

**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): RAC5809, RAC6809 & RAC7809**

**Applicant: Regulatory Affairs Consulting 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 compound (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.

ERMA New Zealand

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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:** Regulatory Affairs Consulting Limited  
**Address:** Level 1, 451 Mt. Eden Road,  
Mt. Eden, Auckland 1024  
**Phone:** 021 607 273

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

**Address:**

### 1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions on behalf of the applicant that relate to processing the application, or have the ability to go to the appropriate authority.

**Name:** Kristen Manson  
**Position:** Consultant  
**Address:** Level 1, 451 Mt. Eden Road, Mt. Eden, Auckland 1024  
**Phone:** 021 607 273  
**Email:** kmanson@rac.co.nz

## 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 |

Propose to import active ingredient (pellets) from 2 different sources, to manufacture 2 paste formulations, for use as a veterinary medicine. Manufacture of the active ingredient in NZ is never likely.

Also propose to import the paste formulations made from the pellets from overseas.

One of these paste formulations is already approved by ERMENZ for importation and use. This approved formulation is RAC2508.

### 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)

Refer to Confidential Appendix 2.

### 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 formulation, manufacturing and product details are confidential to my client for commercial reasons. Full disclosure will be made to ERMENZ.

**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)

<b>Name of Approval</b>	<b>Application made</b>
Agricultural Compounds and Veterinary Medicines Act 1997	<b>Yes/No/NA</b>
Food Act 1981	<b>Yes/No/NA</b>
Medicines Act 1981	<b>Yes/No/NA</b>
Chemical Weapons (Prohibition) Act 1996	<b>Yes/No/NA</b>
Radiation Protection Act 1965	<b>Yes/No/NA</b>
Biosecurity Act 1993	<b>Yes/No/NA</b>
Resource Management Act 1991	<b>Yes/No/NA</b>
Other (please specify):	<b>Yes/No</b>

## 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, eg from; inhouse 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 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 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)

These details are confidential and are provided in Appendices 1, 2 & 3.

- RAC5809 The formulated paste, manufactured using the active ingredient (pellets containing omeprazole)
- RAC6809 Active ingredient (supplier 1)
- RAC7809 Active ingredient (supplier 2)

### **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

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

These details are confidential and are provided in Appendices 1, 2 & 3.

- RAC5809 The formulated paste, manufactured using the active ingredient (pellets)
- RAC6809 Active ingredient (supplier 1)
- RAC7809 Active ingredient (supplier 2)

### **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).

The details of hazard analysis are provided in Appendices 1 & 2.

**Active ingredient (Suppliers 1 and 2)**

<b>Hazardous Property</b>		<b>Classification category and criteria</b>
<b>Explosive</b>		-
<b>Flammable</b>		-
<b>Oxidising</b>		-
<b>Corrosive</b>		-
<b>Toxicity</b>		
Acute toxicity	Oral	-
	Dermal	-
	Inhalant	-
Skin irritancy		<b>6.3B</b>
Eye irritancy		<b>6.4A</b>
Sensitisation		+/- <b>6.5B *</b>
Mutagenicity		-
Carcinogenicity		-
Reproductive/ Developmental toxicity		-
Target Organ		<b>6.9B</b>
<b>Ecotoxicity</b>		
Aquatic		-
Soil		-
Terrestrial Vertebrate		-
Terrestrial Invertebrate		-

\* The hazard profiles of the active ingredient supplied by 2 different suppliers are similar, but not the same. The product from one supplier triggers 6.5B, but the other does not.

**Paste:**

<b>Hazardous Property</b>		<b>Classification category and criteria</b>
<b>Explosive</b>		-
<b>Flammable</b>		-
<b>Oxidising</b>		-
<b>Corrosive</b>		-
<b>Toxicity</b>		
Acute toxicity	Oral	-
	Dermal	-
	Inhalant	-
Skin irritancy		<b>6.3B</b>
Eye irritancy		-
Sensitisation		<b>6.5B</b>
Mutagenicity		-
Carcinogenicity		-
Reproductive/ Developmental toxicity		<b>6.8C</b>
Target Organ		<b>6.9B</b>
<b>Ecotoxicity</b>		
Aquatic		-
Soil		-
Terrestrial Vertebrate		-
Terrestrial Invertebrate		-

### **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)

#### *Active ingredient (Suppliers 1 & 2):*

T1, T2, T4, T5, T7  
I1, I9, I16, I17, I18, I19, I21, I28  
P1, P3, P13, PS4  
D4, D6, D7, D8  
EM1, EM6, EM8, EM11, EM12

#### *Paste:*

T1, T2, T4, T5, T7  
I1, I9, I16, I17, I18, I19, I21, I28  
P1, P3, P13, PS4  
D4, D6, D7, D8  
EM1, EM6, EM8, EM11, EM12

### **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/Transportation/Storage**

RAC5809 paste would be either manufactured overseas, or in New Zealand (using the active ingredient from either supplier). RAC5809 paste manufactured overseas would be imported in plastic containers (< 0.1L), labelled and ready for sale. Both imported and locally manufactured RAC5809 paste would be stored in a secure warehouse until packed for delivery (eg. into cardboard cartons). RAC5809 paste would be delivered to retail outlets including veterinary clinics around New Zealand (mostly by land transport). Stocks would be kept at retail outlets and smaller amounts are likely to be stored by animal owners and handlers.

The active ingredient (either RAC6809 or RAC7809) would be used to manufacture RAC5809 paste in New Zealand. This would be imported and stored at the manufacturing plant, until used to manufacture the veterinary medicine.

Packaging and transportation of both the active ingredient and RAC5809 would meet New Zealand domestic transportation requirements. Package labelling would conform to the requirements of ERMANZ and the NZFSA, supplying required safety, handling, use and disposal information.

- **Uses**

RAC5809 paste is a veterinary medicine for use in domestic animals. The paste is administered into the animals mouth, using a syringe.

The active ingredient (either RAC6809 or RAC7809) is only for use in manufacture of RAC5809.

- **Other potential uses**

None known to the applicant.

- **Who may use the substance**

Veterinarians, veterinary staff and animal owners/handlers are the persons likely to use RAC5809 paste.

Staff at the manufacturing plant(s) are the only persons likely to use the active ingredient.

- **How it is intended to be used**

RAC5809 paste is delivered to animals using a syringe.

The active ingredient (either RAC6809 or RAC7809) would only be used within the manufacturing plant, to manufacture RAC5809 paste.

- **Disposal**

Most would be disposed of 'by use'. All of the active ingredient would be used at the manufacturing plant. Unused RAC5809 paste (small amounts) and used packaging could be disposed of in local landfills.

## 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, eg from; inhouse 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, 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. 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)

## Identification of potential risks

### 1. *Human Health*

*Risk: Skin irritation (6.3B)*

Skin irritation could potentially occur following skin contact with the active ingredient or RAC5809 paste.

*Risk: Eye irritation (6.4A)*

Eye irritation could potentially occur following eye contact with the active ingredient.

*Risk: Sensitisation (6.5B)*

Contact allergies could potentially arise following skin contact with the active ingredient or RAC5809 paste.

*Risk: Reproductive toxicity (6.8C)*

Adverse effects could potentially arise from repeated ingestion of very high doses of the RAC5809 paste.

*Risk: Target organ toxicity (6.9B)*

Adverse effects could potentially arise from repeated ingestion of very high doses of the active ingredient or RAC5809 paste.

## 2. *Environmental Effects*

Neither the active ingredient, nor RAC5809 paste, present risks to the environment.

## 3. *Effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga*

No new risks identified. See section #4.3.

## 4. *Effects on New Zealand's international obligations.*

Risks, costs and benefits related to New Zealand's international obligations are not assessed by the applicant. See section #4.4.

### **Identification of Risks**

Lifecycle activity	Associated Source of risk
Local transport	Transport or handling incident during transportation or loading/unloading, resulting in spillage and subsequent exposure of people or the environment. <ul style="list-style-type: none"><li>• Transport accident: Spills of plastic containers of RAC5809. Spills of active ingredient.</li><li>• Loading/unloading: Dropped containers spilling contents. Spills of containers of paste or of containers of active ingredient.</li></ul>
Storage	Incident during storage at warehouse facilities, veterinary clinic or end users' sites resulting in spillage and subsequent exposure of people or the environment. <ul style="list-style-type: none"><li>• Accidental spillage of RAC5809 in storage areas (eg. warehouse, vet clinics, farms).</li><li>• Accidental spillage of active ingredient in storage areas (eg. only at the manufacturing plant).</li></ul>
Use	Exposure of end users while handling RAC5809 during use. Incident during use (spillage) and subsequent exposure of people. Exposure of workers to the active ingredient (at the manufacturing plant)
Disposal	Disposal of substance and containers resulting in release of substance and subsequent exposure of people or the environment. <ul style="list-style-type: none"><li>• Paste and active ingredient are both primarily disposed of by use.</li><li>• Small amounts and empty containers could be disposed on in local landfills.</li></ul>

**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 ie 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)

Significant human exposure is unlikely to occur. The active ingredient (RAC6809 & RAC7809) is only handled within a secure manufacturing facility by trained staff. Storage of the active ingredient and RAC5809 is likely to be limited to ‘places of work’. RAC5809 would be stored in a secure warehouse at the manufacturing site and would only leave the manufacturing site within closed labelled packages ready for sale. The only persons with access are trained staff. The RAC5809 paste only likely to be handled or used by persons at their place of work (retail premises, veterinary clinics, farms, racing stables). Access by children is not expected.

**(1) Risk: Human health (skin or eye contact → irritation or sensitisation)**

Source of risk		Impact		Risk
What can happen	How it can happen	Likelihood	Magnitude	
Contact of RAC5809 paste or the active ingredient with eyes or skin	Spillage (transportation accident, storage)	Very unlikely	Minimal	Insignificant
	Skin contact during use. Hand to eye transfer.	Possible	Minimal	Insignificant
	Access by children <ul style="list-style-type: none"> <li>• Active ingredient:</li> <li>• RAC5809 paste:</li> </ul>	Not at all likely	Minimal	Insignificant
	Incorrect disposal	Very unlikely	Minimal	Insignificant

**(2) Risk: Human health (repeated ingestion → target organ & reproductive toxicity)**

Repeated ingestion is not at all likely.

### ***Benefits***

<b>Benefit</b>	<b>Impact</b>	<b>Action through</b>
Improvement of animal health	Direct	Improved health.
Improvement of the overall animal performance	Indirect	Healthy animals → improved productivity.
Increased consumer choice.	Direct	Increased choice → likely to reduce prices

### ***Costs- Economic risk***

Taking into account the level of risk to human welfare, no sources of risk have been identified that could result in adverse economic impact on a community.

**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)

When used as directed, and noting the nature of the product packaging, it is assessed that this active ingredient and this product will have an insignificant effect on the environment or other cultural interests of Maori. Similar products are already in wide use in New Zealand. Although direct consultation with Maori has not taken place, it is anticipated that there are unlikely to be any particular aspects of this product that are likely to affect Maori tradition or culture.

**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 ACVM Group of the NZFSA will assess the risk of food residues resulting from the use of RAC5809.

#### **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 means 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.

#### Toxic properties

Proposed controls for the active ingredient are: T1, T2, T4, T5, T7

Proposed controls for RAC5809 are: T1, T2, T4, T5, T7

#### Identification & Packaging

Default controls will direct efforts for proper packaging and provision of information (Safety Data Sheets, labelling and signage).

Proposed controls for the active ingredient are: I1, I9, I16, I17, I18, I19, I21, I28  
P1, P3, P13, PS4

Proposed controls for RAC5809 are: I1, I9, I16, I17, I18, I19, I21, I28  
P1, P3, P13, PS4

#### Disposal

The default controls will direct efforts for supply of sound advice (labelling, SDS) for the disposal of both hazardous substances and packaging, to prevent release to the environment and exposure of people.

Proposed controls for the active ingredient are: D4, D6, D7, D8

Proposed controls for RAC5809 are: D4, D6, D7, D8

#### Emergency Management

The default controls will direct efforts for supply of sound advice (labelling, SDS) to aid prevention of emergencies.

Proposed controls for the active ingredient are: EM1, EM6, EM8, EM11, EM12

Proposed controls for RAC5809 are: EM1, EM6, EM8, EM11, EM12

#### **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)

Direct benefits to animal welfare and indirect benefits to the New Zealand economy balance risks associated with substance toxic/ecotoxic effects - judged to be ‘insignificant’ with controls in place.

## 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)

RAC5809 paste is an approved by the APVMA for sale in Australia.

## **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)

**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)

## 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 (eg 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)

- RAC5809 The formulated paste, manufactured using the active ingredient (pellets)
- RAC6809 Active ingredient (supplier 1)
- RAC7809 Active ingredient (supplier 2)

### 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 RAC5809, and import RAC6809 and RAC7809 to be used in the manufacture of RAC5809, for the treatment and prevention of gastric ulcers in horses.

### 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 use
Industry category:	1	Agricultural Industry
Function/Use category:	41	Pharmaceuticals - 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)

This application proposes the NZ manufacture and/or importation of a veterinary medicine (a paste, RAC5809), for the treatment of domestic animals by mouth.

This application also proposes the importation of the active ingredient (pellets) for the manufacture of RAC5809 (RAC6809 and RAC7809).

RAC5809 breaches HSNO thresholds for irritation (6.3B), sensitisation (6.5B), reproductive toxicity (6.8C) and target organ toxicity (6.9B).

The active ingredients (RAC6809 and RAC7809) breach HSNO thresholds for irritation (6.3B, 6.4A), +/- sensitisation (6.5B) and target organ toxicity (6.9B).

Neither RAC5809, nor the active ingredients (RAC6809 and RAC7809), are hazardous to the environment.

Risks to human health are judged insignificant. Human skin or eye contact could possibly occur (i) Following spillage of the paste or pellets during transport, in storage areas or during use, (ii) During paste manufacture (workers in the manufacturing plant), or (iii) During the paste administration to animals. Repeated ingestion of either the paste or pellet formulations is not at all likely. Implementation of default controls (for labelling, safety data sheets, signage, equipment, packaging, disposal, emergency management) would remove any concerns.

RAC5809 will not pose any additional economic, social or environmental costs. The introduction of this product to the market will increase consumer choice. This increased choice may translate into cheaper prices. RAC5809 is significantly beneficial in terms of animal welfare.

# CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes
Fees enclosed	No*
Application signed and dated	Yes

Signed

Date

\*Please send me details so I can instruct my client how to pay ERMENZ electronically  
(kmanson@rac.co.nz )

## Appendix 1. Commercially Sensitive Information