

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TĀIAO



FORM HS3

Application for approval to IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE IN CONTAINMENT

under section 31 of the
Hazardous Substances and New Organisms Act
1996

Name of Substance(s):

Applicant:

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 E of the User Guide covers applications under Section 31 of the Act and all of the cross references to this guide that are in this application form relate to Part E.
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 a range of substances for similar purposes to be tested in a field trial.
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:

Address:

Phone:

Fax:

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

Address:

1.3 Name of the contact person for the application :

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

Name:

Position:

Address:

Phone:

Fax:

Email:

Section Two – Application Type and Related Approvals Required

This form is only to be used for an application to import a hazardous substance into containment or manufacture a hazardous substance in containment.

If you are making the application for some other reason, you will need a different form.

2.1 Is this application to manufacture or import a hazardous substance in containment for any of the following purposes:

Containment applications can only be made for a limited range of purposes. In particular it is not intended for commercial manufacture or sale.
(See comments under “Section 2.1 of Form” in the User Guide)

- Small amounts of any hazardous substance for use as an analytical standard where approval to import or manufacture that substance has been declined? Yes/No
- Research on any hazardous substance to acquire information for use in assessing that substance for a HSNO approval? Yes/No
- Research and development on any hazardous substance? Yes/No
- Use in an emergency? Yes/No
- Other purposes? Yes/No

2.2 If you answered yes to one of the purposes listed above, please provide some supporting detail. If you answered yes to “other purpose”, describe the purpose and explain why this purpose is appropriate to a containment application. (See comments under “Section 2.2 of Form” in the User Guide)

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 the substance(s) only? Yes/No
- Manufacture the substance(s) only?
Yes/No
- Import and manufacture the substance(s)?
Yes/No
- If import only, indicate whether or not manufacture is likely in New Zealand
Yes/No

2.4 If the information in the application relates to manufacture of the substance(s) in New Zealand, provide information on the proposed manufacturing process and any alternatives.
(See comments under “Section 2.4 of Form” in the User Guide)

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	Yes/No/NA
Food Act 1981	Yes/No/NA
Medicines Act 1981	Yes/No/NA
Chemical Weapons (Prohibition) Act 1996	Yes/No/NA
Radiation Protection Act 1965	Yes/No/NA
Biosecurity Act 1993	Yes/No/NA
Resource Management Act 1991	Yes/No/NA
Other (please specify):	Yes/No
	Yes/No

Section Three – Information on the Substance(s)

Note all information that is commercially sensitive must be attached as an Appendix. The application form should be cross-referenced to the Appendix but should be able to be read as a stand-alone document which will be publicly available.

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 enough information to unequivocally identify the substance(s) and may include:

- Chemical Name (Chemical Abstracts Preferred Index name or IUPAC name)
- Common Name
- Synonyms
- Trade Names
- Molecular Formula
- Structural Formula
- CAS Registry Number
- 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)

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)

**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 should consider each of the six hazardous properties below and provide information on those hazardous properties. This information is needed in order to assess risks and determine whether or not and how the substance can be adequately contained.

- 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)

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

The information provided needs to reflect the containment character of the application. It will be used in the development of exposure scenarios and the assessment of risks and hence the specification of the containment conditions.

(See comments under “Section 3.4 of Form” in the User Guide)

3.5 Provide information on the quantity of the substance proposed to be imported or manufactured.

This information is used in the development of exposure scenarios and the assessment of risks.

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

Section Four – Information on the Proposed Containment System

4.1 Provide information on the proposed containment system.

It is essential that good information is provided on the containment system because the adequacy of containment in conjunction with the hazardous properties of the substance will have a major impact on whether or not approval is given.

You will need to provide a description of the containment proposed AND information on how you intend to address the following issues (proposed controls):

- methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility.
- methods for excluding unwanted organisms from the facility or to control organisms within the facility
- methods for excluding unauthorised people from the facility
- methods for preventing unintended release of the substance by experimenters
- methods for controlling the effects of any accidental release of the substance
- inspection and monitoring requirements of the containment facility

A management plan may be attached as an appendix. This plan should specify the procedures for implementing the above methods for containing the substance(s), and provide details of the qualifications of the person responsible for implementing those controls.

(See comments under “Section 4.1 of Form” in the User Guide)

Section Five: Identification and Assessment of Risks

In completing this section, it is important that you take account of the proposed containment system you described in Section 4. We are particularly interested in knowing about risks that may still remain with the containment system in place. You will need to consider the effects on the environment and public health including any social effects. For more details see comments under “Section Five of Application Form” in the User Guide.

You should also take account of the quantity of material involved and the number of different locations that may be involved.

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.

5.1 Identify all of the risks of the substance(s).

Include information on potentially significant possible risks of the substance and whether or not these risks are likely to be significant. 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 of exposure. Risks should be considered in relationship to:

- the sustainability of native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health (including occupational exposure)
- the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga
- the economic and related benefits to be derived from the use of the hazardous substance
- New Zealand’s international obligations.

(See comments under “Section 5.1 of Form” in the User Guide)

5.2 Provide an assessment of the potential risks identified in Section 5.1.

An explicit risk assessment only needs to be provided for those risks which might be significant. The assessment should consider whether the identified risks can be adequately managed by the proposed containment system and the substance(s) itself adequately contained.

The assessment should include the nature, probability of occurrence and magnitude of each adverse effect. The uncertainty bounds of the information contained in the assessment should also be discussed.

(Optional) (See comments under “Section 5.2 of Form” in the User Guide).

Section Six – International Considerations

- 6.1 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 6.1 of Form” in the User Guide)

Section Seven – Miscellaneous

7.1 Provide a glossary of scientific and technical terms used in the application.
(See comments under “Section 7.1 of Form” in the User Guide)

7.2 Provide here any other information you consider relevant to this application not already included.
(See comments under “Section 7.2 of Form” in the User Guide)

Section Eight – 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.

8.1 Name of the substance(s) for the public register:

Please use a maximum of 80 characters.

(See comments under "Section 8.1 of Form" in the User Guide)

8.2 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 8.2 of Form" in the User Guide)

8.3 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 8.3 of Form" in the User Guide).

8.4 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, intended uses, and disposal
- an assessment of the adverse effects of the substance
- information on the proposed containment

(See comments under "Section 8.4 of Form" in the User Guide)

CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes/ NA
Initial fee enclosed	Yes
Application signed and dated	Yes
Electronic copy of application e-mailed to ERMA NZ	Yes

Signed

Date

Appendix 1. Commercially Sensitive Information