Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
Veterinary Medicines

To obtain approval to import or manufacture a veterinary medicine

Send to Environmental Protection Authority preferably by email (HSApplications@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140)
Payment must accompany application; see our fees and charges schedule for details.

Name of the substance to be approved

RXI

Date

06 April 2020

Completing this application form

1. This form has been approved under section 28 of the Hazardous Substances and New Organisms Act 1996 (HSNO Act). It only covers the import or manufacture of veterinary medicines to be released in New Zealand under section 28 of the HSNO Act. If you wish to make an application for another type of substance (such as a pesticide) or for another type of application (such as emergency, special emergency or containment), a different form will have to be used. All forms are available on our website.
2. Many veterinary medicines will be covered by Group Standard approvals and will not need a Part 5 application. Further information is available on our website.
3. It is recommended that you contact an Applications Advisor at the Environmental Protection Authority (EPA) as early in the application process as possible. An Applications Advisor can assist you with any questions you have during the preparation of your application including advising on any consultation requirements.
4. Before submitting this application, you may make an informal Status of Substance (SOS) advice request to the EPA. Further information on this process is available on our website. Please note that this is not mandatory and an SOS request is only informal advice.
5. This application form may be used to seek approvals for more than one hazardous substance, if the substances and uses are of a similar nature.
6. Please make sure that you obtain all appropriate permissions for the use of any data that you have used or provided in this application form, if you are not the owner of such data.
7. Unless otherwise indicated, all sections of this form must be completed for the application to be formally received and assessed. If a section is not relevant to your application, please provide a comprehensive explanation why this does not apply. If you choose not to provide the specific information, you will need to apply for a waiver under section 59(3)(a)(ii) of the HSNO Act. This can be done by completing the section on the last page of this form.
8. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included with the application form when it is submitted.
9. Please add extra rows/tables where needed.
10. You must sign the form (the EPA will accept electronically signed forms) and enclose the application fee (including GST) unless you are already an approved EPA customer. To be recognised by the EPA as an “Approved customer”, you must have submitted more than one application per month over the preceding six months, and have no history of delay in making payments, at the time of presenting an application.
11. Information about application fees is available on the EPA website. If you wish to claim a fee reduction for a reduced-risk-formulated product the appropriate justification must be submitted at the pre-lodgement stage for consideration.
12. All application communications from the EPA will be provided electronically, unless you specifically request otherwise.

Commercially sensitive information

13. The EPA strongly advises applicants to provide as much information relating to the hazard classification and use of their substance as possible to help inform the EPA's assessment as well as for submitters and decision-makers. We expect this information to be publicly available in the application unless there is a genuine argument for it to be considered as commercially sensitive.
14. Commercially sensitive information may be put in a confidential appendix to this form (also available on our website) and be identified as confidential. If you consider any information to be commercially sensitive, please show this in the relevant section of this form providing your detailed reasons for considering it to be commercially sensitive and cross referencing to where that information is located in the confidential section.
15. Any information you supply to the EPA prior to formal lodgement of your application will not be publicly released, unless it has already been made publicly available as part of the consultation process. Following formal lodgement of your application any information in the body of this application form and any non-confidential appendices will become publicly available.
16. Once you have formally lodged your application with the EPA, any information you have supplied to the EPA about your application is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, your view will be considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be required to provide further justification for your claim of confidentiality.

Definitions

Active ingredient	Component of a formulated substance responsible for the therapeutic effect
CAS Number	Chemical Abstracts Service number. This is a unique identifier for a chemical substance
Hazardous substance	Any substance with one or more of the following intrinsic properties: • Explosiveness • Flammability • A capacity to oxidise • Corrosiveness • Toxicity (including chronic toxicity) • Ecotoxicity, with or without bioaccumulation, or • which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in this definition
Public register name	Name of the formulated substance to be mentioned in a publicly available register that can be different from the final marketing name
Relabelling	Action of changing the label of a formulated substance intended to be imported in New Zealand in order to meet the EPA criteria for information content. This action

	can also occur when the formulated substance is repacked into packaging of different sizes
Repackaging	Movement or transfer of a substance from one container to another, without a change in composition of the formulation or the labelling content, for sale or distribution
Status Of Substance (SOS) advice	The advice provided in a SOS advice request will include: • Whether or not a substance is hazardous • Whether or not the substance is covered by an existing approval • The hazard classifications of the substance The potential relevant approval pathway for the substance
Substance	Any of the following: • Any element, defined mixture of elements, compounds or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof; • Any isotope, allotrope, isomer, congener, radical or ion of an element or compound which has been declared by the Authority, by notice in the Gazette, to be a different substance from that element or compound; • Any mixtures or combinations of any of the above; • Any manufactured article containing, incorporating or including any hazardous substance with explosive properties. (section 2(1) HSNO Act)
Veterinary medicine	Any of the following: • Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in/on animals (other than man) • Articles (other than food) intended to affect the structure or any function of the body of animals (other than man) Articles intended for use as a component of any articles specified in the above two bullet points.

1. Applicant details

1.1. Applicant

Company Name: Randlab Australia Pty Ltd

Contact Name: [redacted]e

Job Title: [redacted]r

Postal Address (provide only if not the same as the physical)**:**

Physical Address: [redacted]

Phone (office and / or mobile)**:** [redacted]

Fax: [redacted]

Email: [redacted]

1.2. New Zealand agent or consultant (if applicable)

Company Name: Vetmed Consultants Ltd

Contact Name: [redacted]m

Job Title: [redacted]

Postal Address (provide only if not the same as the physical)**:** [redacted]

Physical Address:

Phone (office and / or mobile)**:** [redacted]

Fax:

Email: [redacted]

1.3. Formal correspondence contact

All formal correspondence will be sent to the contact person identified here

Company Name: Vetmed Consultants Ltd

Contact Name: [redacted]

Job Title: [redacted]

Postal Address (provide only if not the same as the physical)**:** [redacted]

Physical Address:

Phone (office and / or mobile)**:** [redacted]

Fax:

Email: [redacted]

1.4. Invoice contact

Only if different from 1.3. Formal correspondence contact - invoice will be sent to the contact person identified here

Company Name: Randlab Australia Pty Ltd

Contact Name: [redacted]

Postal Address (provide only if not the same as the physical)**:**

Physical [redacted]a

Phone (office and / or mobile)**:** [redacted]

Fax: [redacted]

2. Information about the substance

2.1. Purpose statement/executive summary of the application for the public register

No more than 1,100 characters including the description of the formulated substance to be approved, e.g. liquid containing 10g active ingredient/L

The purpose of this application is to seek EPA approval for RXI. This product is an analgesic, sedative and skeletal muscle relaxant for use in horses and deer.

RXI is a liquid containing 100 g xylazine (as hydrochloride)/L.

2.2. Type of application

Tick the box(es) that best describe your application

Has 'Status of Substance (SOS) Advice' been obtained from the EPA?

☐ Yes ☒ No

If yes, show the SOS reference number:

If yes, is the formulation of the substance different to that submitted at the SOS stage?

(In either case, please provide the composition to the EPA. This may be provided as part of the confidential appendix)

☐ Yes ☐ No

Is the product a new active ingredient to New Zealand?

☐ Yes ☒ No

Does the product contain any viable new organisms, including GMOs?

☐ Yes ☒ No

Does the product contain an ingredient originating from an organism (plant, animal, etc)?[1]

☐ Yes ☒ No

[1] If you tick 'Yes' and the product is being imported, then include a Biosecurity Clearance from the Ministry for Primary Industries New Zealand. If one has been provided with a previous application and is still valid, this may be referenced.

Does the formulated substance contain any nanomaterial?

☐ Yes ☒ No

3. Identity of the substance

Any commercially sensitive information may be provided in the confidential appendix of this form
Provide details on the active ingredient(s) as well as the mixture in this section

3.1. Identity of the active ingredient(s)

Active ingredient (International non-proprietary name): NA

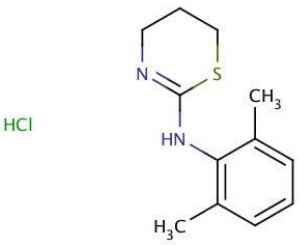
Active ingredient (European pharmacopoeia): NA

Active ingredient (National pharmacopoeia): NA

Active ingredient (Common name): Xylazine HCl

Molecular formula: C12-H16-N2-S.Cl-H

Structural formula:



Manufacturer's development codes: NA

Anatomical Therapeutic Chemical Vet Code and Group:

CAS No: 23076-35-9

Function: An analgesic, sedative and skeletal muscle relaxant

Minimum purity of the active ingredient as manufactured (g/kg): Included in the confidential appendix

Note: Any impurities must be provided to the EPA. A certificate of analysis may be included in the confidential appendix.
Included in the confidential appendix

3.2. Regulatory status of the active ingredient(s)

Jurisdiction	Regulatory status					Comment*
	Never approved	Pending	Approved	Restricted	Not renewed	
Australia	☐	☐	☒	☐	☐	
Canada	☐	☐	☐	☐	☐	
Europe	☐	☐	☐	☐	☐	
Japan	☐	☐	☐	☐	☐	
New Zealand	☐	☐	☒	☐	☐	
USA	☐	☐	☐	☐	☐	
Other jurisdictions (specify in comments)	☐	☐	☐	☐	☐	

*For instance specify here under which regulation(s)/directive(s).

When restricted or not renewed, explanations should be provided: NA

3.3. Identity of the formulated substance

Formulated substance name: RXI

Manufacturer development codes: NA

Unique names for public register: RXI

Active ingredient(s) and content (g/kg or L and % w/w):

Xylazine 100 g/L (10.0%)

3.4. Physical and chemical properties of the formulated substance

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

Appearance (colour, odour, physical state and form): Clear colourless liquid free of particulate

pH: 4.5 – 5.0

Density: 1.00 – 1.05

Vapour pressure: 2.37 kPa at 20°C (water vapour pressure)

Boiling/melting point: Approximately 100°C at 100kPa

Solubility in water: Completely soluble in water

Water/Octanol partitioning co-efficient: Not available

3.5. Regulatory status of the formulated substance

Jurisdiction	Regulatory status					Comment*
	Never approved	Pending	Approved	Restricted	Not renewed	
Australia	☐	☐	☒	☐	☐	
Canada	☐	☐	☐	☐	☐	
Europe	☐	☐	☐	☐	☐	
Japan	☐	☐	☐	☐	☐	
New Zealand	☐	☒	☐	☐	☐	MPI registration approval
USA	☐	☐	☐	☐	☐	
Other jurisdictions (specify in comments)	☐	☐	☐	☐	☐	

*For instance, specify here under which regulation(s) or directive(s).

Has an application been made for an approval under the Agricultural Compounds and Veterinary Medicines Act?

☒ Yes ☐ No

3.6. Composition details of the formulated substance

Full composition details for the substance must be provided to the EPA. These may be included in the confidential appendix

Included in the confidential appendix.

4. Life cycle of the substance

Manufacturing

Will your formulated substance be manufactured in New Zealand?

☐ Yes ☒ No

Importation

Will your formulated substance be imported into New Zealand by air and/or sea?

☐ Sea ☒ Air

Will your formulated substance be imported in bulk containers or packaged ready for sale?

☐ Bulk Containers ☒ Packaged ready for sale

If your formulated substance will be imported in bulk containers, please describe these containers: NA

Will repackaging of your formulated substance be carried out in New Zealand?

☐ Yes ☒ No

Will relabelling of your formulated product be carried out in New Zealand?

☐ Yes ☒ No

Please provide any additional relevant information relating to the importation of your formulated substance:

Transport

Will your formulated substance be transported by road, rail, air and/or sea within New Zealand?

☒ Road ☐ Sea ☐ Rail ☐ Air

Please provide any additional information relating to transport of your formulated substance:

It will be transported by air from Sydney to Auckland NZ.

UN Number: NA

UN Transport Hazard Classes: NA

UN Packing Group Number (UN Model Regulations[2]): NA

Marine Pollutant? (IMDG Code[3]): NA

Packaging

Pack sizes: 50 mL

Type of packaging: Multi dose glass vial type 1, chlorobutyl bung

Type of closure (consider opening size, type of cap, child resistant packaging):

Aluminium cap and flip top seal

Please provide any additional information relating to the packaging of your formulated substance:

NA

Storage

Provide details of how the substance will be stored, and the facilities it will be stored in:

Store below 30°C (room temperature).

Warehouse storage

Provide details of how the formulated substance will be stored:

Store below 30°C (room temperature).

Containment of spillages:
In case of spillage wear appropriate protective clothing and prevent material from entering water ways. Absorb spills with inert material and place in waste containers. Wash area with water and absorb with further inert material. Dispose of waste safely. Avoid contamination of any water supply with product or empty container. Avoid release to the environment.

Decontamination of areas, personnel, vehicles and buildings:

Wear appropriate protective clothing and prevent material from entering water ways. Absorb spills with inert material and place in waste containers. Wash area with water and absorb with further inert material. Dispose of waste safely. Avoid contamination of any water supply with product or empty container. Avoid release to the environment. If splashed in the eyes, wash out immediately with water. If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Disposal

Disposal of damaged packaging, contaminated absorbents and other materials:

Dispose at an approved landfill or other approved facility.

[2] UN Model Regulations mean Model Regulations annexed to the most recently revised edition of the Recommendations on the Transport of Dangerous Goods published by the UN
[3] IMDG Code means that International Maritime Dangerous Goods code, as amended

Detailed instructions for safe disposal of the formulated substance and its packaging:

Dispose of product and packaging at an approved landfill or other approved facility.

Methods other than controlled incineration for disposal:

NA

5. Intended uses of the formulated substance

5.1. Intended uses

Tick one or more boxes as appropriate

Category		Scope
Immunobiological	☐	Vaccines
Sterile injectables	☒	Sterile pharmaceuticals
Non-sterile veterinary medicines	☐ ☐ ☐ ☐ ☐ ☐ ☐	Creams / Ointments Liquids / suspensions Medicated collars Pastes Powders Sprays / aerosols Tablets / capsules / boluses
Large volume ectoparasiticides	☐	Dips / drenches

Species and subtypes recommended for use:

☐ Aquatic species	☐ Avian	☐ Bovine
☐ Canine	☐ Caprine	☒ Cervidae
☒ Equine	☐ Feline	☐ Ovine
☐ Porcine	☐ Rodents	☐ Other (specify)

Used for treatment of food-producing animals ☒ Yes ☐ No

Proposed dosage (by age / species / use pattern):

In all species the degree of sedation and analgesia depend on the dose rate given and special care must be taken with old and debilitated patients. Excitable and fractious animals may require the higher dose rates.
Horses: 2.9-5.0mL per 450kg BW by slow IV injection.
Deer: 0.2-1.6mL per 40 kg BW by IM or IV injection depending on species (Table 1).
Intramuscular dose rates should be halved for intravenous administration.
Table 1: Doses for Intramuscular administration of Randlab Xylazine 100mg/ml Injection in Deer

Deer	Sedation		Immobilization			
			Xylazine-Randlab Xylaze 100		Ketamine-Ketamine Injection	
	mg/KG BW	mL/40kg BSW	mg/KG BW	mL/40kg BSW	mg/KG BW	mL/40kg BSW
FALLOW	1.5-2.0	0.6-0.8	4.0	1.6	4.0	1.6
RED	0.5-1.0	0.2-0.4	2.0-3.0	0.8-1.2	2.0-3.0	0.8-1.2
CHITAL	0.5	0.2	1.5-2.0	0.6-0.8	1.5-2.0	0.6-0.8
RUSA	0.5-1.0	0.2-0.4	2.0-3.0	0.8-1.2	2.0-3.0	0.8-1.2

Proposed administration:

☒ Restricted ☐ Unrestricted

Method of Administration:

☒ Intravenous Injection ☐ Topical ☐ Oral

☒ Parenteral (non-intravenous) Injection ☐ Bath / dip ☐ Products intended for use in the eyes and / or ears

☐ Other

6. HSNO hazard classifications of the formulated substance

The information you provide here will form the basis of your substance's HSNO classification.

Please consider each of the hazardous properties in the table below and provide information on those properties that trigger any threshold level for your substance. Use the justification column to record the reason for your classification. If your substance is a mixture, you can apply mixture rules to the hazardous components of the mixture. If you do this, you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings. See Assigning A Product to an HSNO Approval on our website for more information.

Please use the following abbreviations if needed.

NA: Not Applicable – For instance when testing is technically not possible: testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: eg very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible.

ND: No Data or poor quality data (according to Klimisch criteria) – where there is a lack of data.

No: Not Classified based on actual relevant data available for the substance – the data is conclusive and shows the threshold for classification is not triggered.

Hazard Class/Subclass	Formulated substance classification	Justification
Examples		Flashpoint = 46 deg C (closed cup) Calculated LD50 = 1250 mg/kg (mixture rules)
Class 1 Explosiveness	No	
Class 2, 3 & 4 Flammability	No	
Class 5 Oxidisers/Organic Peroxides	No	
Subclass 8.1 Metallic corrosiveness	No	
Subclass 6.1 Acute toxicity (oral)	**6.1D**	in the confidential appendix
Subclass 6.1 Acute toxicity (dermal)	No	
Subclass 6.1 Acute toxicity (inhalation)	No	
Subclass 6.1 Aspiration hazard	No	
Subclass 6.3/8.2 Skin irritancy/corrosion	**6.3B**	in the confidential appendix
Subclass 6.4/8.3 Eye irritancy/corrosion	**6.4A**	In the confidential appendix
Subclass 6.5A Respiratory sensitisation	No	
Subclass 6.5B Contact sensitisation	No	
Subclass 6.6 Mutagenicity	No	
Subclass 6.7 Carcinogenicity	**6.7A**	in the confidential appendix
Subclass 6.8 Reproductive/ developmental toxicity	No	
Subclass 6.8 Reproductive/ developmental toxicity (known, presumed or suspected)	No	
Subclass 6.8 Reproductive/ developmental toxicity (*via* lactation)	No	
Subclass 6.9 Target organ systemic toxicity[4]	**6.9B**	in the confidential appendix
Subclass 9.1 Aquatic ecotoxicity	No	
Subclass 9.2 Soil ecotoxicity	No	
Subclass 9.3 Terrestrial vertebrate ecotoxicity	No	
Subclass 9.4 Terrestrial invertebrate ecotoxicity	No	

[4] identify classification for single and / or repeat dose target organ toxicity for oral, dermal or inhalation routes

7. Risks, costs and benefits

These are the positive and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. In considering risks, cost and benefits, it is important to look at both the likelihood of occurrence (probability) and the potential magnitude of the consequences, and to look at distribution effects (who bears the costs, benefits and risks).

You will need to consider the effects on the environment and human health and welfare, including any social effects.

In each section below, set out the information under the following three sub-headings:

- Costs and benefits which can be stated in monetary (dollar) terms
- Non-monetary risks and costs
- Non-monetary benefits.

You must fully complete this section referencing supporting material. You will need to provide a description of where the information in the application has been sourced from, eg from in-house research, independent research, technical literature, community or other consultation, and provide that information with this application.

7.1. Identify all of the potential risks, costs and benefits of the substance(s)

Identification is the first step in assessing risks, costs and benefits. 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 and likelihood of exposure.

You should try to think as widely as possible about every potential risk, cost and benefit and give a brief description.

Potential Risks	**Lifecycle**	**Impact**
Failure to follow safety precautions and instructions for use	Any stage	Human health Environment
Damage to packaging causing spillage of substance	Storage Transport	Human health Environment
Incorrect disposal	Disposal	Human health Environment
Transport accident causing spillage of substance	Transport	Human health Environment

Costs and benefits
RXI is an analgesic, sedative and skeletal muscle relaxant for use in horses and deer, it offers a way of managing the conditions for which it is indicated.

The major cost associated with the substance is the financial cost to the user. This includes the initial purchase price and administer the treatment.
The hazardous classifications and the label restrictions will eliminate any potential costs to the economy, society or the environment from the use of the substance.

7.2. Provide an assessment of those risks, costs, and benefits identified in Section 7.1.

This section excludes risks, costs, and benefits which relate specifically to Māori taonga or to international agreements. See Sections 7.3 and 7.4 for those aspects.

A full assessment must be provided of all the risks, costs and benefits identified in Section 7.1. For the risk assessment our preferred format is quantitative, however, you may also provide a qualitative assessment if you can justify this. If you are providing your risk assessment in supporting documentation with this application you can provide a summary of all the risks this in this section

Please note that if you do not complete a full assessment of all risk, costs and benefits this may result in the EPA requesting further information from you, which will mean that your application takes longer to process.

Potential Risks	Impact	Likelihood of occurrence	Distribution of effect	Effect	Level of risk
Failure to follow safety precautions and instructions for use	Human Health Environment	Unlikely	Localised	Minor	Insignificant
Damage to packaging	Human Health Environment	Unlikely	Localised	Minor	Insignificant
Incorrect disposal	Human Health Environment	Unlikely	Localised	Minor	Insignificant
Transport accident	Human Health Environment	Unlikely	Localised	Minor	Insignificant

7.3. Provide an assessment of any risks, costs and benefits which arise from the kaitiaki relationship of Māori and their culture to the environment

Please note that consultation with Māori may be appropriate for this application. Please refer to the EPA policy 'Engaging with Māori for applications to the EPA' which can be found on the EPA website (www.epa.govt.nz) or contact the EPA for advice.

An example of the issues to consider include whether the substance poses any risk to native or valued species, or waterways.

Under normal conditions, it is unlikely that there will be any particular aspects of this product that are likely to affect Maori tradition or culture. Nor would accidental misuse lead to significant effects on the environment or cultural interests of Maori if dealt with appropriately.

7.4. Provide an assessment of any risks, costs or benefits to New Zealand's international obligations

Please show if approving or declining the substance would have any impact upon New Zealand's international obligations

The active ingredient of this product is Xylazine, this ingredient is approved for use in New Zealand.

7.5. Provide information on the proposed management of the substance

Please outline how the risks of the substance will be managed. This may include default controls triggered by the hazardous property classification(s) and reference to Codes of Practice or to standard operating procedures that will be followed

Hazardous classifications	6.1D-Acute toxicant 6.3B-Skin irritant 6.4A-Eye irritant 6.7A-Carcinogen 6.9B-Target organ toxicity
Toxic properties	The product is restricted veterinary medicine. The labelling of the product contains warnings to people handling about appropriate care when handling this product. The people handling and dispensing who will be most exposed to this product will be veterinarians skilled at handling horses and deer and familiar with handling this and the other many similar products on the New Zealand market.
Identification	The 50 mL will be labelled to identify the product, state how to use it and that it is a hazardous substance. Horse and Deer veterinarians using this product are familiar with similar products on the market and their toxicity. The labelling, and the Safety Data Sheet are all suitable documentation to meet these requirements for workplace documentation, as logically for this product to exert ecotoxicity requires large volumes to get into the environment and skin/eye irritation requires close contact, so labels on the containers are visible by that point.
Precautions	The product will be applied directly from container to the horse and deer by veterinarians. Persons handling the product should wear their normal protective clothing i.e. gloves, and wash their hands and equipment after handling the product. The product is restricted veterinary medicine
Packaging	50mL multi dose glass vial type 1, chlorobutyl bung with aluminium cap and flip top seal. This product is not for home use therefore does not need to be childproof access. The product is restricted veterinary medicine.
Disposal	The Label and SDS can meet Regulations. Dispose of product and packaging at an approved landfill or other approved facility.
Emergency Management	Spill should be cleaned up promptly, wear appropriate protective clothing and prevent material from entering waterways. Absorb spills with inert material and place in properly labelled waste container. Wash area with water and absorb with further inert material. Dispose of waste safely. Do not eat, drink or smoke during clean-up operation.
Labelling containing information on:	Indications Directions for use Dosage and administration Precautions Handling precautions First aid Disposal Storage

Safety Data Sheet containing information on:	Identification of the product Hazard classification, Prevention statements, Response statements First aid Accidental release Handling and Storage Personal protection Disposal method
Certified handler	The local distribution, storage and administration of the finished product will not trigger this requirement. The product is restricted veterinary medicine.
Supervision and training of workers	Every worker who uses, handles, manufactures, or stores a hazardous substance (including hazardous waste) will be provided with training and instruction on: -The physico-chemical and health hazards associated with the hazardous substances the worker uses at work. -The procedures for the safe use, handling, manufacture, storage, and disposal of the hazardous substances. -Practice in the safe use of plant, including personal protective equipment. -The actions that the worker should take in an emergency involving the hazardous substance.
Tracking	Not necessary for this product.

7.6. Provide an overall evaluation of the combined impact of all of the risks, costs and benefits set out in sections 6.2, 6.3 and 6.4.

Please express a view on the relative importance of the different risks, costs and benefits and how they should be brought together in making a decision

Any risks associated with the importation, distribution and sale of RXI can be minimised and reduced to acceptable levels using the recommended HSNO statements and label restrictions.

8. Pathway determination and rapid assessment

Under the HSNO Act, applications may be processed under different pathways, including a rapid assessment. The pathway for your application will be determined after its formal receipt, based on the data provided in this application form. If you would like your application to be considered for rapid assessment (as per the criteria below), we require you to complete the attached statutory declaration and provide a signed hard copy.

Please note that the EPA will not be able to proceed with the rapid assessment without the statutory declaration.

8.1. Rapid assessment

Under the HSNO Act, a hazardous substance may be approved under a rapid assessment if one of the three following options is satisfied. Please show the section that is relevant to your application.

A substance having a similar composition and similar hazardous properties has been approved	☒ Yes ☐ No If Yes, please give the name of the reference substance: included in the confidential appendix
The substance has one or more hazardous properties and each has the least degree of hazard for that property; or	☐ Yes ☐ No
The substance has been formulated so that one or more of its hazardous properties has a lesser degree of hazard than any substance that has been approved under the Act.	☐ Yes ☐ No If Yes, please give the name of the reference substance:

8.2. Statutory Declaration

I Ansam Ganim, of Vetmed Consultants Ltd PO Box 21788, Henderson, Auckland 0650, Director, being the applicant or authorised to do so on behalf of the applicant, verify that the information contained in this application for **RXI** is true and correct. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Signature

Declared at on this day of , 20 before me.

Witness signature

[name] Barrister or Solicitor of the High Court of New Zealand

[or Justice of the Peace, Notary Public, or other person authorised to take a statutory declaration]

9. Checklist

This checklist is to be completed by the applicant

Application		**Comments/justifications**
All sections of the application form completed or you have requested an information waiver under section 59 of the HSNO Act	☒ Yes ☐ No (If No, please discuss with an advisor to enable your application to be further processed)	
Confidential data as part of the confidential form. Please note the EPA strongly encourages applicants to provide as much information as possible in the main body of the application form unless there is a genuine argument that it is commercially sensitive.	☒ Yes ☐ No	
Supplementary optional information attached:		
• Copies of additional references	☐ Yes ☐ No	
• Letter(s) of access	☐ Yes ☐ No	
• Relevant correspondence	☐ Yes ☐ No	
• Draft label	☒ Yes ☐ No	
• Draft Safety Data Sheet (SDS)	☒ Yes ☐ No	
Administration		
Are you an approved EPA customer?	☐ Yes ☒ No If yes are you an: Applicant: ☐ Agent: ☐	
If you are not an approved customer, payment of fee will be by:		
• Direct credit made to the EPA bank account (preferred method of payment) Date of direct credit:	☒ Yes ☐ No ☒ Payment to follow	
• Cheque for application fee enclosed	☐ Yes ☐ No ☐ Payment to follow	
Electronic signed copy of application e-mailed to the EPA	☒ Yes	
Physical copy of signed statutory declaration sent to the EPA, (rapid assessment only)	☐ Yes	

Signature of applicant or person authorised to sign on behalf of applicant

☒ I am making this application, or am authorised to sign on behalf of the applicant or applicant organisation.

☐ I have completed this application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

[redacted] 06 April 2020

Signature **Date**

Request for information waiver under section 59 of the HSNO Act

☐ I request for the Authority to waive any legislative information requirements (i.e. concerning the information that has been supplied in my application) that my application does not meet (tick if applicable).

Please list below which section(s) of this form are relevant to the information waiver request: