

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



## FORM HS1

# Application for approval to IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE FOR RELEASE

under section 28 of the  
 Hazardous Substances and New Organisms Act  
 1996

**Name of Substance(s):**

**NOR003**

**Applicant:**

**Norbrook NZ Ltd**

### Office use only

Application Code:         Date received: \_\_\_\_/\_\_\_\_/\_\_\_\_

ERMA NZ Contact: \_\_\_\_\_ Initial Fees Paid: \$

Application Version No: \_\_\_\_\_.

## IMPORTANT

1. Before you fill in this application form, you may find it helpful to consult the *User Guide to Hazardous Substance Applications under the HSNO Act 1996*. This User Guide can either be downloaded from our website or purchased from ERMA New Zealand. The level of information that you need to provide in this application is dependent upon the scale and the significance of the risks and/or whether these risks are well understood and controlled. The User Guide will offer further advice on this.
2. Part B of the User Guide covers applications under Section 28 of the Act and all of the cross references in this application form are to Part B.
3. You can also talk to an applications officer at ERMA New Zealand 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.
4. This application form may be used to seek approvals for more than one hazardous substance where the substances are related, for example a concentrated component (active ingredient) and its related formulations or the two parts of an epoxy glue.
5. 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.
6. Commercially sensitive information must be collated in a separate Appendix.
7. Applicants must sign the form and enclose the correct application fee. The initial application fee can be found in our published *Schedule of Fees and Charges*. Make sure that you have an up to date copy of the Schedule. Please check with ERMA New Zealand staff. We are unable to process applications that do not contain the correct fee.
8. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed. Where an applicant is unable to complete the sections marked optional, this information may be derived by ERMA New Zealand and the costs of doing so will be recovered from the applicant as part of the processing costs.

You can get more information at any time by contacting us. One of our staff members will be able to help you.

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## Section One – Applicant Details

See comments under “Section One of Application Form” in the User Guide for guidance.

### 1.1 Name and postal address in New Zealand of the organisation making the application:

**Name:** Norbrook NZ Ltd  
**Address:** c/- PharmVet Solutions.  
P O Box 78037  
Grey Lynn  
Auckland, 1245  
**Phone:** 09-378-4467  
**Fax:** 09-378-4466

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

**Address:** Norbrook NZ Ltd  
KPMG Centre,  
18 Viaduct Harbour Avenue  
Auckland

### 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 on behalf of the applicant that relate to processing the application, or have the ability to go to the appropriate authority.

**Name:** Ansam Ganim  
**Position:** Technical Consultant, PharmVet Solutions  
**Address:** P.O. Box 78037  
Grey Lynn  
Auckland, 1245  
**Phone:** 09-378-4467  
**Fax:** 09-378-4466

**Email:** Ansam@PharmVetSolutions.com

## Section Two – Application Type and Related Approvals Required

This form is only to be used for an application to import and/or manufacture a hazardous substance for ‘release’ and if it does not meet the requirements for rapid assessment. Please note that it is the substance(s) which is approved, and thus the approval covers both import and manufacture.

If you are making the application for some other reason, you will need a different form.

**2.1 Is the information in this application relevant to import, manufacture or both:**

(See comments under “Section 2.1 of Form” in the User Guide)

- |  |        |
|--|--------|
| • Import only?   | Yes/No |
| • Manufacture only?  | Yes/No |
| • Import and manufacture?  | Yes/No |
| • If import only, indicate whether or not manufacture is likely in New Zealand | Yes/No |

**2.2 If the information in the application relates to manufacture in New Zealand, provide information on the proposed manufacturing process and any alternatives.**

(See comments under “Section 2.2 of Form” in the User Guide)

Not applicable for this application.

**2.3 If you have reasons for not providing detailed information in this application, explain what they are and provide some justification.**

An example of a reason for not giving detailed information is where an approval has been given by another jurisdiction and information that led to that approval can be referenced or the substance will be used in low risk situations or ways.

(See comments under “Section 2.3 of Form” in the User Guide)

The amount of information provided is believed to be sufficient for this application. The product is registered in the UK as a Veterinary Medicine for the same application and method of use proposed in NZ. It requires ERMA approval to support its New Zealand ACVM registration process.

The application relies mainly on information about its ingredients.

**2.4 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?**

(Optional) (See comments under “Section 2.4 of Form” in the User Guide)

**Name of Approval**

**Application made**

Agricultural Compounds and Veterinary Medicines Act 1997

Yes

Food Act 1981

Yes

Medicines Act 1981

NA

Chemical Weapons (Prohibition) Act 1996

NA

Radiation Protection Act 1965

NA

Biosecurity Act 1993

NA

Resource Management Act 1991

NA

Other (please specify):

NA

NA

## Section Three – Information on the Substance(s)

Note 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.

You will need to provide a brief description of where the information in the application has been sourced from, e.g. from in-house data, research, technical literature, etc. See the introductory comments under “Section Three of the Form” in the User Guide for more details.

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
- Significant 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 i.e. the chemical name, CAS number, function (e.g. 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 ERMA New Zealand. These must include the provision of a unique identifier of some kind.

(See comments under “Section 3.1 of Form” in the User Guide)

## Introduction

**NOR003** is a generic product and contains one active compound; Carprofen, which is already available for use in New Zealand.

**Appendix I** contains confidential information on - properties of the substance; method of manufacture; the identity of active ingredient, and outlines CAS Registry Numbers, proportions and functions of the components of the substance.

### Composition of the Mixture:

<b>Component</b>	<b>Function</b>
Component A	Active - Nonsteroidal anti-inflammatory
Component B	excipient
Component C	excipient
Component D	excipient
Component E	excipient
Component F	excipient
Component G	excipient

See **Appendix I** (Section 3.1 - Confidential information on individual ingredients of the substance) for details on the components of this product.

#### **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] e.g.

- 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

(See comments under “Section 3.2 of Form” in the User Guide)

#### **Chemical & Physical properties of the hazardous substance:**

<b>Physical State</b>	<b>action</b>
Odour	N/A
Colour	A clear colourless solution
Relative Density @ 20°C	1.060-1.063 g/ml
pH @ 20°C	6.7– 7.3
Specific Gravity	1.060-1.063 g/ml
Viscosity @ 20°C	N/A

Information for all components of the mixture has been supplied in the **Appendix I**.

### **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 must consider each of the six hazardous properties below and provide information on those hazardous properties that trigger any threshold level. If you wish, you may assign the relevant HSNO classification category to each hazardous property that exceeds these threshold levels.

- 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.

(See comments under “Section 3.3 of Form” in the User Guide).

See **Appendix II**, which tabulates confidential information relating to the hazardous properties of the individual ingredients of the substance; and using the mixture rules, derives hazardous properties the substance.

The resulting thresholds triggered and classifications are shown in the following table:

Hazardous Property	Threshold	Classification	Comment/relevant data
<b>Explosive</b>	Not triggered		
<b>Flammable</b>	Not triggered		
<b>Oxidising</b>	Not triggered		
<b>Corrosive</b> Metallic Dermal Eye	Not triggered		
<b>Toxic</b> Acute oral Acute dermal Acute inhalation Skin irritation Eye irritation Sensitisation  Mutagenic Carcinogenic Reproductive/ Developmental Target organ/Systemic	Triggered Not triggered Not triggered Not triggered Not triggered Not triggered  Not triggered Not triggered Not triggered Triggered	<b>6.1D</b>  <b>6.3A</b>  <b>6.5B</b>    <b>6.9B</b>	LD <sub>50(mixture)</sub> = 1960 mg/kg  May cause skin irritation  Frequent or prolonged exposure can cause hypersensitivity leading to contact dermatitis, possibly of an eczematoid nature.  Gastro intestinal tract effects
<b>Ecotoxic</b> Aquatic Soil  Terrestrial vertebrate Terrestrial invertebrate	Triggered Not triggered  Triggered Not triggered	<b>9.1D</b>    <b>9.3C</b>	Slightly harmful in the aquatic environment or are otherwise designed for biocidal action. LD <sub>50</sub> Rat= 149mg/kg

### 3.4 Identification of the default Controls on the substance(s).

A range of default controls are triggered by the hazardous property classification(s) attached to the substance. If you wish, you can list what these default controls are. If you don't provide this information, ERMA New Zealand will do it for you. Regardless, you need to be aware of what the default controls are so that you can take them into account when assessing risks – see Section 4. **(Optional)** (See comments under “Section 3.4 of Form” in the User Guide)

## Mixture

Hazardous Property	Threshold	Control Regulations
<b>Explosive</b>	Not triggered	No components in mixture known to be explosive
<b>Flammable</b>	Not triggered	No components in mixture known to be flammable
<b>Oxidising</b>	Not triggered	No components in mixture known to be oxidising
<b>Corrosive</b> Metallic Dermal Eye	Not triggered Not triggered Not triggered	No components in mixture known to be corrosive.
<b>Toxic</b> Acute oral  Acute dermal Acute inhalation Skin irritation  Eye irritation Sensitisation  Mutagenic Carcinogenic Reproductive/Developmental Target organ/Systemic	<b>6.1D</b>  Not triggered Not triggered <b>6.3A</b>  Not triggered <b>6.5B</b>  Not triggered Not triggered Not triggered <b>6.9 B</b>	T1,T2,T4,T5,T7,T8 I1,I8,I9,I16,I17,I18,I19,I20,I21,I28,I29,I30 P1,P3,P13*,PS4 D4,D6,D7,D8 EM1,EM6,EM8,EM11,EM12,EM13  T1,T2,T4,T5 ,I7 I1,I9,I16,I17,I18,I19,I21,I28 P1,P3,PS4 D4,D6,D7,D8 EM1,EM6,EM8  T1,T2,T4,T5 I1,I9,I16,,I19,I21,I28 P1,P3, P13*,PS4 D4,D6,D7,D8 EM8  T1,T2,T4,T5 I1,I9,I16,I17,I18,I19,I21,I28 P1,P3,PS4 D4,D6,D7,D8 EM8
<b>Ecotoxic</b> Aquatic  Soil  Terrestrial vertebrate  Terrestrial invertebrate	<b>9.1D</b>  Not triggered  <b>9.3C</b>  Not triggered	E1,E2,E6 I1,I9,I11,I19,I21,I29 P1,P3,PS4 D5,D6,D7,D8 EM1,EM7,EM8,EM11, EM12,EM13  E1,E2,E4,E6 I1,I3,I9,I11,I19,I21,I23,I29 P1,P3,PS4 D5,D6,D7,D8

P13\* = regulation 19(2) and (3) only apply

Controls	Regulation /s	Description
<b>Toxic Property Controls</b>		
T1	11 - 27	Limiting exposure to toxic substances; setting values for acceptable daily intake (ADE)/reference dose (RfD), potential daily exposure (PDE), tolerable exposure limit (TEL); prohibition on use of substances in excess of TEL
T2	29 - 30	Controlling exposure in places of work and other 'use' situations; setting of workplace exposure standards (WES)
T4	7	Requirements for equipment used to handle substances
T5	8	Requirements for protective clothing and equipment
T7	10	Restrictions on carriage of toxic substances on passenger service vehicles
T8	28	Restrictions on use of terrestrial vertebrate pest controls
<b>Identification</b>		
I1	6,7,32-35,36 (sections 1-7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
I3	9	Priority identifiers for ecotoxic substances

I8	14	Primary identifiers for toxic substances
I9	18	Secondary identifiers for all hazardous substances
I11	20	Secondary identifiers for ecotoxic substances
I16	25	Secondary identifiers for toxic substances
I17	26	Use of generic names
I18	27	Requirements for using concentration ranges
I19	29 – 31	Additional information requirements, including situations where substances are in multiple packaging
I20	36(8)	Durability information for acute toxicity substances
I21	37 – 39, 47 – 50	General documentation requirements
I23	41	Specific documentation requirements for ecotoxic substances
I28	46	Specific documentation requirements for toxic substances
I29	51, 52	Signage requirements
I30	53	Specific documentation requirements for advertising corrosive and toxic substances
<b>Ecotoxins</b>		
E1	Regs 32-45	Limiting exposure to ecotoxic substances, the environmental exposure limit (EEL) approach
E2	46-48	Restrictions on use of substances in application areas
E4	Regs 50, 51	Controls relating to protection of terrestrial vertebrates
E6	7	Requirements for equipment used to handle substances
<b>Packaging</b>		
P1	5 – 7(section 1), 8	General packaging requirements
P3	9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria
P13*	19(2)-(3)	Specific packaging requirements for toxic substances (class 6)
PS4	Schedule 4	Packaging requirements as specified in Schedule 4
<b>Disposal</b>		
D4	8	Disposal requirements for Class 6, 8 substances (toxics and corrosives)
D5	9	Disposal requirements for class 9 substances (ecotoxic)
D6	10	Disposal requirements for packages
D7	11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge
D8	13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge
<b>Emergency Management</b>		
EM1	6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge
EM6	8 (section e)	Information requirements for toxic substances
EM7	8(f)	Information requirements for ecotoxic substances
EM8	12 – 16, 18 - 20	Level 2 information requirements for suppliers and persons in charge
EM11	25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans
EM12	35 – 41	Level 3 emergency management requirements: secondary containment
EM13	42	Level 3 emergency management requirements: signage

**3.5 Provide information on what will happen to the substance throughout its whole life from its introduction into New Zealand, its uses, through to disposal.**

This information is used in the development of exposure scenarios and the assessment of risks, costs and benefits and should therefore be as expansive as possible.  
(See comments under “Section 3.5 of Form” in the User Guide)

**Importation:**

NOR003 will be imported either via sea or air from Northern Ireland .  
Amount expected to be imported is 1000 vials annually.

**Transport and Storage.**

The substance will transported throughout New Zealand in accordance with the relevant New Zealand transport legislation.

It will arrive packaged in containers of 50mL multidose amber glass (grade 1) vials with 20mm Bromobutyl Bung and 20mm Aluminum seals.

These vials contain the final formulation of NOR003. Vials and bungs are to meet EP requirements.

On arrival in NZ after clearing customs Norbrook NZ Ltd will store NOR003.

The product arrives prepacked in its final containers. The detailed information on the labels meets ACVM regulations. Norbrook NZ Ltd will distribute it. There are restriction placed on the sale and use of PAR 1 veterinary medicines and they can only be sold by an authorised PAR trader, with standards to be met before a person can become a trader.

The product is to be stored (not manufactured) in New Zealand.

The product is to be stored securely by Norbrook in an Auckland warehouse premises. Norbrook NZ Ltd intends to sell the product to wholesalers, stock agents and veterinary clinics.

NOR003 may be used as intended immediately, or stored for later use.

The treatment will be administered directly into the cattle and horses intravenously or subcutaneously.

It is not expected that members of the public and especially children will have access to this product.

Disposal of empty containers is to occur according to standard instructions i.e. dispose of product and packaging at an approved landfill or equivalent facility.

**Form of the Substance.**

NOR003 is a liquid which will always be packaged into:

50 mL containers of multidose amber glass. Bromobutyl Bung and 20mm Aluminum seals.

It is the intention of Norbrook NZ Ltd to sell this product primarily to veterinarians and veterinary practices. The substance may be used as intended immediately, or stored for later distribution and use.

**Intended use of the substance**

NOR003 is an injectable anti-inflammatory, analgesic, antipyretic for cattle and horses. Indicated in cattle for the treatment inflammatory conditions such as acute mastitis and pneumonia.and in horses for the control of post-operative inflammation, and musculoskeletal problems.

**Other Potential Uses/Recycling Options.**

There are no other potential uses for this substance outside that of veterinary medicine and there is no opportunity for recycling the container following use. Ingredients of the injection once given to the animal are metabolised.

**Product Used By**

NOR003 is to be used by veterinarians.

**How is it intended to be used**

Cattle: 1.4 mg/kg (1mL/35kg) – for intravenous or subcutaneous use.

Horses: 0.7 mg/kg (1mL/70kg) – for intravenous use only.

**Known Adverse Effects from Unintentional Use –****Human**

The active ingredient and the excipients are used worldwide in a variety of pharmaceuticals, and there is no dose rate recorded as fatal in people.

**Environmental**

The substance will be imported in the final packs for use, which are:  
50 mL containers of multidose amber glass. Bromobutyl Bung and 20mm Aluminum seals.  
The outer packaging is fibreboard boxes with full label instructions.  
Packaged product in quantities such as stored by the distributor and wholesalers will be held securely along with similar products.

### **Disposal of Substance**

A standard label statement regarding disposal is proposed, viz:

#### **DISPOSAL:**

Preferably dispose of product by use. Otherwise dispose of product, packaging and at an approved landfill or equivalent facility.

It is proposed that the following information appears on the product label:

Preferably dispose of product by use. Dispose of product and packaging at an approved landfill or equivalent facility.

## **Section Four: 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 set out below, it might be easier for you, and most useful for ERMA New Zealand, if the information is set out under the following three sub sections:

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

Complete this section as far as you can. If the analysis provided is incomplete, then it will be completed by ERMA New Zealand. However, the costs of doing this will be chargeable.

You will need to provide a brief description of where the information in the application has been sourced from, e.g. from in-house research, independent research, technical literature, community or other consultation.

(See comments under “Section 4 of Form” in the User Guide)

### **4.1 Identify all of the potential risks, costs and benefits of the substance(s)**

Identification is the first step in assessing risks, costs and benefits. The introductory part of “Section 4 of Form” in the user Guide provides detailed guidance on what kinds of costs, risks and benefits should be thought about. It is important to think about the source of the risk, i.e. 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. The range of matters that you will need to think about is discussed in the User Guide. You must also decide how significant that risk, cost or benefit is likely to be. If the risk, cost, or benefit is obviously not significant (and you can give reasons), then there is no need to further assess that risk, cost, or benefit.

(See comments under “Section 4.1 of Form” in the User Guide)

**Tables 4.1 and 4.2 summarise the identification of risks of the substance NOR003.**

**Table 4.1 Summary of Risk Identification of Substance NOR003.**

Source of risk Event/incident	Hazardous property	Possible reasons for event (including lifecycle)	Effect/impact	Exposure pathway
Release/spillage of substance	Aquatic/ Terrestrial vertebrate ecotoxin	<ol style="list-style-type: none"> <li>1. Transport accident (import, transport)</li> <li>2. Damaged packaging (import, storage, transport, use)</li> <li>3. Failure to follow safety precautions and instructions for use (any stage)</li> <li>4. Natural disaster, e.g. earthquake (any stage)</li> <li>5. Sabotage (any stage)</li> <li>6. Theft (any stage)</li> <li>7. Incorrect disposal (disposal)</li> </ol>	<p>Adverse effect on Environmental health</p> <ol style="list-style-type: none"> <li>1. Harmful in the aquatic environment</li> <li>2. Harmful to Terrestrial vertebrates.</li> </ol>	NOR003 release to the environment
Release/spillage of substance	Acute Oral/Skin Target Organ toxin	<ol style="list-style-type: none"> <li>1. Transport accident (import, transport)</li> <li>2. Damaged packaging (import, storage, transport, use)</li> <li>3. Failure to follow safety precautions and instructions for use (any stage)</li> <li>4. Natural disaster, e.g. earthquake (any stage)</li> <li>5. Sabotage (any stage)</li> <li>6. Theft (any stage)</li> <li>7. Incorrect disposal (disposal)</li> </ol>	<p>Adverse effect on human health (workers and public):</p> <ol style="list-style-type: none"> <li>1. Acute toxicant</li> <li>2. Skin irritant &amp; sensitizer</li> <li>3. Target Organ Toxin</li> </ol>	- Accidental ingestion by user

**Table 4.2 Potentially significant risks of substance NOR003 (assuming default controls in place)**

Potentially significant risk	Lifecycle	Hazardous property	Adverse effect/impact
Transport accident causing spillage of substance	Transport	Acute Oral/Target Organ toxin Aquatic/Terrestrial vertebrate ecotoxin	Human health Aquatic/Terrestrial environment
Damage to packaging causing spillage of substance	Storage Transport	Acute Oral/Target Organ toxin Aquatic/Terrestrial vertebrate ecotoxin	Human health Aquatic/Terrestrial environment
Failure to follow safety precautions and instructions for use	Any stage	Acute Oral/Target Organ toxin Aquatic/Terrestrial vertebrate ecotoxin	Human health Aquatic/Terrestrial environment
Incorrect disposal	Disposal	Acute Oral/Target Organ toxin Aquatic/Terrestrial vertebrate ecotoxin	Human health Aquatic/Terrestrial environment

### Potential Benefits – Financial & social

- When registered by the ACVM, it is likely that NOR003 will be one of the few non-steroidal anti-inflammatory ingredient analgesic injections for cattle and horses in NZ. NOR003 is intended to be administered to food producing animals (cattle & horses).
- The substance also has a new combination of certain toxic and ecotoxic properties.
- Non-steroidal anti-inflammatory are rapidly and well absorbed after administration.
- Indicated for anti-inflammatory, analgesic, antipyretic for cattle and horses. Indicated in cattle for the treatment inflammatory conditions such as acute mastitis and pneumonia.and in horses for the control of post-operative inflammation, and musculoskeletal problems.
- Administration directly into the animal system minimises the chance of spillage.

### Possible Costs

The product will occur in New Zealand only in containers of 50 mL of multidose amber glass, bromobutyl Bung and 20mm Aluminum seals. , the potential for spillage of a large amount is insignificant.

**4.2 Provide an assessment of those risks, costs, and benefits identified in Section 4.1 which might be significant.**

This section excludes risks, costs, and benefits which relate specifically to Māori taonga or to international agreements. See Sections 4.3 and 4.4 below for those aspects.

Assessments only need to be done for those risks, costs and benefits which Section 4.1 shows might be significant. Section 4.2 in the User Guide provides a detailed explanation of how to do an assessment. Remember that assessments can be qualitative i.e. based on judgements, if there is no analytical information available. But it is essential that a firm conclusion is drawn about the size and likelihood of the risks, costs or benefits, and also about the certainty of the assessment.

In assessing risks especially, it is important to take account of the extent to which risks will be reduced by the default or other controls (see Section 3.4 above and 4.5 below).  
(See comments under “Section 4.2 of Form” in the User Guide)

Table 4.3 summarises the assessment of significant risks, costs and benefits of the substance NOR003

**Table 4.3. Summary of Risks, Costs and Benefits of the Substance (NOR003)**

Source of potentially significant risk	Adverse effect/impact	Likelihood	Distribution of effects (geographic)	Distribution of effects (demographic)	Distribution of effects (temporal)	Reversible/Irreversible	Voluntary/Involuntary	Magnitude <sup>1,2</sup>	Level of residual risk <sup>1</sup> (following review of controls as detailed in Section 4.5)
Transport accident (overland)	Human Health	Very Unlikely	Localised	Not expected	Short term	Reversible	Involuntary	I	Insignificant
	Aquatic life	Very Unlikely	Localised	Not expected	Short term	Reversible	Involuntary	I	Insignificant
Damage to packaging	Human Health	Unlikely	Localised	Not expected	Short term	Reversible	Voluntary & Involuntary	I	Insignificant
	Aquatic life	Unlikely	Localised	Not expected	Short term	Reversible	Voluntary & Involuntary	I	Insignificant
Failure to follow safety precautions and instructions for use	Human Health	Unlikely	Localised	Workers/Users	Short term	Reversible	Voluntary	I	Insignificant
	Aquatic life	Unlikely	Localised	Workers/Users	Short term	Reversible	Voluntary	I	Insignificant
Incorrect disposal	Aquatic life	Unlikely	Localised	Users	Short term	Reversible	Voluntary	I	Insignificant
	Human Health Aquatic life	Unlikely	Localised	Users	Short term	Reversible	Voluntary	I	Insignificant

<sup>1</sup> Refer to the Technical Guide on *Preparing Information on Risks, Costs and Benefits* for information on qualitative measures of magnitude and risk.

<sup>2</sup> Tables 4.3.1, 4.3.2 and 4.3.3 detail the qualitative analysis used

**Qualitative measures of consequence or impact**

Level	Descriptor	Description
1	Minimal	Mild reversible adverse effect on health affecting 1-2 people (eg; minor skin damage), highly localised and contained environmental impact (eg, spillage on to soil, but not reaching waterway)
2	Minor	Up to 10 people suffer mild reversible adverse health effects, localised and contained environmental impact (eg; reaches small waterway, but able to be cleaned up)
3	Moderate	More than 10 people suffer reversible adverse health effects, measurable damage to an aquatic ecosystem (such as a small stream or lake)
4	Major	Significant irreversible adverse health effects affecting up to 10 people and/or more than 10 people suffer serious reversible adverse health effects, irreversible damage to localised ecosystem but no species loss
5	Massive	Significant irreversible adverse health effects to more than 10 people extensive irreversible environmental effects, including species loss.

**Qualitative risk analysis matrix: level of risk**

	Consequence				
	<i>Minimal</i>	<i>Minor</i>	<i>Moderate</i>	<i>Major</i>	<i>Massive</i>
<b>Likelihood</b>	1	2	3	4	5
<i>A (very unlikely)</i>	I	I	M	H	H
<i>B (unlikely)</i>	L	L	M	H	E
<i>C (moderate)</i>	L	M	H	E	E
<i>D (likely)</i>	M	H	H	E	E
<i>E (very likely)</i>	H	H	E	E	E

I = Insignificant risk

M = Moderate risk

E = Extreme risk

L = Low risk

H = High risk

**Qualitative measures of likelihood**

Level	Descriptor	Description
A	Very unlikely	Not impossible, but only occurring in exceptional circumstances
B	Unlikely	Could occur, but is not expected to occur under normal conditions
C	50% Likelihood	Equally unlikely/likely, mean chance
D	Likely	Will probably occur at some time
E	Very likely (almost certain)	Is expected to occur

**4.3 Provide an assessment of any particular risks, costs and benefits which arise from the relationship of Māori and their culture and traditions with their taonga, or which are, for other reasons, of particular relevance to Māori.**

We have asked for a separate response in this area because these requirements are different to other risks, costs and benefits. These are explained in more detail in Section 4.3 of the User Guide. Please note that if there are potentially significant risks in this area, it will almost certainly be necessary to consult with Māori in preparing an assessment. (See comments under “Section 4.3 of Form” in the User Guide)

Activity	Identification and Description of any Effects on Environmental Values	Outcomes of Consultation in relations to Identified Effects	Identification and Description of any Effects on Cultural Values	Outcomes of Consultation in relation to Identified Effects
Product manufacture, storage, transportation, dispensing and preparation and application of drench mixture.	Minor or nil impact upon: <ul style="list-style-type: none"> <li>• Traditional food sources</li> <li>• Indigenous or valued flora and fauna</li> <li>• Natural habitats</li> <li>• Life sustaining capacity of air, land, or water.</li> </ul>	As identified impacts are minor or nil no consultation was required.	Minor or nil impact upon: <ul style="list-style-type: none"> <li>• Maori cultural health and well being</li> <li>• Maori cultural, spiritual, ethical or socio-economic values</li> <li>• Maori traditional knowledge</li> <li>• The mauri of land, and air and other taonga</li> <li>• The maintenance, expression and control of traditional practices.</li> </ul>	As identified impacts are minor or nil no consultation was required.
Disposal of used containers.	Container Disposal by burying above water level therefore minor or nil impact upon: <ul style="list-style-type: none"> <li>• Traditional food sources</li> <li>• Indigenous or valued flora and fauna</li> <li>• Natural habitats</li> <li>• Life sustaining capacity of air, land, or water.</li> </ul>	As identified impacts are minor or nil no consultation was required.	Minor or nil impact upon: <ul style="list-style-type: none"> <li>• Maori cultural health and well being</li> <li>• Maori cultural, spiritual, ethical or socio-economic values</li> <li>• Maori traditional knowledge</li> <li>• The mauri of land, and air and other taonga</li> <li>• The maintenance, expression and control of traditional practices.</li> </ul>	As identified impacts are minor or nil no consultation was required.



**4.4 Provide an assessment of any risks, costs or benefits to New Zealand’s international obligations.**

This is a specialist area which ERMA New Zealand will handle. However, any information you are able to provide on relevant international agreements would help us and save time and cost.

**(Optional)** (See comments under “Section 4.4 of Form” in the User Guide)

The active ingredient of this product is well recognised and there are several products using this active ingredient already registered by the ACVM and available for purchase in this country and others.

**4.5 Provide information on the proposed management of the substance.**

This section should provide information on managing the effects identified and assessed in Sections 4.1 - 4.4 above. The starting point for this is the range of default controls triggered by the hazardous property classification(s) attached to the substance (see Section 3.4). You should describe how these controls would be implemented and indicate other mean of managing risks.. The information provided must be specific to the substance(s) and cover all areas of intended use. Reference should be made to Codes of Practice or standard operating procedures that will be followed. If changes to the default controls triggered by the substance classification are proposed, the reasons for these changes should be provided.

Please note that you will find it easiest to complete this section in conjunction with section 4.2. That is because the management of risks will influence their residual level.  
(See comments under “Section 4.5 of Form” in the User Guide)

### Implementing Default Controls

**NOR003** is for use by veterinarian, for analgesia and reduction of inflammation by intravenous or subcutaneous administration to individual animals. This will not normally cause exposure to air or water, nor is it likely to affect the public.

### Toxic properties controls.

**Regulation 28** is not applicable, as the substance is not laid outdoors as part of a bait to inhibit reproduction, inhibit growth, or cause death in terrestrial vertebrates.

The people manufacturing and distributing/storing this product are employed for their knowledge and ability to safely handle products of this low toxicity and even higher toxicity that are distributed throughout NZ.

The labelling of the product contains warnings to people handling about appropriate care when handling this product. It is envisioned that the people handling and dispensing who will be veterinarian. The current label provides the same amount of warning as other similar products currently available in NZ, under :

### Warnings and contra-indications

#### Handling Precautions:

May be harmful if swallowed and may possibly affect gastrointestinal tract.

Wash hands and exposed skin before meals and after use.

**Regulation 5(1), 6** are provided for as the injection will be applied directly from container to the cattle/horse subcutaneously/intravenously to avoid distribution in the environment, or public places.

Again, the requirements of **Regulation 7** are met by the injection going from container directly into the cattle/horse. Thus risk of environmental contamination is minimal.

In **Regulation 8's** application, we suggest that while inside the container no special protective equipment is needed, persons opening and dispensing the product should wash their hands after handling the product. This should be sufficient as NOR003 is not a carcinogen or respiratory irritant - it is only 6.1D and 6.9B.

Regarding **Regulations 11-27** any ADE/Rfd must be considered relative to existing similar products on the market not affected by these restrictions, and the irregular nature of exposure for those using this product.

It is metabolised by mammals and does not accumulate in the body.

### **Ecotoxic property controls**

**Regulations 32-45** are not applicable to this product, as it is not designed for release into the environment.

**Regulations 46-48** are not applicable, as NOR003 is not intentionally released into the environment.

**Regulation 5(2) 6** is discussed in Toxic property controls.

**Regulation 7** is discussed in Toxic property controls.

**Regulation 9** is not necessary as the expense of such a veterinary medicine makes for its careful storage and when being carried in transit.

### **Identification**

The 50 mL amber glass, will be labelled to identify the product, state how to use it and that it is a hazardous substance. Veterinarians using this product are familiar with similar products on the market and their toxicity. The labelling, any information insert provided by the manufacturer and the Data Sheet are all suitable documentation to meet these requirements for workplace documentation.

### **Packaging**

**Regulations 5, 6, 7(1) & 8.-**

Vials: 50mL multidose amber glass

Bungs: 20mm Bromobutyl

Caps: 20mm Aluminum seals

are "fit for purpose", and consistent with the industry standard.

**Regulation 19** -This product is not for home use therefore does not need to be childproof access.

**Regulation 21** -schedule 4 applies, as 5 kg or less will be shipped in all predicted conditions.

### **Disposal**

As the product is metabolised by the cattle and horses, **Regulations 8 & 9** are fulfilled.

The label and SDS can meet Regulations 11, 12, 13 & 14.

### **Emergency Management –**

A veterinary clinic may have large volumes of this type of product in storage awaiting sale, however at present there is no requirement for a Emergency plan.

### **Tracking- TR1**

The manufacturer intends to sell to veterinary clinics, where knowledgeable staff are always on hand. This factor helps address risk to the environment, and risk to those using the product.

### **Approved handling – AH1**

As a veterinary medicine adequate handling of this product is provided for by normal commercial activity applying to such veterinary medicines in New Zealand. The expense and nature of the product means the end use handling will mainly be by veterinarians, who are familiar with handling potentially toxic substances in a safe manner . Storepersons who may be involved in handling large volumes of similar substances may require approved handler status or similar.

### **Controls may be implemented by:**

#### **Labels containing advice on the following:**

Hazard classification

Recommended dose/rates of application

Disposal methods

### **Data Sheets containing information on the following:**

Hazard classification

Precautions; Recommended protective equipment and storage

Disposal methods

#### **4.6 Provide an overall evaluation of the combined impact of all of the risks, costs and benefits set out in sections 4.2, 4.3 and 4.4.**

Doing this overall evaluation is the main task of the Authority. However, you may wish to 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.

**(Optional)** (See comments under “Section 4.6 of Form” in the User Guide)

NOR003 represents a nonsteroidal anti-inflammatory for cattle and horses, being an injection with one active ingredient intended to give analgesia.

When registered by the ACVM, NOR003 will be a new product for cattle and horses.

There are not now nor have been in the past any special requirements attached to the tracking, handling and labelling of these products beyond those required by ACVM regulations.

Overall NOR003 risks and costs, to humans and the environment, that are typical of other non-steroidal anti-inflammatory preparations, and are not exceptional.

## **Section Five – International Considerations**

#### **5.1 ERMA New Zealand 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)** (See comments under “Section 5.1 of Form” in the User Guide)

The active ingredient has been approved by ACVM and other authorities worldwide for use in veterinary medicines. The active ingredient has been approved by part V application, or via transfer, by ERMA.

## **Section Six – Miscellaneous**

#### **6.1 Provide a glossary of scientific and technical terms used in the application.**

(See comments under “Section 6.1 of Form” in the User Guide)

**Acute:** An acute effect on human or animal is one that has severe symptoms developing rapidly and coming quickly to a crisis.

**Acute toxicity:** acute effects resulting from a single dose of, or exposure to a substance.

**Cancer:** Any disease characterised by an uncontrolled proliferation of one kind of cell.

**Carcinogenicity:** The ability of a substance to cause cancer.

**Dermal:** of, or related to the skin.

**EC50:** A statistically derived concentration of a substance that can be expected to cause a 50% reduction in the growth or growth rate of the test organism exposed for a specified time.

**Ecotoxicology:** The study of the effects of environmental toxicants on populations of organisms originating, being produced, growing or living naturally in a particular region or environment.

**Ecotoxicological:** Related to the study of the effects of environmental toxicants on populations of organisms originating, being produced, growing or living naturally in a particular region or environment organisms.

**Formulation:** The form in which a substance is supplied by the manufacturer for use.

**Irritation:** A reversible inflammatory effect on living tissue by chemical reaction at the site of contact.

**LD50:** A statistically derived concentration of a substance delivered as a single dose that can be expected to cause death in 50% of test subjects when administered.

**Mutagen:** A substance capable of causing mutations in the genetic material in a living cell.

**Mutagenicity:** The ability of a substance to cause mutations in the genetic material in a living cell.

**Mutation:** A stable change in the genetic material in a living cell.

**Teratogen:** A substance that causes birth defects. (related Teratogenicity; Teratogeny)

**Tumorigenesis :** A substance that can cause a tumour.

**6.2 Provide here any other information you consider relevant to this application not already included.**

(See comments under “Section 6.2 of Form” in the User Guide)

Full registration pursuant to the Agricultural Compounds and Veterinary Medicines Act, 1997 is also being sought.

## **Section Seven – Summary of Public Information**

The information provided in this section may be used in the Authority’s public register of substances required under Section 20 of the HSNO Act.

This summary information will be used to provide information for those people and agencies (e.g. Ministry for the Environment, Department of Conservation, Regional Councils, etc), who 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.

**7.1 Name of the substance(s) for the public register:**

Please use a maximum of 80 characters.

(See comments under “Section 7.1 of Form” in the User Guide)

### **NOR003**

**7.2 Purpose of the application for the public register:**

This should include (in a maximum of 255 characters) an abstract giving information on the intended use of the substance and why an application is needed based on its hazardous properties.

(See comments under “Section 7.2 of Form” in the User Guide)

To import or manufacture NOR003 as a non-steroidal anti-inflammatory injection intended for use in cattle and horses (Category A).”

### 7.3 Use Categories of the substance(s):

ERMA New Zealand 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 - see User Guide for details.
- Industry category: There are 16 industry categories - see User Guide for details.
- Function/Use category: There are 55 function/use categories - see User Guide for details.

**(Optional)** (See comments under “Section 7.3 of Form” in the User Guide)

Main category	3 – non-dispersive
Industry category	1 – Agricultural industry
Function/use category	41 – Veterinary medicines

### 7.4 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 and intended uses
- an assessment of the risks, costs and benefits
- the methods implemented to manage the risks, particularly in relation to emergency management and disposal.

(See comments under “Section 7.4 of Form” in the User Guide)

NOR003 is a non-steroidal anti-inflammatory formulation with analgesic action. It is indicated for treatment of inflammatory conditions such as acute mastitis and pneumonia in cattle and for the control of post-operative inflammation and musculoskeletal problems in horses.

This application is being made to gain approval for NOR003 to be imported and released in New Zealand. Products containing the same active ingredient are already on the market; however this formulation requires assessment according to the HSNO Act.

NOR003 is expected to trigger thresholds for acute oral toxicity, skin effects, target organ effects; and ecotoxic effects (aquatic and terrestrial vertebrate).

The main risks associated with this product are those to the user if not handled appropriately, or to Terrestrial vertebrate in the case of accidental release to the environment or inappropriate disposal.

The likelihood of these risks are judged to be minimal as these events are unlikely; and in the event that they did occur would be of localized and of short duration.

The product labeling and the defined method of administration will further control these risks.

The toxicological and eco-toxicological properties of the product will be managed by observing appropriate handling procedures, which will be provided in a Safety Data Sheet and through labelling.

Therefore residual risks to persons or the environment resulting from release of this product will be insignificant.

### Potential Benefits – Financial & social

- When registered by the ACVM, it is likely that NOR003 will be one of the few non-steroidal anti-inflammatory ingredient analgesic injections for cattle and horses in NZ. NOR003 is intended to be administered to food producing animals (cattle & horses).
- The substance also has a new combination of certain toxic and ecotoxic properties.
- Non-steroidal anti-inflammatory are rapidly and well absorbed after administration.

- Indicated for anti-inflammatory, analgesic, antipyretic for cattle and horses. Indicated in cattle for the treatment inflammatory conditions such as acute mastitis and pneumonia. and in horses for the control of post-operative inflammation, and musculoskeletal problems.
- Administration directly into the animal system minimises the chance of spillage.

## CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes
Fees enclosed	Yes
Application signed and dated	Yes

Signed

Date

02 September 2009

Ansam Ganim  
Technical Consultant