

ERMA NEW ZEALAND

INFORMATION SHEET

NUMBER 14
MAY 2001

Determining the status of a substance – do I need to get an approval?

Introduction

Under the HSNO Act, anybody who wants to manufacture or import a hazardous substance into New Zealand **for the first time** will need to get an approval for that substance. However, there are a number of circumstances under which an approval is not required. You do not need to get an approval if:

1. your substance is not hazardous; or
2. your substance is exempt or excluded from the provisions of the HSNO Act; or
3. your substance was legally existing in New Zealand before 2 July 2001.

This information sheet will give you some simple guidance to help you determine whether or not the substance you intend to import or manufacture meets any of the above criteria. If, after reading this information sheet, you are unable to determine if you need to get an approval, you may need to seek further advice – check with a Hazardous Substances Applications Officer at ERMA New Zealand.

What is a hazardous substance?

The HSNO Act defines substances very broadly. A substance can be a single chemical or it can be a mixture of chemicals (a formulated product). A **hazardous** substance is broadly defined as one that is flammable, explosive, corrosive, oxidising, or is harmful to people (toxic) or harmful to the environment (ecotoxic). A manufactured article that contains a substance with explosive properties (such as a flare or detonator) is also defined as a hazardous substance for the purposes of the HSNO Act.

Is my substance exempt from the HSNO Act?

If your substance is exempt or excluded from the provisions of the HSNO Act, you do not need to get an approval. The following exemptions are provided for:

Exemption for small-scale use of hazardous substances in research and development or teaching:

Substances that are imported into, or manufactured in New Zealand in small amounts for scientific investigation, teaching, or research and development are exempt from the HSNO Act, providing they are made or kept in laboratories that meet the requirements of the *Hazardous Substances (Exempt Laboratories) Regulations*. In essence, this means that if you meet these requirements, you do not need to make an application for approval. Further information on this exemption can be found in *Information Sheet on Exemptions from the Provision of the HSNO Act for Small-Scale Research on Hazardous Substances*.

Food and Medicines

A food (in ready to eat form) is defined as not hazardous for the purposes of the HSNO Act. However, food additives (which are hazardous substances) that have not been mixed with or added to the food are not exempt from the Act.

Medicines (with some exceptions) are also exempt from the provisions of the HSNO Act.

Is my substance otherwise excluded from the HSNO Act?

Manufactured articles that contain a hazardous substance (with properties other than explosives) are **not** considered to be substances under the HSNO Act (e.g. a battery is not a hazardous substance). However, products such as glues, paints, or pesticides are substances regardless of their type of container. The difference is that a manufactured article is something for which its intended use is mainly to do with its design or physical shape, rather than its chemical composition. Our information sheet on *Manufactured Articles* expands on this definition and gives examples.

The HSNO Act does not cover **radioactive substances** (UN Class 7) unless they are flammable, explosive, corrosive, oxidising, toxic, or ecotoxic.

Infectious substances (UN Class 6, Division 6.2) are also not covered by the hazardous substances part of the HSNO Act.

The generation of **hazardous wastes** is not something that normally requires a separate approval under the HSNO Act. However, if you intend to import a hazardous waste (that is also a new substance) for disposal or for any other purpose within New Zealand, you **will** need to get an approval. More detail on the Authority's policy position on hazardous wastes is contained within the Series 2 Protocol *Interpretations and Explanations of Key Concepts* available on our website, www.ermanz.govt.nz or in hard copy from our office.

Is my substance hazardous?

In most cases it will be relatively easy to determine if a substance is hazardous or not by checking the documentation and labelling which comes with the substance. For example, if the substance has a UN number, it is regulated for transport and it is probably hazardous. It is also probably hazardous if the Material Safety Data Sheet or label contains any risk or safety phrases or precautionary statements.

If at first glance you think that the substance is hazardous, you should then check to see if it is covered by an existing approval (i.e. it is legally existing in New Zealand). If you are not sure about whether it is hazardous or not, you should still check to see if it is covered by an existing approval before proceeding to an assessment of the substance against the HSNO hazardous property thresholds (see section below on the HSNO thresholds).

How can I check if my substance is covered by an existing approval?

In the long term, the first place to check whether or not your substance has already been approved is the ERMA New Zealand public register. The Register is available for inspection at our offices in Wellington during ordinary office hours and is also accessible through our website www.ermanz.govt.nz.

However, the register will be empty initially because no approvals will have been given under Part V of the Act, and no existing approvals will have been transferred.

In the short term, there are a number of lists that you can check as a first step toward finding out if a substance is covered by an existing approval. However, these lists may not be complete. They are:

- Authorised Explosives listed on the Explosives Authorisation Order 1994 (administered by OSH, Department of Labour)
- Registered pesticides and licensed animal remedies currently listed on databases administered by the ACVM Group, Ministry of Agriculture and Forestry

ERMA New Zealand has also compiled a composite list of the single component substances so far identified for transfer. This list contains identified dangerous goods covered in Part C of the Seventh Schedule to the HSNO Act, scheduled toxic substances which are specifically listed in the schedules to the Toxic Substances regulations, and common (notified more than 5 times) notified toxic substances (NOTS). You can view a copy of the list on our website www.ermanz.govt.nz

In addition to these lists, ERMA New Zealand has a database of toxic substances that have been notified under section 32 of the Toxic Substances Act (NOTS). Because of conditions of confidentiality, this database is not publicly searchable, and users, manufacturers or importers of hazardous substances that they have not notified themselves may need to check with ERMA New Zealand on the status of the substance.

You can request that ERMA New Zealand check their records (the Register or the NOTS database), but you will need to provide sufficient information in order for us to do so. The minimum information you will need to provide for each substance is full compositional details (the chemical name, (including the Chemical Abstracts name, trade names or synonyms) CAS registry number, and percentage of all the components, including impurities). In some cases, there may be a charge for this service – check the latest version of our *Fees and Charges Schedule* contained in the ERMA *Quick Guide to our Fees and Charges*, or ask a Hazardous Substances Applications Officer at ERMA New Zealand.

Does my substance trigger the HSNO hazardous property thresholds?

If your substance does not fit into any of the categories above, you will need to determine whether or not it is hazardous before making an application for approval. In HSNO terms, a substance is considered hazardous if it triggers any one of the threshold levels defined in the *Hazardous Substances (Minimum Degrees of Hazard) Regulations* for any of the hazardous properties – explosiveness, flammability, oxidising capacity, corrosiveness, toxicity or ecotoxicity.

There are several options for finding out if your substance triggers any of the hazardous property thresholds:

1. You can carry out the determination yourself - ERMA New Zealand has developed some guidance material in the form of the *User Guide to HSNO Thresholds and Classifications*, (available in short (summary) or long form) which will help you to assess substances against the thresholds and to decide whether or not the substance is hazardous;
2. You can employ a consultant to do the work for you; or
3. You can ask ERMA New Zealand to carry out the determination for you (see the following section)

The *User Guide to HSNO Thresholds and Classifications* is available from our offices or can be accessed through our website www.ermanz.govt.nz.

Formal determination of the status of a substance

You can apply to the Authority for a formal determination as to whether or not a substance is a hazardous substance. This is published in the Gazette and formally recorded on our statutory register. However, we will charge for this service and the initial timeliness of response will be constrained by our own technical staff resources. A request for a formal determination should therefore be made well in advance of any need to import or manufacture a substance.

You will need to provide sufficient information in order to unequivocally identify the substance. An indication of the type of information required for a substance is:

- Full compositional details (the chemical name, (preferably the Chemical Abstracts Preferred Index name) CAS registry number, and percentage of all the components, including impurities).
- The chemical and physical properties of the substance
- Information on the hazardous properties of the substance

For mixtures or formulated products, information on the properties of the mixture or product is preferred, but if this information is not available, you should provide such information on each of the components of the substance.

In the longer term

Over the 3-5 years following commencement of the hazardous substances provisions of the HSNO Act, we will be progressively transferring existing substances to the framework of the HSNO Act. As this happens, the substances that legally existed in New Zealand before 2nd July 2001 will be transferred to the Register, so determining the HSNO status of substances will become simpler.

Where can I get further information?

Our publications are available free for downloading off our website www.ermanz.govt.nz. Alternatively we can send them to you, but there may be a charge for this. For further information contact:

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ERMA NEW ZEALAND INFORMATION SHEETS:

ERMA New Zealand publishes information sheets on a range of topics to provide background information on current issues or proposals being dealt with by the Authority.

Please feel free to photocopy this material. Acknowledgement of ERMA New Zealand would be appreciated.

The information sheets are available from

ERMA New Zealand, PO Box 131 Wellington. Phone: 64 4 473 8426. Fax: 64 4 473 8433. Email: info@ermanz.govt.nz

The information sheets can also be viewed and downloaded on our website at www.ermanz.govt.nz