The two active ingredients (diphacinone and cholecalciferol) are currently registered for use in New Zealand for controlling possums and rats under the trade name DoubleTap® and this bait has the hazardous classifications of 6.9B and 9.1D. The gel bait to be trialled has the hazardous classifications of 6.1B, 6.4A, 6.8B, 6.9A and 9.3B

The gel bait will be housed inside the Possum Spitfire device and under the control of an Approved Handler, personal protective equipment will be worn, appropriate equipment utilised, and documented procedures followed. Packaging will be labelled, and a Material Safety Data Sheet will be available.

An Animal Ethics approval will be obtained for field trials on possums. The persons carrying out the trial will be Approved Handlers and will be provided with copies of the approval documents and a Safety Data Sheet.

Any unused gel bait in pouches and any possum carcasses recovered will be disposed of in an approved landfill.

[redacted]

29/01/2021

Signature **Date**

Appendix 1– Commercially sensitive information