



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): L2036PR

Applicant: Bomac Laboratories 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.

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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: Bomac Laboratories Ltd
Address: Cnr Wiri Station Road and Hobill Avenue, Manukau City,
P.O Box 76-369, Auckland, New Zealand.
Phone: (09) 262-3169
Fax: (09) 262-3008

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

Address: As above

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: Paulina Rodriguez
Position: Bomac Latin-American Representative
Address: Cnr Wiri Station Road and Hobill Avenue, Manukau City,
P.O Box 76-369, Auckland, New Zealand.
Phone: (09) 262-3169
Fax: (09) 262-3008
Email: p.rodriguez@bomac.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 |
| • Manufacture only? | No |
| • Import and manufacture? | No |
| • If import only, indicate whether or not manufacture is likely in New Zealand | 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)

The manufacturing process will be all conducted overseas. Only the relabeling will be conducted in NZ.

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)

All requested information is provided.

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

~~Yes/No/NA~~

~~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)

- Chemical Name (Chemical Abstracts Preferred Index name or IUPAC name): N/A
- Common Name: N/A
- Synonyms: N/A
- Trade Names: L2036PR
- CAS Registry Number: N/A
- Molecular Formula: N/A
- Structural Formula: N/A
- Significant impurities: N/A

The full composition of L2036PR is confidential and details are provided in the confidential section.

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)

Chemical and physical properties of the mixture:

- Appearance (colour, odour, physical state or form): A pale yellow suspension.
- pH: 4.0- 5.0
- Density: 1.050-1.100
- Vapour pressure: N/A
- Boiling/melting point: N/A
- Solubility in water: N/A
- Water/octanol partitioning co-efficient: N/A

Chemical and physical properties of each hazardous component the mixture:

Refer to the confidential section.

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).

Summary Table of Hazardous Properties, Thresholds and Classification for L PR

Hazardous Property	Threshold	Classification category and criteria
Explosiveness	Not triggered	-
Flammability		
• Liquid	Not triggered	-
Oxidising properties	Not triggered	-
Corrosiveness	Not triggered	-
Toxicity		
• Acute Oral	Triggered	6.1 D
• Acute dermal	Not triggered	-
• Acute inhalation	Not triggered	-
• Skin irritation	Triggered	6.3B
• Eye irritation	Not triggered	-
• Sensitisation	Triggered	6.5B
• Mutagenic	Triggered	6.6 B
• Carcinogenic	Not triggered	-
• Reproductive/Developmental	Not triggered	-
• Target organ/Systemic	Triggered	6.9A
Ecotoxicity		
• Aquatic	Not Triggered	
• Soil	Triggered	9.2 D
• Terrestrial vertebrate	Triggered	9.3 C
• Terrestrial invertebrate	Not triggered	-
• Biocides	Not triggered	-

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)

	Default
Toxic property controls	T1, T2, T3,T4, T5, T7,T8
Ecotoxic property controls	E1, E2, E4,E6
Identification	I1, 18,I9,I11,I16, I17, I18, I19, 120,I21, I28, I29,130
Packaging	P1, P3, P13*, PS4,PG3
Disposal	D4, D5,D6, D7, D8
Emergency Management	EM1, EM6, EM7,EM8, EM11, EM12, EM13

Note: Controls T1 and T2, and E1, E2 and E6 are considered not relevant to the use of this substance. It is proposed that these controls are deleted. The reasons as to why these controls are not considered relevant are discussed in section 4.5.

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)

The finished product will be imported to NZ and will have Biosecurity clearance at the border. Storage of the product will be in the Bomac Laboratories Ltd in Manukau, Auckland where the product will be relabelled by Bomac Laboratories and distributed to the Vet Clinics in NZ once the product has ACVM Registration. The product will be transported to the customers (wholesalers, vet clinics and rural resellers), either by road, rail or sea. Then, the product will be sold to Veterinarians. The Veterinarian will apply the substance subcutaneously in the middle of the neck. The substance will be absorbed rapidly from the injection site and once is absorbed it will be metabolised and 40% will be eliminated in urine within 12 hours. Animals treated with L2036 PR should not be sent to the slaughter house before 21 days.

While the product is not used, the vaccine should be kept under refrigeration. The product will be packed in 200mL and 500 mL flexipacks (HDPE/LDPE) and will be labelled with instructions for the end-user regarding directions for its use, storage and appropriate disposal. Unused vaccine must be discarded within 10 hours of opening. Preferable dispose product by use. Otherwise dispose of product and packaging at an approved landfill or other approved facility. Triple rinse empty container and add rinsate to dip wash. Burn in an appropriate incinerator, if circumstances such as wind direction permit. Otherwise crush or puncture and bury in a suitable landfill, or if appropriate recycle. Do not contaminate surface water or drains with product or used containers. The local or regional council should be contacted regarding disposal options. Additional information about the disposal of empty containers and spills can also be found on the material safety datasheet. It is unforeseeable that the substance will be used for any other reason and there are no known adverse effects from unintentional use.

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; 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, 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)

The physical environment:

Risk: Harmful to terrestrial vertebrate and soil ecotoxicity.

Adverse effects on terrestrial vertebrate could potentially arise from exposure to L2036PR. This product can also be harmful to the soil environment. The product should not be released to the environment..

Human health and welfare:

Risk: Acute oral toxicity, skin irritant, sensitizer, mutagenic and target organ toxicant.

Adverse effects to the skin and target organ could potentially arise from exposure to L2036PR.

Maori concerns:

The manufacture and use of L2036PR introduce no new ingredients or factors into New Zealand that do not already exist. Additionally, L2036PR does not pose any risks to the environment. As a consequence, it will not affect the relationship between Maori and their environmental taonga.

International obligations:

Risks to New Zealand's international obligations with regard to food residues are to be assessed by the ACVM Group. Other risks, costs and benefits related to New Zealand's international obligations are not assessed by the applicant.

Identification of potential risks

Source of Risk	Elements at risk	Likelihood of the effect happening	Magnitude of the effect	Methods to identify and manage the risk	Level of residual risk
<u>USAGE AND RELEASE</u>					
Incorrect disposal	Human health Aquatic life and soil ecotoxicity	Improbable	Minimal	GMP guidelines, ERMA HSNO guidelines	Insignificant
The substance being released into the environment	Human health Aquatic life and soil ecotoxicity	Improbable	Minimal	ACVM and ERMA HSNO guidelines	Insignificant
<u>SPILLAGE</u>					
Transport accident	Human health Aquatic life and soil ecotoxicity	Highly improbable	Minimal and localised	ERMA HSNO guidelines	Insignificant
Natural disaster (e.g. earthquake)	Human health Aquatic life and soil ecotoxicity	Highly improbable	Minimal and localised	ERMA HSNO guidelines	Insignificant

Identification of potential costs

The introduction of L2036PR to the New Zealand market will not impose any additional cost. The addition of this substance to the market will not increase the total amount of the active ingredient exposed to the environment and is no more hazardous than similar substances already on the market. Therefore, it will not pose any additional risk to the environment. The controls implemented during the lifecycle of L2036PR are deemed sufficient to control its low level of risk to the physical environment and human welfare.

Identification of potential benefits

- No long-term health problems can be foreseen.
- The ability of this substance to improve animal health also has a positive effect on the well-being of Maori people.
- The importation of this vaccine will lower cost to the end-user (farmers).

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)

The overall risks, costs and benefits of the introduction of L2036PR have been assessed in section 4.1.

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)

This formulation has been developed overseas for use as a veterinary medicine, for the benefit of animal health in New Zealand. The antigens and the anthelmintic are found in many registered veterinary products already marketed in NZ.. Maori consultation was not sought when preparing this application as this substance has the potential to significantly improve the health of their animals. Maori have a positive view on the introduction of new formulations that would help protect the Maori taonga and are extremely unlikely to have any objections to the addition of L2036PR to the New Zealand market.

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 importation of this vaccine to New Zealand will represent big benefit to farmers given that market pressure decreases prices. Therefore, more animals will be vaccinated and protected against one of the most common diseases present in all farm animals. Similar products have been manufactured over 100 years and the efficacy and safety profile has been established. The anthelmintic is broad spectrum and has been used in NZ and around the world for many years.. There are several similar products already registered by the ACVM and available for purchase in this country and others. The withholding periods for residues in products originating from animals treated with this vaccine will be granted by the ACVM Group and take into consideration New Zealand’s external trade. This will be covered in the assessment of L2036PR by the NZFSA.

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)

Toxic property controls

The default toxic property controls triggered by this substance are T1, T2, T3, T4, T5, T7 and T8. Default control T1 relates to setting tolerable exposure limits which limit public exposure to toxic substances. They do not apply to a place of work if the public does not have access to that place. The public do not have access to the manufacturing plant at Bomac Laboratories therefore default control T1 is not necessary. Default control T2 relates to setting standards for human workplace exposure to the substance. The properties and use profile are such that this control is deemed not applicable.

Ecotoxic property controls

The default ecotoxic property controls triggered by this substance are E1, E2, E4 and E6, which are not applicable to the use of the substance. Consequently, none of these default controls are proposed for this substance.

Identification controls

The default identification controls triggered by this substance are I1, I8, I9, I11, I16, I17, I19, I20, I21, I28, I29 and I30. These controls will be implemented on the label of the substance, which will comply with both HSNO and ACVM requirements, and other appropriate documentations, to manage the potential risks of the substance.

Packaging controls

The default packaging controls triggered by this substance are P1, P3, P13* PG3 and PS4. These will be implemented by manufacturing this substance to GMP standards to manage the potential risks.

Disposal controls

The default disposal controls triggered by this substance are D4, D5, D6, D7 and D8. At manufacturing stage, these controls will be implemented by adhering to GMP standards to manage the potential risks. When the substance is released for sale, these controls will be implemented by adding appropriate disposal instructions on the label.

Emergency Management

The default emergency management controls triggered by this substance are EM1, EM6, EM7, EM8, EM11, EM12 and EM13. This substance is for use only under the authority or prescription of a veterinarian, therefore the potential risks of the substance will be adequately managed.

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 the animal welfare and indirect benefits to the New Zealand economy through product development and reduction of economic loss to sheep farms, would outweigh any risk associated with the potential possibility of toxic effect that might occur because of improper handling, an accidental spillage or inappropriate disposal. Such events are extremely unlikely to happen due to the appropriate controls that are to be implemented, as a result of the assessment of this substance and the thresholds it triggers. It should also be stressed that although risks do exist, as no substance is completely devoid of risks:

- The risk is highly unlikely to be involuntary
- The risk is not persistent
- The risk is almost certainly always localised and will not spread uncontrollably
- There is no significant risk to the health of the public

The fact that this substance is for use only under the authority or prescription of a veterinarian further minimises the risks.

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)

This formulation is based on a combination of known ingredients that are already legally present in New Zealand. An application to the ACVM will be sent this week.

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)

Not applicable.

- 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)

All information has been provided.

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)

L2036PR

- 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 L2036PR as a veterinary medicine for production animals.

- 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. Pharmaceuticals, subcategory: veterinary medicine

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 is submitted to gain an approval to import and release L2036PR in New Zealand. L2036PR is formulated for use in farm animals. It will not pose any economic, social or environmental cost. It will however, produce a number of benefits in relation to animal welfare and profitability to sheep farmers among others. The importation of this substance to New Zealand will represent big benefit to farmers given that market pressure decreases prices. Therefore, more animals will be vaccinated and protected against one of the most common diseases present in all farm animals. Similar products have been manufactured over 100 years around the world and the efficacy and safety profile of these products has been established. The anthelmintic is broad spectrum and has been used in NZ and around the world for many years.. There are several similar products already registered by the ACVM and available for purchase in this country and others. The product is to be applied in the anterior half of the neck and injected subcutaneously. The withholding periods for residues in products originating from animals treated with this substance will be granted by the ACVM Group and take into consideration New Zealand’s external trade. This will be covered in the assessment of L2036PR by the NZFSA.

Substances containing the ingredients found in L2036PR are already available in New Zealand, however because this particular formulation has not been notified as a toxic substance, an assessment by ERMA under the HSNO Act 1996 is required. The hazard classifications are as follows: 6.1D, 6.3 B, 6.5 B, 6.6 B, 6.9A, 9.2 D, 9.3 C.

L2036PR triggers the threshold for skin irritation and sensitisation, target organ toxicity, ecotoxicity. The main risks attributed to this substance are those associated with inappropriate handling and disposal of the substance. The magnitude of these risks is judged to be minimal as these events are unlikely and, in the event that they did occur, would be localised. In addition, these risks are further minimized and controlled by the instruction on the label of the substance and the fact that this substance is for use only under the authority or prescription of a veterinarian. Therefore, it can be concluded that the risks resulting from this substance will be insignificant. The leaflet will contain information on adequate use of equipment and of the product. Storage conditions are also included in the label. The product should be discarded as follows: Unused product must be discarded within 10 hours of opening.

CHECKLIST

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

Signed

Date 17 August, 2009.