

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):**

BD1620RH,  
DAI

**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.

ERMA New Zealand  
20 Customhouse Quay  
PO Box 131  
Wellington  
NEW ZEALAND  
Telephone: 64-4-473 8426  
Facsimile: 64-4-473 8433  
E-mail: [info@ermanız.govt.nz](mailto:info@ermanız.govt.nz)  
[www.ermanız.govt.nz](http://www.ermanız.govt.nz)

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## Section One – Applicant Details

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

**Name:** BOMAC Laboratories Limited.  
**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:** Rounak Haddadi  
**Position:** Registration Officer  
**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:** [r.haddadi@bomac.co.nz](mailto:r.haddadi@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 – the active ingredient Yes/No
- **Manufacture only**- the substance 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)

The manufacturing process is confidential. This is provided in Appendix 1. There are no alternatives to the manufacturing process other than what is provided in the Appendix.

### 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 – however applications will be made in the future.

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/NA

Yes/No/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, 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)

#### Identification of *BD1620RH*

- Chemical Name: Not applicable
- Common Name: Not applicable
- Synonyms: Not applicable
- Trade Name: *BD1620RH*
- Molecular Formula: Not applicable
- Structural Formula: Not applicable
- CAS Registry Number: Not applicable
- Impurities: Not applicable

The full composition details of the substance *BD1620RH* are confidential. Details of the formulation and components are provided in the Appendix.

Identification of the active ingredient (DAI) in the substance is confidential. Details are available in the appendix.

### 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 BD1620RH:**

• Description	A clear, yellow, oily solution with a faint odour
• Relative density	0.945 – 0.975 @20°C

#### **Chemical and physical properties of the Components:**

The chemical and physical properties of the components are confidential. Please see the Appendix.

#### **Chemical and Physical properties of the active ingredient, DAI:**

• Description:	white crystalline powder
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### 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  
BD1620RH**

<b>Hazardous Property</b>	<b>Threshold</b>	<b>Classification category and criteria</b>
Explosive	Not triggered	-
Flammable <ul style="list-style-type: none"> <li>Liquid</li> </ul>	Not triggered	-
Oxidising	Not triggered	-
Corrosive	Not triggered	-
Toxic <ul style="list-style-type: none"> <li>Acute Oral</li> <li>Acute dermal</li> <li>Acute inhalation</li> <li>Skin irritation</li> <li>Eye irritation</li> <li>Sensitisation</li> <li>Mutagenic</li> <li>Carcinogenic</li> <li>Reproductive/Developmental</li> <li>Target organ/Systemic</li> </ul>	Not triggered Not triggered Not triggered Triggered Triggered Not triggered Not triggered Not triggered Triggered Not triggered	- - - <b>6.3A</b> <b>6.4A</b> - - - <b>6.8A, 6.8C</b> -
Ecotoxic <ul style="list-style-type: none"> <li>Aquatic</li> <li>Soil</li> <li>Terrestrial vertebrate</li> <li>Terrestrial invertebrate</li> <li>Biocides</li> </ul>	Triggered Triggered No triggered Triggered Not applicable	<b>9.1A</b> <b>9.2C</b> - <b>9.4A</b> -

The hazardous properties relating to the individual components of *BD1620RH* are confidential. Please see the Appendix.

**Summary Table of Hazardous Properties, Thresholds and Classification for *The Active Ingredient (DAI) in the Substance***

<b>Hazardous Property</b>	<b>Threshold</b>	<b>Classification category and criteria</b>
Explosive	Not triggered	-
Flammable <ul style="list-style-type: none"> <li>Liquid</li> </ul>	Not triggered	-
Oxidising	Not triggered	-
Corrosive	Not triggered	-
Toxic		

<ul style="list-style-type: none"> <li>• Acute Oral</li> <li>• Acute dermal</li> <li>• Acute inhalation</li> <li>• Skin irritation</li> <li>• Eye irritation</li> <li>• Sensitisation</li> <li>• Mutagenic</li> <li>• Carcinogenic</li> <li>• Reproductive/Developmental</li> <li>• Target organ/Systemic</li> </ul>	<ul style="list-style-type: none"> <li>Triggered</li> <li>Not triggered</li> <li>Triggered</li> <li>Not triggered</li> <li>Not triggered</li> <li>Not triggered</li> <li>Not triggered</li> <li>Not triggered</li> <li>Triggered</li> <li>Not triggered</li> </ul>	<ul style="list-style-type: none"> <li><b>6.1C</b></li> <li><b>6.1C</b></li> <li><b>6.1C</b></li> <li>-</li> <li>-</li> <li>-</li> <li>-</li> <li>-</li> <li><b>6.8C</b></li> <li><b>6.9A</b></li> </ul>
<p>Ecotoxic</p> <ul style="list-style-type: none"> <li>• Aquatic</li> <li>• Soil</li> <li>• Terrestrial vertebrate</li> <li>• Terrestrial invertebrate</li> <li>• Biocides</li> </ul>	<ul style="list-style-type: none"> <li>Triggered</li> <li>Triggered</li> <li>Triggered</li> <li>Triggered</li> <li>Not applicable</li> </ul>	<ul style="list-style-type: none"> <li><b>9.1A</b></li> <li><b>9.2A</b></li> <li><b>9.3B</b></li> <li><b>9.4A</b></li> <li>-</li> </ul>

### **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)

Raw materials for the active ingredient (DAI) and the excipients will be sourced from New Zealand and abroad, and will then be transported in a controlled manner to New Zealand and within, by sea, rail, road or air freight. These raw materials will be sent to Bomac Laboratories Ltd in Manukau, Auckland where they will be used to manufacture BD1620RH according to GMP. Storage of the raw materials as well as the finished product will be in the Bomac Laboratories Ltd warehouse. The active ingredient (DAI) will not be used for any other purpose than manufacturing pharmaceutical formulations such as BD1620RH. Transportation of the finished product, BD1620RH to customers (wholesalers, vet clinics and rural re-sellers) may be by road, rail or sea. Farmers can then purchase the product from their farming supplies or vet clinic. It is anticipated that the sole users of this product will be farmers. The product will come in a range of 250mL – 20L fluorinated HDPE containers. The active ingredient (DAI) will be handled according to the MSDS and disposal will be by use of the substance, however in case of an accidental spillage, incineration is the recommended method of disposal for this material. The finished product will be labeled with instructions for the end-user regarding storage and directions for use. Do not contaminate surface water or drains with product or used containers. The local or regional council should be contacted regarding disposal options. ERMA recommendations for disposal of such packaging is to triple rinse empty container and add rinsate to dip wash, burn in an appropriate incinerator, if circumstances such as wind direction permits. Otherwise, crush or puncture and bury in a suitable landfill, or if appropriate recycle. It is unforeseeable that the products will be used for any other reason.

## 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)

## **BD1620RH:**

### **1. The Physical Environment**

Risk: Water contamination

*BD1620RH* is toxic to aquatic organisms and will have an adverse effect on fish and phytoplankton should it enter waterways.

Risk: Soil Organisms

*BD1620RH* is toxic to soil organisms.

Risk: Terrestrial invertebrates

*BD1620RH* is toxic to terrestrial invertebrates.

## 2. Human health and welfare

Risk: Irritation

Adverse effects could potentially arise from the exposure of the eyes or skin to *BD1620RH*.

Risk: Reproductive / Developmental Effects

Adverse effects on reproduction/ development could potentially arise from direct ingestion of *BD1620RH*.

## 3. Maori concerns

The manufacture and use of *BD1620RH* introduces no new ingredients or factors into New Zealand that do not already exist.

Effects to Maori, as a consequence of this relationship are related to environmental contamination.

Risk: Maori taonga

Adverse effects could potentially arise from contact of environmental taonga with *BD1620RH* as a result of accidental spillage.

## 4. 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.

### **Active Ingredient found in the substance (DAI):**

#### **1. The Physical Environment**

Risk: Water contamination

*The active ingredient found in the substance* is toxic to aquatic organisms and will have an adverse effect on fish and phytoplankton should it enter waterways.

Risk: Soil Organisms

*The active ingredient found in the substance* is toxic to soil organisms.

Risk: Terrestrial vertebrates and invertebrates

*The active ingredient found in the substance* is toxic to terrestrial vertebrates and invertebrates.

#### **2. Human health and welfare**

Risk: Acute toxicity

Adverse effects could potentially arise from the ingestion or inhalation of or absorption (through the skin) of *The active ingredient found in the substance*.

Risk: Reproductive / Developmental Effects

Adverse effects on reproduction (lactation) could potentially arise from direct ingestion of *The active ingredient found in the substance*.

Risk: Target organ toxicity

Adverse effects could occur to the target organ (nervous system) of the target species as a result of exposure to *The active ingredient found in the substance*.

### 3. Maori concerns

The importation and use of *The active ingredient found in the substance* introduces no new ingredients or factors into New Zealand that do not already exist as there are products already on the market containing this substance.

Effects to Maori, as a consequence of this relationship are related to environmental contamination.

Risk: Maori taonga

Adverse effects could potentially arise from contact of environmental taonga with *The active ingredient found in the substance* as a result of accidental spillage.

### 4. 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- BD1620RH and its active ingredient

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>					
The process of manufacturing the formulation.	Health of workers (occupational exposure during manufacturing)	Highly improbable under GMP work conditions.	Minimal	GMP guidelines, ERMA HSNO guidelines	Insignificant
Incorrect disposal	Human health, soil and aquatic life or terrestrial vertebrates and/or invertebrates.	Improbable	Minimal and localised	GMP guidelines, ERMA HSNO guidelines	Insignificant
The substance being released into the environment	Death or adverse effects on soil and aquatic organisms and terrestrial vertebrates/invertebrates.	Improbable	Minimal	ACVM and ERMA HSNO guidelines	Insignificant
<u>SPILLAGE</u>					
Transport accident	Human health, soil and aquatic life or terrestrial vertebrates and/or invertebrates.	Highly improbable	Minimal and localised	ERMA HSNO guidelines	Insignificant
Natural disaster (e.g earthquake)	Human health, soil and aquatic life or terrestrial vertebrates and/or invertebrates.	Highly improbable	Minimal and localised	ERMA HSNO guidelines	Insignificant

### **Identification of potential costs**

The introduction of *BD1620RH and The active ingredient found in the substance* to the New Zealand market will not impose any additional cost. The addition of this product to the market will not significantly increase the total amount of the active ingredient exposed to the environment and is no more hazardous than similar products already on the market, therefore it will not pose any additional risk to the environment. Although these substances are ecotoxic, it is not expected that an adverse economic effect will occur from their use. The controls implemented during the lifecycle of *BD1620RH and The active ingredient found in the substance* are deemed sufficient to control the low level of risk to the physical environment and/or human welfare.

### **Identification of potential benefits**

- No long-term health problems can be foreseen
- Parasites are a huge burden to livestock and pose a significant economic loss to farmers. Treatment with products such as *BD1620RH* is found to be highly effective in reducing parasite numbers, which in turn decreases economic loss and improves the profitability of the farm. This can lead to further benefits by enhancing the wellbeing of the wider community and future generations.
- *BD1620RH and The active ingredient found in the substance* does not leach, bioaccumulate, volatilize or persist in the environment.
- The ability of these products to improve animal health also has a positive effect on the wellbeing of Maori people.
- Product development in New Zealand has the potential to provide many economic advantages:
  - New value-added products enhance the intellectual property rights held within New Zealand, and have potential for export earnings.
  - Manufacturing value-added products within New Zealand provides the manufacturer with a competitive advantage (over imported products), and lower cost to the end-user (farmers).
  - Manufacturing of value-added products within New Zealand provides employment and prosperity to the community. This enhances the wellbeing of current and future generations.

**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)

Assessment of the overall risks, costs and benefits of the introduction of *BD1620RH* has been addressed 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)

The formulation has been developed for use as veterinary medicines, for the benefit of animal health in New Zealand. The ingredients and action of use are found in many veterinary formulations already marketed. Maori consultation was not sought when preparing this application as these products have the potential to significantly improve the health of 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 *BD1620RH* to the New Zealand market. The risks associated with the introduction of *BD1620RH* and *The active ingredient found in the substance* specific to Maori would be in case of accidental entry into the environment. However, as stated in section 4.1 these risks are very low/insignificant because measures (GMP, ERMA, ACVM guidelines) will be taken to ensure controlled use of these products.

**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)

*BD1620RH* has been developed by Bomac Laboratories Ltd in New Zealand. The active compound of this product is well recognized and there are several similar products 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 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)

It is believed that the combination of the default controls and the instructions / warnings on the label will manage the risks of the substance.

**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 farmers, would outweigh any risk associated with the potential possibility of toxic or ecotoxic effects that might occur because of improper handling, and 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 triggered threshold of toxicity and ecotoxicity of these products. It should also be stressed that although risks do exist (no substance, chemical etc is completely devoid of risks):

- The risk is highly unlikely to be uncontrolled
- 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

## 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 formulation is based on a combination of known ingredients that are already legally present in New Zealand. An application for registration of this formulation with the ACVM Group will be made in the near future.

## 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 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)

BD1620RH,  
DAI

### 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 DAI, and manufacture BD1620RH, for use as a veterinary medicine for topical use in cattle

### 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 being made to gain approval for the importation of *The active ingredient found in the substance, BD1620RH* and to manufacture *BD1620RH* and released in New Zealand. Products containing the ingredients found in *BD1620RH* are already on the market; however, because this formulation has not been notified as a toxic substance, it requires assessment by ERMA under the HSNO Act 1996. *BD1620RH* triggers the thresholds for toxicity and ecotoxicity (6.3A, 6.4A, 6.8A, 6.8C, 9.1A, 9.2C and 9.4A). *The active ingredient found in the substance* triggers the thresholds for toxicity and ecotoxicity (6.1C, 6.8C, 6.9A, 9.1A, 9.2A, 9.3B, 9.4A).

The main risks attributed to this product and its active ingredient are those associated with the user if not handled appropriately or to soil and aquatic organisms and terrestrial vertebrates and invertebrates in the case of accidental spillage or inappropriate disposal. The magnitude of these risks are judged to be minimal as these events are unlikely as measures (GMP, ERMA guidelines) will be taken to ensure the proper use / controlled use of this substance and in the event that they did occur would be localized and would be of short duration. In addition, these risks are further minimized and controlled by the

instruction on the product label and the selected method of administration. Therefore, it can be concluded that the risks resulting from this product will be insignificant.

*BD1620RH* is formulated for the treatment and control of internal parasites in ruminants. 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 farmers among others.

## CHECKLIST

Mandatory sections filled out	<b>Yes</b>
Appendices enclosed	<b>Yes/ NA</b>
Fees enclosed	<b>No – please invoice</b>
Application signed and dated	<b>Yes</b>

Signed

Date: