ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

ERMA New Zealand

FORM HS1

Application for the REASSESSMENT of a HAZARDOUS SUBSTANCE

under section 63 of the Hazardous Substances and New Organisms Act 1996

Name of Substance(s):

1080 (sodium fluoroacetate) and substances containing 1080

Applicant:

Animal Health Board and
Director General of the Department of Conservation

Office use only

Application Code: ☐☐☐☐☐☐☐☐ Date received:____/____/____

ERMA NZ Contact: _____ Initial Fees Paid: $

Application Version No: _____.

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: Animal Health Board (Inc) (AHB) & Director General of the Department of Conservation (DOC)

Address: AHB: Level 9, Guardian Trust House, 15 Willeston Street, PO Box 3412, Wellington
Ph: 04 472 2858 Fax: 04 473 8786

DOC: 59 Boulcott Street, PO Box 10-420, Wellington
Ph: 04 471 0726 Fax: 04 471 1082

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:	William McCook	Alastair Morrison
Position:	Chief Executive	Acting Director General
Address:	as above	as above
Phone:	04 472 2858	04 471 0726
Fax:	04 473 8786	04 471 1082
Email:	mccookw@ahb.org.nz	amorrison@doc.govt.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.

2.1 Is the information in this application relevant to import, manufacture or both:
(See comments under "Section 2.1 of Form" in the User Guide)

- Import only? ~~Yes~~/No
- Manufacture only? ~~Yes~~/No
- Import and manufacture? Yes/~~No~~
- If import only, indicate whether or not manufacture is likely in New Zealand N/A

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 Section 3.5 Lifecycle, for description of manufacturing process in New Zealand.

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)

N/A

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)

Existing approvals are in place under the Agricultural Compounds and Veterinary Medicines Act 1997

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.

1080 Substances to be Reassessed

Sodium fluoroacetate (referred to as technical grade **active**)

Paste containing **0.6 – 0.8 g/kg** sodium fluoroacetate

Paste containing **1.5 g/kg** sodium fluoroacetate

Paste containing **10 g/kg** sodium fluoroacetate

Pellets containing **0.4 – 0.8 g/kg** sodium fluoroacetate

Pellets containing **1.0 g/kg** sodium fluoroacetate

Pellets containing **1.5 – 2.0 g/kg** sodium fluoroacetate

Gel containing **1.5 g/kg** sodium fluoroacetate

Gel containing **50 g/kg** sodium fluoroacetate

Gel containing **100 g/kg** sodium fluoroacetate

Stock solution containing **200 g/litre** sodium fluoroacetate

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)

See Section 3.1 of Application

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)

See Section 3.2 of Application

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).

See Section 3.3 of Application

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)

See Section 3.4 of Application

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)

See Section 3.5 of Application

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.

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)

See Section 4.1 of Application

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)

See Section 4.2 of Application

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)

See Section 4.3 of Application

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)

See Section 4.4 of Application

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 mean of managing risks.. The information provided must be specific to the substance(s) and cover all areas of intended use. Reference should be made to Codes of Practice or standard operating procedures that will be followed. If changes to the default controls triggered by the substance classification are proposed, the reasons for these changes should be provided.

Please note that you will find it easiest to complete this section in conjunction with section 4.2. That is because the management of risks will influence their residual level.
(See comments under "Section 4.5 of Form" in the User Guide)

See Section 4.5 of Application

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)

See Section 4.6 of Application

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)

See Section 5 of Application

Section Six – Miscellaneous

6.1 **Provide a glossary of scientific and technical terms used in the application.**
(See comments under "Section 6.1 of Form" in the User Guide)

6.2 **Provide here any other information you consider relevant to this application not already included.**
(See comments under "Section 6.2 of Form" in the User Guide)

See Section 6 of Application

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)

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)

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)

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)

See Section 7 of Application

CHECKLIST

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

Signed S Clarke Date 16 October 2006

SARA CLARKE
PROJECT MANAGER FOR REASSESSMENT