

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
 NGĀ KAIWHAKATŪPATO WHAKARARU TĀIAO



## 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):** Equilintex Veterinary Dressing

**Applicant:** Saddlery Warehouse 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:** Saddlery Warehouse Ltd.  
**Address:** PO Box 100780, North Shore Mail Centre, Auckland  
**Phone:** 09 970 1055  
**Fax:** 09 970 1070

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

**Address:** 1/5 Airborne Road, Albany, 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:** Sarah Willing  
**Position:** Purchasing Assistant  
**Address:** PO Box 100780, NSMC, Auckland  
**Phone:** 09 970 1055  
**Fax:** 09 970 1070  
**Email:** sarah@saddles.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 |

### 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.

### 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)

### 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

Agricultural Compounds and Veterinary Medicines Act 1997

Food Act 1981

Medicines Act 1981

Chemical Weapons (Prohibition) Act 1996

Radiation Protection Act 1965

Biosecurity Act 1993

Resource Management Act 1991

Other (please specify):

#### Application made

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No

Yes/No

### **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)

The substance is a veterinary dressing containing the active ingredients boric acid (CAS # 10043-35-3) and tragacanth (CAS # 9000-65-1) and other ingredients. The full composition is provided in Confidential Appendix 1.

### **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)

The substance is a solid dressing.

### **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).

Equilintex Veterinary Dressing has been determined to have the following hazardous properties:

6.3A Skin irritancy

6.4A Eye irritancy

6.5B Contact sensitisation

6.8B Reproductive/developmental toxicity

### **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)

### **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)

Once imported and cleared by our customs agent, this product will be transported to our warehouse by truck in well packaged, sealed cardboard cartons which we will then place on shelves in our retail shops and also mail order throughout New Zealand via courier. Customers will purchase and use on their horse(s) when required (for example: wound protection or drawing out an abscess from a hoof etc), then dispose of as advised on our label as follows:

***Disposal** – always wrap and place all used dressings in household rubbish bin. Do not flush down drain.*

## **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)

#### Risks and Costs

The risks associated with this substance relate to exposure to the hazards identified in section 3.3 and are summarised in the following table:

#### Summary of risk identification for Vet Direct Equilintex

Source of risk Event/incident	Haz Property	Possible reasons for event	Effect/impact	Exposure Pathway
Contact with skin or eyes	6.3A (skin irritant), 6.4A (eye irritant), 6.5B (contact sensitizer) and 6.8B (reproductive/developmental toxicant)	Users failing to wash hands after applying dressing (use)	May cause irritation to skin or eyes (extremely minimal risk)	Through dermal absorption and then contact with eyes

#### Benefits of Vet Direct Equilintex

- \* Highly versatile wound dressing suitable for a wide range of applications. Main use is to draw fluids from wounds.
- \* Plastic backing keeps in moisture and warmth and keeps out external contamination.
- \* Soft cotton inside layer is designed not to stick to skin so the wound is not damaged when the poultice is removed.
- \* Acts as a protective layer from knocks and bumps.
- \* Economical to use as it can be cut to the required size with the remaining amount able to be used at a later date.

*Overall, Equilintex Veterinary Dressing will be an economical and effective dressing that promotes fast healing and wound protection for horses to aid in their welfare if injured or infected. As a result, we confidently foresee a very significant demand for this product across all New Zealand horse owners / animal welfare workers.*

**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)

Boric Acid is only 2.0 grams of the entire 46g; therefore it is a very minimal amount resulting in the risks identified in 4.1 being very unlikely.

On our label we have recommended all users wash their hands after use, keep out of reach of children and clearly state it is for use only on horses and dogs.

Instructions for disposal are to "always wrap and place all used dressings in household rubbish. Do not flush down drains."

**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)

There are no particular risks, costs or benefits relating to Maori or their culture and traditions associated with this substance.

**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)

There are no particular risks, costs or benefits relating to New Zealand’s international obligations associated with this substance.

**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.

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)

See section 4.2

**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)

## **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)

We have already approached the ACVM and requested a Class Determination for ‘Equilintex’. This product was found to be exempt under the ACVM Regulations and does not require registration to be imported, marketed, distributed or sold in New Zealand. (refer to attached letter).

## **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)

Equilintex Veterinary Dressing

**7.2 Purpose of the application for the public register:** Approval to import Vet Direct Equilintex

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 Equilintex Veterinary Dressing for use as a dressing for 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)

Industry

Non Dispersive Use

Agriculture (Veterinary)

**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)

Saddlery Warehouse Ltd is applying for approval to import Equilintex Veterinary Dressing, a veterinary dressing which contains boric acid, tragacanth and other ingredients. Equilintex Veterinary Dressing is an economical and effective dressing that promotes fast healing and wound protection for horses to aid in their welfare if injured or infected.

The substance has the following hazard profile:

- 6.3A skin irritant
- 6.4A eye irritant
- 6.5B contact sensitiser
- 6.8B reproductive/developmental toxicant

The likelihood of exposure of users to the hazards identified above is considered minimal as the chemicals are released from the dressing slowly over a period of time. Warning statements on the label will further minimise the likelihood of exposure.

The used dressing should be wrapped and may be disposed of with household rubbish. Dressings should not be flushed down the drain.

# CHECKLIST

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

Signed

Date

## **Appendix 1. Commercially Sensitive Information**