ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

FORM HS2/2

Application for approval to

IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE FOR RELEASE by Rapid Assessment

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

Under the Criterion that is Similar to a Substance with an Existing HSNO Approval

Name of Substance(s): JG1122

Applicant: Bomac Laboratories Limited

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.
2. Part D of the User Guide covers applications under Section 28A of the Act using the criterion that it is 'similar' to a substance with an existing HSNO approval and all of the cross references to this guide that are in this application form relate to Part D.
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. 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.
5. Commercially sensitive information must be collated in a separate Appendix.
6. 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.
7. 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 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: Jyoti Gupta
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: j.gupta@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' that meets the criterion that is "similar" to a substance with an existing HSNO approval. 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 The Authority may make a "rapid assessment" of applications to import or manufacture a hazardous substance for release if certain criteria apply. You need to confirm that the following criterion applies and provide reasons in support of this.
(See comments under "Section 2.1 of Form" in the User Guide)

The application is for a substance(s) that has a similar composition and similar hazardous properties to an approved, existing substance **Yes**/~~No~~

The justification for claiming that criterion has been met is as follows (cross reference to Section 3.1, 3.2, and 3.3 of this form as appropriate):

2.2 Identify the substance with an existing approval for which you wish to use as the reference substance(s). Note you will need to supply an approval number. Applicants will probably find it convenient to cross-reference their response to the details in later sections of the application.
(See comments under "Section 2.2 of Form" in the User Guide)

Please refer to Appendix 1 for details about the Reference substance.

2.3 Is the information in this application relevant to import, manufacture or both?
(See comments under "Section 2.3 of Form" in the User Guide)

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

2.4 **If the application relates to manufacture in New Zealand, provide comparative information on the proposed manufacturing process and any alternatives for the substance(s) being applied for and for the reference substance(s) if relevant.**
(See comments under "Section 2.4 of Form" in the User Guide)

The manufacturing processes are supplied in the confidential section of the application as these are commercially sensitive.

2.5 **If this substance(s) needs an approval under any other legislation, has an application for this approval been made?**
(Optional) (See comments under "Section 2.5 of Form" in the User Guide)

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

Section Three – Comparative 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.

The information you provide should clearly identify the similarities and differences between this substance and the previously approved substance used as a reference.

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 proposed substance(s) and of the reference substance(s).

Because comparative information is being looked for, a tabular layout might be convenient to use.

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 JG1122

Chemical Name:	Not Applicable
Common Name:	Not Applicable
Synonyms:	Not Applicable
Trade Name:	JG1122
Molecular Formula:	Not Applicable
Structural Formula:	Not Applicable
CAS Registry Number:	Not Applicable
Impurities:	Not Applicable

The full details of the substance JG1122 are confidential. Details to identify this substance and the reference substance are provided in Appendix 1.

3.2 Provide comparative information on the chemical and physical properties of the proposed substance(s) and of the reference substance(s).

Provide as much information as possible on the chemical and physical properties of the proposed and reference 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.

You should compare and contrast the properties of the substance(s) for which this application is made with that of the previously approved "similar" substance(s).

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

Chemical and Physical Properties of JG1122

Appearance	A clear, bright pale yellow to browny-orange viscous liquid with characteristic pine odour.
pH	8.0 – 9.5 @ 20°C
Density	1.015 – 1.035 @ 20°C
Vapour pressure	N/A

Boiling/melting point	N/A
Solubility in water	N/A
Water/octanol partition coefficient	N/A

The chemical and physical properties of the Reference substance are not known.

3.3 Provide comparative information on the hazardous properties of the proposed substance(s) and the reference 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.

You should compare and contrast the hazardous properties of the substance(s) for which this application is made with that of the reference substance(s).

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

Summary table of hazardous properties, thresholds and classification for the Reference substance

Hazardous Property	Threshold	Classification category and criteria
Explosive	Not triggered	-
Flammable liquid	Not triggered	-
Oxidising	Not triggered	-
Corrosive	Triggered	8.3A
Toxic Acute oral Acute dermal	 Not triggered Not triggered	 - -

Acute inhalation	Not triggered	-
Skin irritation	Triggered	6.3A
Eye irritation	Not triggered	-
Sensitisation	Triggered	6.5B
Mutagenic	Not triggered	-
Carcinogenic	Not triggered	-
Reproductive/Developmental	Not triggered	-
Target organ/Systemic	Not triggered	-
Ecotoxic		
Aquatic	Triggered	9.1D
Soil	Not triggered	-
Terrestrial vertebrate	Not triggered	-
Terrestrial invertebrate	Not triggered	-
Biocides	N/A	N/A

Summary table of hazardous properties, thresholds and classification for JG1122

Hazardous Property	Threshold	Classification category and criteria
Explosive	Not triggered	-
Flammable liquid	Not triggered	-
Oxidising	Not triggered	-
Corrosive	Not triggered	-
Toxic		
Acute oral	Not triggered	-
Acute dermal	Not triggered	-
Acute inhalation	Not triggered	-
Skin irritation	Triggered	6.3A
Eye irritation	Triggered	6.4A
Sensitisation	Not triggered	-
Mutagenic	Not triggered	-
Carcinogenic	Not triggered	-
Reproductive/Developmental	Not triggered	-
Target organ/Systemic	Not triggered	-
Ecotoxic		
Aquatic	Triggered	9.1D
Soil	Not triggered	-
Terrestrial vertebrate	Not triggered	-
Terrestrial invertebrate	Not triggered	-
Biocides	N/A	N/A

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 and check that they are the same as those on the reference substance(s). 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 if there are any risks to be assessed. See Section 4.
(Optional) (See comments under "Section 3.4 of Form" in the User Guide)

	Default controls on JG1122	Controls on the reference product
Toxic Property Controls	T1, T2, T4, T5, T7,	T2, T4, T5, T7
Identification	I1, I9, I11, I16, I19, I21, I28, I29	I1, I2, I3, I9, I10, I11, I16, I17, I18, I19, I21, I22, I28, I29, I30
Packaging	P1, P3, P13*, PS4	P1, P3, P13*, P14, PG3
Disposal	D4, D5, D6, D7, D8	D4, D5, D6, D7, D8
Emergency management	EM1, EM6, EM7, EM8, EM11, EM12, EM13	EM1, EM2, EM6, EM7, EM8, EM11, EM12, EM13
Ecotoxic Property Controls	E1,E2, E6	E2, E6
Tracking	-	-
Approved Handler	-	-

*Regulations 19(2) and (3) only apply

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

Similarity of use is not one of the criteria for a rapid assessment, but comparaive information is still required. This is because if uses are significantly different, risks may differ even if the hazardous properties are similar. Information on other aspects of "whole of life history" through to disposal are also required.

(See comments under "Section 3.5 of Form" in the User Guide)

Raw materials 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 the substance will be manufactured according to GMP. Storage of the finished product will be in the Bomac Laboratories Ltd warehouse. Transportation to customers (wholesalers, vet clinics and rural re-sellers) may be by road, rail or sea. The substance will be labelled with instructions for the end-user regarding storage and directions for use. Do not contaminate surface water or drains with substance or used containers. The local or regional council should be contacted regarding disposal options. Preferably dispose of the product by use. Otherwise dispose of the product and packaging in an approved landfill or other approved facility. It is unforeseeable that the substance will be used for any other reason and there are no known adverse effects from unintentional use.
The information on packaging and use of the substance are confidential and are provided in the Appendix.

Section Four: Identification and Assessment of any Significant Variations in Risk between the Proposed Substance(s) and the Reference Substance(s)

It is noted that full risk assessments may not be required in the case of a "similar substance" rapid assessment application. It is sufficient to provide information which is able to confirm that any risks are "similar" to the risks posed by the reference substance(s).

You should compare and contrast the risks of the substance(s) for which this application is made with that of the reference substance(s). If the hazardous properties are similar then any difference should arise from differences in exposure scenarios.

In providing this analysis, applicants should have regard to the definition of environment and all the matters set out in Part II of the Act.

The formulation of JG1122 is based on a combination of known active ingredients, which are already present in New Zealand in products designed for similar purposes, therefore the risks associated with this substance, when used with controls, are insignificant.

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

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)

N/A

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.

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)

JG1122

7.2 Purpose of the application for the public register:

This should include (in a maximum of 255 characters) an abstract giving information on the intended use of the substance and why an application is needed based on its hazardous properties.
(See comments under "Section 7.2 of Form" in the User Guide)

To import or manufacture JG1122 as a veterinary medicine for the treatment of infections in all species.

7.3 Use Categories of the substance(s):

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

- Main category: There are four main categories - see User Guide for details.
- Industry category: There are 16 industry categories - see User Guide for details.
- Function/Use category: There are 55 function/use categories - see User Guide for details.

(Optional) (See comments under "Section 7.3 of Form" in the User Guide)

Main category	3 – Non-dispersive use
Industry category	1 – Agricultural industry

Function/Use category	41 – Pharmaceuticals Subcategory – Veterinary Medicine

7.4 Executive Summary:

In this section, you are required to provide a summary of the significant components of the application. This information **will be** available for public scrutiny and as such should not contain any commercially sensitive or confidential material. The information required for this section includes a summary of:

- the identification of the substance(s), its hazardous properties and intended uses, and its disposal,
- any information on the significant risks (adverse effects) of the substance(s),
- the similarities and differences between this substance(s) and the previously approved substance(s).

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

This application is being made to gain approval for JG1122, which is a veterinary medicament, to be manufactured and released for sale in New Zealand. Products containing the same active ingredients are already on the market; however this formulation has not been notified as a toxic substance and therefore requires assessment according to the HSNO Act. JG1122 triggers the thresholds for skin irritation (6.3A), eye (6.4A) irritation, and aquatic ecotoxicity (9.1D).

The formulation of JG1122 is based on a combination of known active ingredients, which are already present in New Zealand in products designed for similar purposes, therefore the risks associated with this substance, when used with controls, are insignificant. The main risks associated with this product are those to production workers if not handled appropriately, or to aquatic organisms in the case of accidental spills or inappropriate disposal. The magnitude of these risks are judged to be minimal as these events are highly improbable and in the event that they did occur would be localised and of short duration due to the nature of the final product and packaging.

These risks will be further controlled by the product labelling, which will instruct the end-user on storage, directions for use and disposal of the product. The end user will be instructed to contact the local or regional council regarding disposal options and not to contaminate surface water or drains with substance or used containers. Preferably the product should be disposed of by use, otherwise the product and packaging should be disposed of in an approved landfill or other approved facility. It is unforeseeable that the substance will be used for any other reason and there are no known adverse effects from unintentional use. Therefore the risks resulting from this product will be insignificant.

JG1122 will not pose any economic, social or environmental cost. The introduction of this product to the market will simply increase market choice. This increased choice may translate into cheaper prices and JG1122 will also have a number of benefits in terms of animal health and welfare.

The details of the intended use of the substance are provided in the Appendix.

CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes
Initial fee enclosed	No-please invoice
Application signed and dated	Yes
Electronic copy of application e-mailed to ERMA NZ	Yes

Signature and Statutory Declaration

I, _____[full name], of

_____ [Address],

_____[Occupation/position]
being the applicant or authorised to do so on behalf of the applicant, verify that the information contained in this application is true and correct. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

_____
Signature

Declared at _____on this _____day of _____, 200____ before me:

_____
Signature

_____
[Name] Barrister or Solicitor of the High Court of New Zealand
[or Justice of the Peace, Notary Public, or other person authorised to take a statutory declaration]