Summary User Guide to the HSNO Thresholds and Classifications of Hazardous Substances

June 2001

$15.00

ER-UG-04-1 6-01

Summary User Guide to the HSNO Thresholds and Classifications

Preface

The Hazardous Substances and New Organisms (HSNO) Act 1996 reforms and restates the law relating to the management of hazardous substances and new organisms in New Zealand. With particular reference to hazardous substances, the HSNO Act replaced the Dangerous Goods Act 1974, the Explosives Act 1957, the Pesticides Act 1979 and the Toxic Substances Act 1979 upon commencement on 2 July 2001. The Regulations associated with the replaced Acts are initially carried across into the transitional provisions of the HSNO Act. The reforms will be complete once the transitional period (three years from commencement, plus a possible two year extension) expires.

A key feature to the management of hazardous substances under the HSNO Act is determining what substances are classed as 'hazardous substances'.

The initial responsibility for making this judgement rests with the importer, manufacturer or user of the substance. To assist you in making this decision ERMA New Zealand has prepared this User Guide. This is a summary guide. More detailed explanation and interpretation of the hazardous property thresholds and classification system can be found in the ERMA New Zealand *User Guide to the HSNO Thresholds and Classifications*. The determination as to whether a substance is 'hazardous' is not only a technical determination but also a legal one. The manufacture, importation or use of a hazardous substance **without an approval** is an offence under section 25(1) of the HSNO Act. If a company is using a hazardous substance, otherwise than in accordance with a HSNO Act approval, it could be prosecuted by a HSNO enforcement agency such as Occupational Safety and Health (OSH).

Therefore, we strongly recommend that if, after completing an evaluation, you decide that your substance is not hazardous you thoroughly document your reasons. You may also wish to obtain expert advice to support your decision. Please do not send your evaluation to ERMA New Zealand for validation. ERMA New Zealand will only make determinations in special circumstances[1].

However, if you conclude that your substance is hazardous you will need to come to ERMA New Zealand for an approval. If you are considering making an application to import or manufacture it, our staff will be happy to provide advice. You may obtain more information on the HSNO Act and ERMA New Zealand procedures from our website **www.ermanz.govt.nz**.

[1] These circumstances include the determination of whether or not a substance is a hazardous substance under s.26 of the HSNO Act and Regulations made under section 75(1)(g) of the HSNO Act declaring a substance not to be hazardous for the purposes of the Act. See *Information Sheet 14: Determining the Status of a Substance*

Contents

1. Introduction

This summary guide provides a framework to determine whether a substance is hazardous and, if so, how it will be classified subject to the requirements of the Hazardous Substances and New Organisms (HSNO) Act 1996.

Hazardous substances occur in many parts of our daily lives. They include a wide range of materials such as petrol, pesticides, bleaches, some paints, dishwashing powders, various industrial solvents, fireworks, medicines, flea powders, dynamite, liquefied petroleum gas (LPG), and many more.

The HSNO Act has a very broad definition of **'substance'**. It may be a pure chemical element or compound, it may be a mixture of compounds (often called a product) or it may be a mixture of compounds with the components specified in defined ranges (eg a product range). When you are considering how to define your substance you will need to consider these aspects and define it in accordance with the HSNO Act.

A substance is considered to be a **'hazardous substance'** when it triggers any one or more of the thresholds (minimum degrees of hazard) of the following intrinsic properties:

Explosiveness
Flammability
Oxidising capacity
Corrosiveness
Toxicity
Ecotoxicity

The thresholds and classification schemes for explosiveness, flammability and oxidising capacity are based on the United Nations Recommendations for the Transport of Dangerous Goods (UNRTDG). The thresholds and classification schemes for corrosiveness, toxicity and ecotoxicity are based on OECD Advisory Group for the Harmonisation of Classification and Labelling, as part of the Global Harmonisation System (GHS). The thresholds and classification categories reflect the international trend towards harmonisation.

The HSNO Act states 'no hazardous substance shall be imported or manufactured otherwise than in accordance with an approval issued under this Act or in accordance with Parts XI to XVI of this Act'. These latter Parts refer to the transitional provisions for existing pesticides, toxic substances, dangerous goods and explosives.

The responsibility for making a judgement as to whether a substance is hazardous rests with the importer or manufacturer of the substance. You are required to assess each substance that you wish to import, or manufacture in New Zealand, for each of the above properties. The Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 (henceforth referred to as the Threshold Regulations), set the level of hazard below which any substance is not considered hazardous. This guide aims to assist you to interpret the Threshold Regulations, apply them to your substance and help you to decide whether or not your substance is hazardous.

If the substance you wish to import or manufacture is hazardous you will need to make an application for approval under the HSNO Act.

During the application and consideration process the substance will be classified, following the criteria contained in the *Hazardous Substances (Classification) Regulations* 2001, in accordance with its intrinsic properties and the degrees of hazard of those properties. Then, if approved by the Authority after evaluation of the risks posed by the substance or as part of the transfer process, the controls prescribed for those hazard classifications will be assigned to the substance.

If it is not a **hazardous** substance, the provisions of the HSNO Act do not apply.

This guide also contains an overview of the criteria contained in the *Hazardous Substances (Classification) Regulations* 2001 for prescribing the types of hazard and the number of degrees of hazard for these for each of the hazardous substance properties.

2. How to use this guide

The guide has separate sections for each hazardous property. While some substances will only be hazardous for one property, many other substances will trigger more than one threshold in different hazardous properties. Therefore it is necessary to evaluate each substance against the thresholds in each section. This evaluation can be a moderately complex technical task.

We have developed this summary guide on the presumption that you have sufficient scientific and technical knowledge and experience to determine whether a substance is hazardous or not. It requires you to address each hazardous property individually and to address the specific criteria within each property that may trigger the threshold. If you do not have the ability to address the technical issues, you should seek advice from people who do. ERMA New Zealand has developed the *User Guide to the HSNO Thresholds and Classifications* to assist in the interpretation of the threshold and classification requirements. This User Guide contains a considerably greater amount of detail to assist in this process.

To evaluate a substance you should collect as much relevant information about the characteristics of the substance as you reasonably can. You should then compare this information with the criteria in each property threshold. An inability to access the information does not necessarily mean there is no such information. If you do not have adequate information you will have to use technical judgement, and answer questions including:

- do similar substances have properties that would give reliable guidance?
- is it plainly unreasonable to expect the substance to have such a property?
- Should this gap be referred to an expert in the field?

If a substance does not trigger any of the thresholds, it is not 'hazardous' and does not need an approval from the Authority. However if a substance does trigger a threshold level, then it cannot be imported or manufactured in New Zealand other than in accordance with an approval from the Authority. If your substance is hazardous, you will need to make an application prior to importing or manufacturing it. Further information about the application process can be obtained from ERMA New Zealand, particularly *Quick Guide to Applying for a Hazardous Substance Approval* and *Quick Guide to Making Applications*.

2.1 Mixtures

As mentioned in the introduction, the definition of 'substance' includes mixtures. This section indicates how the hazardous property thresholds can be applied to substances that are multi-component chemical products.

When test data is available on a mixture (eg a product or preparation), then this data will generally be used to evaluate and classify the product as if it were a single chemical substance. The *User Guide to the HSNO Thresholds and Classifications* provides guidance on how to classify mixtures based on data available for the whole substance.

The term 'mixture' is used for substances that are combinations of two or more single chemical entities, which have not reacted to form other chemical entities at the time of classification. A 'single chemical entity' is any material that has been identified separately for hazard classification purposes. For example, certain petroleum products are identified as if they are a single substance, but in fact are mixtures of separately identifiable chemicals that have similar properties such as boiling point. Nevertheless, these mixtures are traded in commerce as single chemical products, are evaluated as single chemical entities, and are identified by the Chemical Abstracts Service as single chemical entities. These mixtures are therefore regarded as single substances.

Recognising that most mixtures have not been tested as a whole for health or environmental hazards, there are several international systems that permit the evaluation of the hazards of mixtures from the properties and concentrations of the components. These systems are referred to as 'mixture rules'. Calculation rules for combining information about the components of the mixture and/or estimation techniques will be accepted as a means of establishing whether or not a given substance triggers a threshold. Guidance in the *User Guide to the HSNO Thresholds and Classifications* details how, and when to apply these mixture rules. Comments on how to deal with mixtures are given, where appropriate, in each section of this guide.

2.2 Substance evaluation sheet

A 'Substance Evaluation Sheet' is provided to guide you through the process of assessing whether a substance is hazardous under the HSNO Act. The sheet helps you to consider if you have the necessary information and leads you through an assessment of the substance for each hazardous property. It has been designed so that one sheet is used for each substance. You may either copy the sheet, or obtain further copies from ERMA New Zealand, or download it from the website **www.ermanz.govt.nz**. By working through the evaluation sheet in conjunction with this guide, you should be able to decide whether your substance is a hazardous substance. The guide and evaluation sheet are for your own use. Please do not send your evaluation to ERMA New Zealand for validation.

2.3 Description of thresholds and classification systems

The thresholds for the HSNO hazardous properties are set out in Schedules 1 to 6 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. Regulation 4 of those regulations states that a substance is not hazardous for the purposes of the HSNO Act unless data indicates it meets the minimum degrees of hazard for at least one of the intrinsic hazardous substance properties specified.

In those regulations, 'data' is defined as including 'values that are directly measured, calculated, or estimated for any of the measures given'. This means that it is not necessary to rely only on directly measured data to determine if a substance exceeds any of the hazardous property threshold criteria. It may be possible to calculate a relevant parameter for a substance based on the directly measured values available on its components by making use of 'mixture rules' (see above). Alternatively, a relevant parameter for a substance may be estimated based on the similarity of that substance to another substance for which the hazardous properties are known.

The classification systems for the HSNO hazardous properties are set out in Schedules 1 to 6 of the *Hazardous Substances (Classification) Regulations* 2001. The classification systems comprise numbered classes (eg Class 6) indicating the intrinsic hazardous property, numbered subclasses (eg Subclass 6.1) indicating the type of hazard, and lettered categories (eg Category A) indicating the degree of hazard. An exception to this is with explosive substances where they are classified into both a Subclass, indicating the type of explosive hazard, and a Category, indicating compatibility groupings, in the combinations permitted by the UN Recommendations on the Transport of Dangerous Goods Model Regulations. Categories for explosive substances do not indicate the degree of hazard.

The combination of numbers and letters used in the classification system (eg 6.1A) constitutes a hazard classification of a substance.

The classes for the hazardous properties are as follows:

Class 1	Explosiveness
Class 2	Flammability, gases
Class 3	Flammability, liquids
Class 4	Flammability, solids
Class 5	Oxidising capacity
Class 6	Toxicity
Class 8	Corrosiveness
Class 9	Ecotoxicity.

Class 7 is unallocated in the HSNO classification system as it is reserved for radioactivity which is outside the scope of the HSNO Act. Class 7 is used in the United Nations Transport of Dangerous Goods classification system for radioactive materials. In New Zealand, these substances are covered by the Radiation Protection Act which is administered by the National Radiation Laboratory of the Ministry of Health.

Similarly, Subclass 6.2 is unallocated in the HSNO classification system for toxicity, as it is reserved in the UN Transport of Dangerous Goods classification system for infectious substances. These are also outside the scope of the hazardous substances part of the HSNO Act.

All of the HSNO hazard classifications can be seen in the tables presented in Appendix 1.

2.4 Substances Excluded from the HSNO Act

Medicines

Medicines are excluded from the HSNO Act unless the substance is already captured by the transitional provisions of the Act as a toxic substance, dangerous good or explosive, or unless the substance is a gas contained at a pressure greater than 170 kPa in a container larger than 100 mL, prior to the time the gas is administered to a person for a therapeutic purpose.

However, new medicines are not excluded from the Act if they meet any of the threshold criteria and are either a substance to which section 3(1)(b) of the Medicines Act 1981 applies

(that is, they are an ingredient of a medicine) or an application is made to also register the substance as a veterinary medicine under the ACVM Act 1997.

Food

Foods, in a ready to consume form, which may meet the hazardous property thresholds are excluded from the HSNO Act unless the substance is already captured by the transitional provisions of the Act as a toxic substance, dangerous good or explosive.
Food additives are not excluded from the Act, if they meet any of the threshold criteria and if they have not been mixed with or added to any other food or drink which is in a ready to consume form.

2.5 Key definitions

The following key definitions are used in the Hazardous Substances (Minimum Degrees of Hazard) Regulations and the Hazardous Substances (Classification) Regulations:

data	*includes values that are directly measured, calculated, or estimated for any of the measures given*
gas	*a substance that:* *a) is completely gaseous at 20^{o}C and at 101.3kPa absolute pressure* *or* *b) has a vapour pressure of more than 300 kPa absolute pressure at 50^{o}C*
liquid	*a) a substance with a melting point of less than or equal to 20^{o}C at 101.3 kPa absolute pressure* *or* *b) a viscous substance, without a defined melting point (additional criteria apply)*
solid	*a substance that is neither a liquid or a gas*
test series	*when followed by a letter or number, means one or more tests as prescribed in the UN Manual of Tests and Criteria*
UN Manual of Tests and Criteria	*the 3rd revised edition of the Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria, published in 1999 by the UN (New York and Geneva)*
UN Model Regulations	*the 11th revised edition of the Recommendations on the Transport of Dangerous Goods Model Regulations, published in 1999 by the UN (New York and Geneva)*

Further definitions used in relation to specific Classes of substances in the Regulations are referenced, as appropriate, in the following sections.

3. Substances with Explosive Properties

3.1 General approach taken for the property of explosiveness

This threshold is derived from the United Nations Recommendations on the Transport of Dangerous Goods (UNRTDG) Model Regulations, 11th Revised Edition, 1999, and its companion volume, UNRTDG Manual of Tests and Criteria, 3rd Revised Edition, 1999. These are available, on order, from the United Nations via their website **www.un.org/Pubs/sales.htm** or in New Zealand (on order) from technical bookshops.

This threshold will maintain the present levels of intervention for explosive hazards used by the Chief Inspector of Explosives under the Explosives Act 1957.

3.2 Elements of the explosive threshold

It is useful to recall that the HSNO Act provides a broad definition of 'substance', which, in the case of explosive substances, includes 'any manufactured article containing, incorporating, or including any hazardous substance with explosive properties'.

There are two elements of the threshold for substances with an explosive property:

- **ability** to cause an explosive effect (explosiveness), coupled with a sufficient **likelihood** of detonation or deflagration, when stimulated (sensitiveness); and

- whether substances are **designed** to detonate, deflagrate or produce a pyrotechnic effect.

3.3 Explosive threshold technical description

If a substance meets **any one** of the following threshold criteria it is considered to be explosive within the meaning of the HSNO Act.

a) UN 'Orange Book' listing

Any substance (including manufactured articles) listed in the Dangerous Goods list in Chapter 3.2 of the UN Model Regulations, as being Class 1 (denoting it as an explosive substance)

b) Sensitiveness and explosiveness threshold

Sensitiveness measures the response of an explosive substance to some accidental stimuli. A substance is above the sensitiveness threshold if it gives a positive result to any of the three types of tests in Test Series 2 of the *UN Manual of Tests and Criteria* (p 47-66), as follows:

i) In a Type 2(a) or UN gap test (UN Manual section 12.4), when confined in the prescribed steel tube and subjected to detonative shock by initiating the prescribed booster charge, which is separated from the test substance by the prescribed spacer, the substance is able to propagate a detonation as shown by fragmenting the tube completely or punching a hole through the prescribed witness plate (UN Manual section 12.4.1.4).

ii) In a Type 2(b) or Koenen test (UN Manual section 12.5), when confined in the prescribed steel tube with a closing plate orifice of 2.0 mm or more and subjected to intense heat as prescribed, the substance is able to propagate a detonation as

shown by the tube being:
fragmented into three of more large pieces (which can still be connected by a narrow strip), or fragmented into many mainly small pieces, or fragmented into many very small pieces and the closing device bulged out or fragmented (UN Manual section 12.5.1.4).

iii) In a Type 2(c) time/pressure test of the effect of ignition (UN Manual section 12.6), when confined in the prescribed steel pressure vessel and ignited by the prescribed electric fusehead, the substance is able to produce a pressure increase from 690 to 2070 kPa absolute pressure or more, within 30 m or less (UN Manual section 12.6.1.4).

c) A substance designed to detonate, deflagrate, or produce a pyrotechnic affect

A substance designed to **detonate** will, when initiated, produce a violent chemical reaction that proceeds through the reacted material at supersonic velocity producing heat and high pressure. The result of the reaction is exertion of extremely high pressures on the surrounding medium forming a propagating shock wave of supersonic velocity. That is, the substance explodes with a sudden loud noise.
A substance designed to **deflagrate** will, when initiated or ignited, produce a chemical reaction which proceeds at subsonic velocity along the surface of, and/or through the reacted material producing hot gases at high pressures. That is, the substance bursts into flames and burns away rapidly. A deflagration under sufficient confinement results in an increase in pressure, rate of reaction and temperature, which may cause detonation.
A substance designed to produce a **pyrotechnic effect** will, when initiated, produce a non-detonative, self-sustaining exothermic chemical reaction producing an effect of heat, light, sound, smoke, gas or motion or a combination of these. Pyrotechnic effect refers to a display of fireworks, or to ignition of a substance for technical or military purposes.

d) External bonfire test for manufactured articles

This is a test performed on explosive articles or packages of explosive articles to determine whether there is a mass explosion or a hazard from dangerous projections, radiant heat and/or violent burning or any other dangerous effect when the articles are involved in a fire. An article is above this threshold if it produces some effect of projection of fragments, fire, smoke, heat, or loud noise external to the article when tested as a stack of articles in accordance with test Type 6(c) in paragraph 16.6 of the *UN Manual of Tests and Criteria* (test criteria in paragraph 16.6.1.4.7, p.155-6).

3.4 Notes on explosive thresholds

a) Acceptable test results

Apart from the criterion of being designed to detonate, deflagrate, or produce a pyrotechnic effect, this threshold specifies the UN Tests as the measure for the threshold of explosiveness. No other tests appear to be in common international usage. Accordingly, the first two sections of the threshold require test results from the UN. These thresholds require the test procedures as set out in the UNRTDG Manual of Tests and Criteria, 3rd revised edition 1999. As these methods require relatively sophisticated testing facilities, it is expected that overseas test data will be the basis for assessing applications.

b) Criterion of being designed to detonate, deflagrate or produce a pyrotechnic effect

This criterion carries over the current scope of the Explosives Act 1957. For example, the criterion covers airbag initiators and model rockets, which are designed to deflagrate, and caps (amorces), which are designed to produce sound by a pyrotechnic effect.

c) Mixture rule for explosive substances

There generally are no mixture rules that apply to explosive hazards. In general, the direct testing of mixtures for explosive hazards is required since the hazards of a mixture are not always reliably predictable from component data.

d) Screening procedures for substances which may have explosive properties

Screening procedures, involving theoretical appraisal and/or small-scale tests, can be used to identify the hazard potential of new substances which are suspected of having explosive properties without the need for the larger scale tests mentioned above. If the screening procedures indicate that there is a hazard, then the full explosive classification procedure should be applied. The screening procedures should not be used for substances expressly manufactured with the intention of producing a practical explosive or pyrotechnic effect.

Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. A substance is unlikely to have explosive properties if:

i) There are no chemical groups typically associated with explosive properties present in the molecule (examples of such groups are C-C unsaturation, C-metal, N-metal, N-N unsaturation, peroxides, N-O, N-halogen, O-halogen); or

ii) The substance contains chemical groups associated with explosive properties which include oxygen but the calculated oxygen balance is less than –200; or

iii) The organic substance or a homogeneous mixture of organic substances contains chemical groups associated with explosive properties but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500^{o}C; or

iv) For mixtures of inorganic oxidising substances with organic materials, the concentration of the inorganic oxidising substance is less than 15%, by mass, of the mixture.

e) Dust explosibility

It is important to note that otherwise inert materials with a fine particle size distribution, that posses solely a dust explosibility hazard when dispersed at above a minimum concentration in air, are excluded from the HSNO definition of an explosive substance. These substances will not pass the threshold tests for explosiveness described above.

3.5 Classification of explosive substances

The explosive property classification scheme groups explosive substances in terms of three effects:

- their degree of sensitiveness to stimuli
- their different types of explosive effect, and
- the different levels at which those explosive effects may be displayed.

Accordingly, the HSNO classification scheme adopted uses the system contained in the UN Model Regulations. Thus, the classification for substances with an explosive property is based on:

- subclasses (divisions) for types and levels of explosiveness and for sensitiveness of the substance to stimuli; and
- categories (compatibility groupings) for explosive type.

Classification requires allocation to both a subclass and a category. A substance or article is classified as being in a particular subclass or category if it meets the criteria set out in Schedule 1 of the *Hazardous Substances (Classification) Regulations* for that subclass or category. These criteria are taken from the *UN Model Regulations* and the *UN Manual of Tests and Criteria*. Substances may only be classified into the combinations of division and grouping permitted by the UN Model Regulations.

a) Explosive classification subclasses

The subclasses (divisions) for types and levels of explosive effect and for sensitiveness of the substance to stimuli are:

Subclass 1.1 Substances and articles that have a 'Mass Explosion Hazard'

Subclass 1.2 Substances and articles that have a 'Projection Hazard' but not a mass explosion hazard

Subclass 1.3 Substances and articles that have a 'Fire Hazard' and either a minor blast hazard or a minor projection hazard, or both, but not a mass explosion hazard

Subclass 1.4 Substances and articles that present 'No Significant Hazard', but a minor fire or projection hazard

Subclass 1.5 'Very Insensitive' substances that have a 'Mass Explosion Hazard'

Subclass 1.6 'Extremely Insensitive' articles which do not have a 'Mass Explosion Hazard'

b) Explosive classification categories

The classification categories (compatibility groupings) for explosive type and properties, such that substances within groups are unlikely to result in unintended detonation or deflagration when in proximity to each other, are as follows:

Category A Primary explosive substances, ie very sensitive to heat, impact or friction or able to transmit detonation or deflagration to secondary explosive substances close to it.

Category B Articles designed to be primers, detonators and detonator assemblies for blasting usually containing a primary explosive substance but not containing two or more effective protective features.

Category C Propellant explosive substances (deflagrating explosive used for propulsion) or other deflagrating explosive substances, and articles containing such explosive substances.

Category D Secondary detonating explosive substances, ie less sensitive than primary detonating substances and more sensitive than substances falling into Category N - or black powder, or articles containing such secondary detonating explosive substances, in each case without means of initiation and without a propelling charge; and articles containing a primary explosive substance and two or more effective protective features.

Category E Articles containing a secondary detonating explosive substance, without means of initiation, but with a propelling charge (other than one containing a flammable liquid or gel or hypergolic liquids which ignite spontaneously on contact with an oxidant).

Category F Articles containing a secondary detonating explosive substance with its own means of initiation, without a propelling charge or with a propelling charge (other than one containing a flammable liquid or gel or hypergolic liquids).

Category G Pyrotechnic substances, or articles containing a pyrotechnic substance, or articles containing both an explosive substance and an illuminating, incendiary, tear- or smoke- producing substance (other than a water-activated article or one containing white phosphorus, phosphides, a pyrophoric substance, a flammable liquid or gel, or hypergolic liquids).

Category H Articles containing both an explosive substance and white phosphorus (for smoke generation but represents a fire hazard from spontaneous ignition on contact with air).

Category J Articles containing both an explosive substance and a flammable liquid or gel.

Category K Articles containing both an explosive substance and a substance with an acute toxicity of HSNO classification 6.1A, 6.1B or 6.1C).

Category L A mixture or an article that contains both an explosive substance and a substance that spontaneously combusts, detonates or deflagrates if exposed to

air, water, oxidising substances or flammable substances, or generates a substance that spontaneously combusts, detonates or deflagrates when exposed to air or water.

Category N Articles containing only extremely insensitive detonating substances where extremely insensitive is as defined in the criteria for Subclass 1.6 above.

Category S Substances or articles where hazardous effects arising from their accidental functioning are confined within the package, or, where the package is degraded by fire, any blast or projection effects are so limited they would not be capable of causing bodily harm within 5 m of the articles, or any blast or projection effects are largely confined to the package.

c) Scheme of classification of substances with an explosive property

The subclasses for explosive effect are combined with the groupings for compatibility to give a classification scheme for organising controls as shown in the following table.

Categories for Explosive Type and Properties	Subclasses for Types and Levels of Explosive Hazard					
	Mass Explosion 1.1	Projection 1.2	Fire and Minor Blast/Projection 1.3	Minor Fire or Projection 1.4	Very Insensitive Mass Explosion 1.5	Extremely Insensitive 1.6
A	1.1A					
B	1.1B	1.2B		1.4B		
C	1.1C	1.2C	1.3C	1.4C		
D	1.1D	1.2D		1.4D	1.5D	
E	1.1E	1.2E		1.4E		
F	1.1F	1.2F	1.3F	1.4F		
G	1.1G	1.2G	1.3G	1.4G		
H		1.2H	1.3H			
J	1.1J	1.2J	1.3J			
K		1.2K	1.3K			
L	1.1L	1.2L	1.3L			
N						1.6N
S				1.4S		

d) Interpretation of terms used in the explosive classification system

effective protective feature *a device incorporated into an explosive article that will prevent accidental functioning during normal conditions of transport, storage or handling*

primary explosive substance *a substance that:*

(a) has the necessary sensitivity to heat, friction or shock to make it suitable for initiating secondary detonating explosive substances and articles; and

(b) when incorporated into an explosive article, is known as a primer or detonator

propellant explosive substance *a substance that deflagrates*

pyrotechnic substance *a substance that produces pyrotechnic effects*

secondary detonating explosive substance *a substance designed to detonate that requires stimulation equivalent to the detonation of a primary explosive substance to initiate it*

4. Substances with Flammable Properties

4.1 General approach taken for flammable properties

The threshold criteria for flammable hazards are largely derived from the UN Model Regulations, and its companion volume, the *UN Manual of Tests and Criteria*.

4.2 Elements of the flammable thresholds

Under the HSNO Act classification system for flammability, there are separate thresholds and classifications for substances in gas, liquid and solid form, with solid substances being further subdivided into different types of flammable property.

Overall, there are nine subclasses to the classification system for flammable substances, with corresponding threshold levels. Briefly these are:

a) ignitibility for flammable gases (subclass 2.1.1)

b) flammable components for flammable aerosols (subclass 2.1.2)

c) ignitibility for flammable liquids (subclass 3.1)

d) liquid desensitised explosives (subclass 3.2)

e) flammable solids, divided into:

   i) flammable solids (readily combustible solids and solids which may cause fire through friction) (subclass 4.1.1)

   ii) self-reactive substances (subclass 4.1.2)

   iii) solid desensitised explosives (subclass 4.1.3)

   iv) substances liable to spontaneous combustion, pyrophoric and self heating substances (subclass 4.2)

   v) substances which in contact with water emit flammable gases (subclass 4.3).

(It should be noted that substances classified as class 4 flammable solids are not necessarily solids)

4.3 Flammable threshold technical description

a) Flammable Gases (subclass 2.1.1)

A substance is a flammable gas if it is a gas or gas mixture, that at 20°C and a standard pressure of 101.3 kPa, has a flammable range when mixed with air. That is, it is sufficiently flammable to be capable of ignition when mixed with air in a proportion within a flammable range.

b) Flammable Aerosols (subclass 2.1.2)

An aerosol is a flammable aerosol if it is a pressurised mixture containing a gas, compressed, liquefied, or dissolved under pressure, with or without a liquid, paste or powder; comprising at least 45% by mass of flammable ingredients. The substance also must be packed under

pressure, in a way that is designed to be released, as solid or liquid particles in suspension in a gas; or as a foam, paste or powder; or in a liquid state; or in a gaseous state.

In this context, 'flammable ingredient' means any substance that meets the threshold for either a 'flammable gas', 'flammable liquid', or 'flammable solid'; or any combination of these.

c) Flammable liquids (subclass 3.1)

A liquid is a flammable liquid if it gives off a flammable vapour which ignites in a closed cup flash point test at a temperature ≤ 93°C.

d) Liquid desensitised explosives (subclass 3.2)

Liquid desensitised explosives are explosive (Class 1) substances which are dissolved or suspended in water or other liquid substances, to form an homogeneous liquid mixture to suppress their explosive properties, where the concentration of the explosive substance is at or above the minimum level deemed subject to the UN Model Regulations. This includes listing in the Dangerous Goods List in Chapter 3.2 of the *UN Model Regulations* as having a Class and division of liquid desensitised explosive. Current entries in the Dangerous Goods List are UN numbers 1204, 2059, 3064 and 3343.

e) Flammable solids (subclass 4.1.1)

This subclass covers substances which are readily combustible or which may cause or contribute to fire through friction.

A solid is a readily combustible flammable solid if it meets the criteria for the burning rate test set out in paragraph 33.2.1.4.4 of the *UN Manual of Tests and Criteria*.

Flammable solids that may cause fire through friction are substances with the following UN numbers:

- 1331 Matches, 'strike anywhere'
- 1343 Phosphorus trisulphide
- 1944 Matches, safety (book, card and strike-on-a-box)
- 1945 Matches, wax 'vesta'
- 2254 Matches, fusee

f) Self-reactive substances (subclass 4.1.2)

A substance is a flammable self-reactive substance if either:

i) a 50 kg quantity of the substance (when contained as specified in any of the tests set out in Test Series H in section 28 (p279-300) *UN Manual of Tests and Criteria*) has a self-acceleration decomposition temperature (SADT) of less than or equal to 75°C, when tested in accordance with such tests; **and**

ii) it has a heat of decomposition greater than 300 J/g, determined using differential scanning calorimetry, or adiabatic calorimetry

or

The substance is listed in paragraph 2.4.2.3.2.3 of the *UN Model Regulations* as having a class and division of a self-reactive substance (UN Division 4.1(b)).

g) Solid desensitised explosives (subclass 4.1.3)

A substance is a flammable desensitised explosive substance if:

i) prior to being desensitised, it would meet the threshold for substances with explosive properties (Class 1); **and**

ii) it has been desensitised to the extent that it would, under Test Series 6(c) of the *UN Manual of Tests and Criteria* show no projection, fire, smoke, heat or noise effect external to the substance itself; **and**

iii) it neither meets the criteria for substances with oxidising properties, nor for self-reactive substances (ie is not also in another hazardous category)

or

it is an explosive substance that has been wetted with water or alcohol or diluted with other substances, to form an homogeneous mixture in order to suppress its explosive properties, where the concentration of the explosive substance is at or above the minimum level deemed subject to the UN Model Regulations. This includes listing in the Dangerous Goods List in Chapter 3.2 of the *UN Model Regulations* as having a class and division of solid desensitised explosive (UN Division 4.1(c))

or

the substance is one of the following substances (UN number):

- 5-*tert*-Butyl-2,4,6-trinitro-*m*-xylene (musk xylene) (UN 2956)
- 2-Bromo-2-nitropropane-1,2-diol (UN 3241)
- Azodicarbonamide (UN 3242), and
- *Iso*-Sorbide-5-mononitrate (UN 3251).

h) Substances liable to spontaneous combustion, pyrophoric and self-heating substances (subclass 4.2)

A substance is a spontaneously combustible substance if, when tested as described in paragraph 33.3.1 of the *UN Manual of Tests and Criteria*, it meets one or more of the following criteria:

i) if the substance is a solid in powder form and in its commercial form ignites while falling or within 5 minutes of settling when poured from about 1 metre height onto a non-combustible surface, in one or more times out of six.

ii) if the substance is a liquid, and if 5 ml of the liquid:
   - when poured into an inert container containing an inert solid powder, ignites when exposed to air for five minutes, in one or more times out of six; or

- when added to a dry filter paper at 25°C, ignition or charring occurs on the filter paper within five minutes of addition of the liquid, in one or more times out of three.

iii) if a solid cube of the substance with sides 100mm long, when heated to 140°C, either spontaneously ignites or experiences a 60°C rise in temperature during a 24 hour period.

i) Substances which in contact with water emit flammable gases (subclass 4.3)

A substance is a flammable substance (dangerous when wet) if, when tested as described in subsection 33.4.1 of the *UN Manual of Tests and Criteria*, it meets one or both of the following criteria:

i) at ambient temperatures, reacts with water and produces a gas which ignites spontaneously; or

ii) when in contact with water produces flammable gas at a rate ≥ 1 litre/kg of substance/hr.

Note:
For sections 4.3 (e), (f), (g), (h)(i), (h)(iii), and (i) of this threshold, the substance should be tested in the finest particle form in which it is reasonably capable of being used or rendered. Where it is known or likely that more than 10% of the mass of the substance will crumble into a finer particle form, or to be used in a finer particle form than the form in which it is initially presented, then the test should be conducted using that finer form.

4.4 Interpretation of terms used in the flammable thresholds

desensitising agent (desensitised has the corresponding meaning)	*a substance or material that, when mixed with a class 1, class 4.1.2, or class 5.2 substance, produces a mixture that has reduced hazardous properties (in terms of those classifications) compared with the original class 1, class 4.1.2, or class 5.2 substance.*
flammability	*the ability of a substance to be ignited and to support combustion in air at 20°C, 101.3 kPa absolute pressure.*
flammable	*able to be ignited and sustain combustion, in air at 20°C, 101.3 kPa absolute pressure.*
flammable ingredient	*a substance that meets one or more of the thresholds for a flammable gas, a flammable liquid, or a flammable solid, or any combination of them*

flammable range	*the range between two ratios of flammable gas or vapour to air, the lower of which contains too much air, and the upper of which contains too little air, to be able to support combustion. The term 'flammable range' includes a minimal range effectively equivalent to a single point.*
flammable vapour	*the gaseous form of a normally liquid or solid substance, that is flammable.*
flash point	*the lowest temperature at which a flammable liquid gives off sufficient vapour to form a flammable mixture with air that ignites, when tested in any closed cup flash point test.*
Ignitable	*able to be set on fire.*
SADT	*self-accelerating decomposition temperature, being the lowest temperature at which self-accelerating decomposition of the substance occurs in the packaging in which it is tested as prescribed in Test Series H in section 28 of the UN Manual of Tests and Criteria.*

4.5 Notes on the flammable thresholds:

a) Threshold tests for substances with flammable properties

The approach taken to defining tests and criteria for thresholds for flammable substances is as follows:

i) In some cases, because of the sensitivity and degree of hazard of the substance, and for the sake of consistency in results, the criteria are dependent on precise testing procedures being followed. In these cases, the Regulations specify the specific testing procedures required, in one of two ways:
   ii) a narrative description of the test method (this allows equivalent tests to be performed); or
   iii) the reference to a particular test is specified in the regulations, in which case only that test will be able to be accepted.

ii) In cases where the criteria have a well-defined and universally understood meaning by themselves (eg 'closed cup flash point test', for which the *UN Model Regulations* lists 19 recognised tests), the Regulation is limited to specifying the criteria, enabling any appropriate test to be used. This approach also permits calculation or estimation methods to be considered – eg for mixtures (see below).

a) Relationship to the Gas Act 1992

The HSNO Regulations are not intended to apply to any gas distribution and transmission system, which comes under the provisions of the Gas Act 1992. While substances such as gas are clearly flammable, the Gas Act generally provides up to date and effective control in these circumstances. Consequently, there are specific provisions included in the HSNO Control Regulations to avoid any overlap of regulation with the Gas Act controls. This follows the existing practice as defined in the Dangerous Goods (Class 2 - Gases) Regulations: '*Nothing*

in these Regulations shall apply to (a) coal gas or natural gas except when packed, stored, conveyed or handled in cylinders or transportable tanks'.

b) Flammable gases - measuring the flammability

The *UN Model Regulations* recommend that 'flammability should be determined in accordance with ISO 10156:1996. Where insufficient data are available to use these methods, tests by a comparable method recognised by a national competent authority may be used'.

The ISO 10156:1996 test involves introducing a known concentration of gas:air mixture, in a reaction tube fitted with an ignition spark plug with 5 mm gap, connected to a 15 kV spark generator, and observing whether a spark results in a flame rising up the tube. The procedure involves beginning with a low concentration of gas, and repeating the test a number of times, each time gradually increasing the concentration of gas until a spark results in a flame rising up the tube. The calculation methods in the ISO standard appear to only apply to certain applications such as special gas mixtures produced to order (in small quantities).

Alternative test methods include:

Coward, HF and Jones, GW *Limits of Flammability of Gases and Vapours*, US Bureau of Mines Bulletin 503, (For calculating limits of flammability of gas mixtures)

Zabetakis, M G *Flammability Characteristics of Combustible Gases and Vapours*, US Bureau of Mines Bulletin 627, 1965

Burgess, D S, Furno, A L, Kutch, J M, and Mura, K E *Flammability of Mixed Gases* Us Department of the Interior, Bureau of Mines Report of Investigations 8709, 1982

BS 5345 Part 1: 1989 *British Standard Code of Practice for Selection, installation and maintenance of electrical apparatus for use in potentially explosive atmospheres (other than in mining applications or explosives processing and manufacture)* Part 1 General Recommendations

ASTM Standard E918 - 83 (1988). *Determining Limits of Flammability of Chemicals at Elevated Temperature and Pressure*

c) Flammable aerosols

The *UN Model Regulations* definition of 'aerosols' (chapter 3.3: notes 63 and 190) combines a description of the substance, and a description of the package, as follows:

i) 63: if the contents include more than 45 percent by mass or more than 250 g, of flammable components*

   * *UN Model Regulations* defines flammable components in aerosols as 'gases that are flammable in air at normal pressure, or are substances or preparations that are in liquid form that have a flash point ≤ 100 °C'.

ii) 190: Aerosols, this means aerosol dispensers, are any non-refillable receptacles made of metal, glass or plastic and containing a gas compressed, liquefied, or dissolved under

> pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder, or in a liquid state, or in a gaseous state.

The definitions of aerosol in European Community Directive 75/324/EEC, and the ICAO Technical Instructions are virtually identical to the *UN Model Regulations* definition. The EC Directive sets a maximum capacity of metal aerosol dispensers of 1000 ml. A recent amendment to the EC legislation requires all aerosols with any flammable contents to be considered as flammable unless tests indicate that it is not.

The approach used to specifying the threshold is required because the regulation making powers in the HSNO Act differentiate between the substance and the controls applied to it. When the above specification of aerosol is combined with the controls on flammable aerosols and the requirements for packages, the end result will be equivalent to the approach taken by the UN, EC, and ICAO.

d) Flammable liquids

i) Measuring the flammability

The classification criteria require flash point to be determined by a closed cup method. There are a number of internationally recognised closed cup test methods and several of these are specified in section 2.3.3, UN Model Regulations. Correspondingly, the Regulations do not specify a particular method and these test methods listed will be acceptable means of determining the classification criteria. However, ERMA New Zealand will generally expect flash points to be determined by one of the following common test methods:

- Pensky Martens Closed Cup (ASTM D93, BS EN 22719, BS 2000 Part 404, IP 404, ISO 2719, AS/NZS 2106)
- Abel Closed Cup (BS 2000 Part 170, IP 170, AS/NZS 2106)
- Abel-Pensky (DIN 51755)
- Tag Closed Cup (ASTM D56)
- Setaflash Closed Cup (ASTM D3278)

Closed cup flash points may be able to be estimated from open cup measurements. The *UN Model Regulations* (para 2.3.1.2) gives the UN Class 3 Packing Group III limit of 60.5^{o}C, closed cup, as being equivalent to an open cup value of 65.6^{o}C. The difference between open cup and closed cup values for a substance would increase as the flash point increases, due to the nature of the two test methods. Therefore, it can be assumed that open cup flash point values of greater than 103^{o}C would correlate with closed cup values in excess of the threshold level of 93^{o}C.

ii) Flash point limit

The threshold criterion that include liquids with a flash point ≤ 93°C originates from an August 1996 proposal of the UNCETDG subcommittee advising the IOMC Co-ordinating Group on flammability to modify the *UN Model Regulations* criteria to make it applicable to other aspects of the lifecycle. The subcommittee has since confirmed this proposal.

iii) Viscous substances

The *UN Model Regulations* exempts some specific types of viscous flammable substances from land transport controls, but the exemption does not apply for sea and air transport. Refer to section 2.3.2.5 in the UN Model Regulations.

Accordingly, no exemptions are provided by reason of viscosity although, as with other hazards, a substance above the threshold is captured for assessment rather than automatically having controls imposed.

iv) Screening procedures for mixtures which may be flammable liquids

Screening procedures, involving theoretical appraisal, can be used to identify the hazard potential of mixtures which are suspected of having flammable properties without the need for experimental determination as mentioned above.

A suitable method for calculating the flash point of mixtures containing both volatile, flammable components and non-volatile components (eg. polymers or additives) is that described by Gmehling and Rasmussen (*Ind Eng Chem Fundament*, 21, 186, (1982)). The basis of this approach is that the non-volatile components only slightly decrease the partial pressure of the solvents and thus, the flash point of the mixture can be calculated from the measured flash points of the flammable volatile components. The criteria used are as follows:

The flash point of mixtures need not be determined experimentally if the calculated flash point of the mixture is at least 5^{o}C greater than the threshold value (93^{o}C) and provided that:

- the composition of the mixture is accurately known
- the flash point (closed cup) of each flammable component is known
- the activity coefficient is known for each component as present in the mixture including the temperature dependence
- the liquid phase is homogeneous.

e) Flammable solids

The threshold proposed is equivalent to that for Division 4.1(a) as set out in the *UN Model Regulations* and the *UN Manual of Tests and Criteria*.

Test Measures

The apparatus and procedure for the Burning Rate Test are set out in s.33.2.1.4 *UN Manual of Tests and Criteria*. If the substance fails the Preliminary Screening Test, the substance may be considered not to be a flammable solid, and no further testing need be carried out. If the substance passes the Preliminary Screening Test, the Burning Rate Test should be carried out. We are not aware of any alternative comparable method recognised by any national competent authority.

This particular test has been specified in the Regulations, and information used in the evaluation must have been obtained using this test. This is because the rate of propagation of

the flame is dependent upon how the test is conducted, eg the cross sectional area of the powder trail, and on how compacted the powder is in the trail.

f) Solids that may cause fire though friction

As indicated there are only a small number of individual 'substances' which may cause fire through friction listed in the UN Model Regulations, accordingly this part of the threshold has been included simply by listing these substances.

g) Self-reactive substances

The threshold proposed is equivalent to that for Division 4.1(b) (including Type G) as set out in the *UN Model Regulations* and the *UN Manual of Tests and Criteria*.

Test Measures

The degree to which these substances will heat up internally depends on:

- the surface to volume ratio of the quantity of substance presented; and
- the nature (eg the thermal conductivity) of the container or package it is in.

Accordingly, the test procedures described in *UN Manual of Tests and Criteria* are directly referred to for this threshold.

Screening procedures for substances which may be self-reactive substances

A substance does not need to be evaluated as a self-reactive substance if there are no chemical groups present in the molecule associated with explosive or self-heating properties. Examples of the former are groups such as: C-C unsaturation, C-metal, N-metal, N-N unsaturation, peroxides, N-O, N-halogen, O-halogen; examples of the latter are groups such as: mutually reactive groups (eg aminonitriles, haloanilines, organic salts of oxidising acids), S=O, P-O, strained rings, unsaturation.

h) Desensitised explosives

The threshold proposed is equivalent to that for Division 4.1(c) as set out in the *UN Model Regulations* and the *UN Manual of Tests and Criteria* and includes substances previously classified as related to self-reactive substances.

i) Substances liable to spontaneous combustion, pyrophoric and self-heating substances

The threshold proposed is equivalent to that for Division 4.2 as set out in the *UN Model Regulations* and the *UN Manual of Tests and Criteria*.

Test Measures

- Pyrophoric solids: the test is set out in section 33.3.1.4 *UN Manual of Tests and Criteria*

- Pyrophoric liquids: the test is set out in section 33.3.1.5 *UN Manual of Tests and Criteria*
- Self-heating solids: the test is set out in section 33.3.1.6 *UN Manual of Tests and Criteria*, including the specifications for the test apparatus - the hot-air circulating oven, cubic sample containers, covers, and cages; and thermocouple.

As we are not aware of any alternative comparable test methods recognised by any national competent authority other than those described above these tests have been used to define the threshold.

Screening procedures for substances which may be liable to spontaneous combustion

A substance does not need to be evaluated as a pyrophoric substance when experience, in production or handling, shows that the substance does not ignite spontaneously on coming into contact with air at normal temperatures (ie the substance is known to be stable at room temperature for prolonged periods of time (days)).

j) Substances which in contact with water emit flammable gases

The threshold proposed is equivalent to that for Division 4.3 as set out in the *UN Model Regulations* and the *UN Manual of Tests and Criteria*.

Test Measures

Details of the test method for substances which in contact with water emit flammable gases, are detailed in Subsection 33.4.1 *UN Manual of Tests and Criteria*. Again, there appear to be no alternative comparable method recognised by any national competent authority so the tests have been used to define the threshold.

Screening procedures for substances which in contact with water may react to emit flammable gases

A substance does not need to be evaluated as a substance which may react with water to emit flammable gases if:

- the chemical structure of the substance does not contain metals or metalloids; or
- experience in production or handling shows that the substance does not react with water (eg the substance is manufactured in water or washed with water); or
- the substance is known to be soluble in water to form a stable mixture.

k) Flammable solids - particle size

The ILO/UN GHS Working Group considered the question of particle size for testing of flammable solids and concluded (ST/SG/AC.10/C.3/Add.3):

- that tests for solids should be carried out on substances in the form as presented (eg for transport)
- if the substance was to be presented (for use) in a different form which might alter its behaviour on testing, it should be re-tested in its different form; and

- if it was reasonably foreseeable that a substance would considerably change its material form during its lifetime, the potential hazards of its changed form should also be taken into consideration.

4.6 Classification of flammable substances

A flammable substance is classified as having a particular hazard classification if it meets the criteria set out in the table in Schedule 2 of the *Hazardous Substances (Classification) Regulations* for that hazard classification.

Summary details of the classification schemes for the various subclasses of flammable substances are given in the following table.

Note that in the case of Subclass 4.1.2 (self-reactive flammable solids), if a substance does not meet the criteria for a 4.1.2A, 4.1.2B, or 4.1.2C hazard classification, then a 4.1.2D classification applies unless sufficient data are provided that show that the substance meets the criteria for hazard classifications 4.1.2E, 4.1.2F or 4.1.2G. With respect to the criteria in the *Hazardous Substances (Classification) Regulations* for Subclass 4.1.2, Test Series A, B, C, D, E, F and G refer to the tests for self-reactive substances and organic peroxides in sections 21, 22, 23, 24, 25, 26 and 27, respectively, of the *UN Manual of Tests and Criteria*.

Flammable Property Classification

Category of Hazard	Subclass of Flammable Hazard								
	[1]Gases 2.1.1	Aerosols 2.1.2	Liquids 3.1	Liquid Desensitised Explosives 3.2	Flammable Solids 4.1.1	[2]Self-Reactive Flammable Solids 4.1.2	[3]Desensitised Explosives 4.1.3	[4]Spontaneously Combustible 4.2	[5]Dangerous When Wet 4.3
A	Ignitable at ≤ 13% volume in air or have a flammable range with air of ≥12%, regardless of LFL	Pressurised mixture containing a gas, compressed, liquefied, or dissolved under pressure; comprising ≥ 45%, by mass, flammable ingredients; under a pressure > 100 kPa	3.1A Flash Point (closed cup) < 23°C and initial boiling point ≤ 35°C	3.2A (corresponds to UN PG I)	4.1.1A (corresponds to UN PG II)	4.1.2A	4.1.3A (equivalent to UN PG I)	4.2A Pyrophoric substances (equivalent to UN PG I)	4.3A (equivalent to UN PG I)
B	Have a flammable range in mixture in air, other than those in category A		3.1B Flash Point (closed cup) < 23°C but initial boiling point > 35°C	3.2B (corresponds to UN PG II)	4.1.1B (corresponds to UN PG III)	4.1.2B	4.1.3B (equivalent to UN PG II)	4.2B Self-heating substances (equivalent to UN PG II)	4.3B (equivalent to UN PG II)
C			3.1C Flash Point (closed cup) ≥ 23°C, but ≤ 60°C	3.2C (corresponds to UN PG III)		4.1.2C	4.1.3C (equivalent to UN PG III)	4.2C Self-heating substances (equivalent to UN PG III)	4.3C (equivalent to UN PG III)
D			3.1D Flash Point (closed cup) > 60°C but ≤ 93°C			4.1.2D			
E						4.1.2E			
F						4.1.2F			
G						4.1.2G			

[1] Gases or gas mixtures at 20°C and at a standard pressure of 101.3 kPa
[2] This classification is broadly consistent with the UNRTDG Division 4.1(b)
[3] This classification is equivalent to UN Division 4.1(c), with the classification criteria as per UNRTDG
[4] This classification is generally equivalent to UN Division 4.2
[5] This classification is equivalent to UN Division 4.3

5. Substances with Oxidising Properties

5.1 General approach taken for oxidising properties.

The oxidising threshold criteria are derived from the *UN Model Regulations* and its companion volume, the *UN Manual of Tests and Criteria*.

5.2 Elements of the oxidising threshold

There are 2 elements of the threshold for substances with an oxidising property:

- **oxidising substances not organic peroxides**, being substances which, while in themselves not necessarily combustible, may cause or contribute to the combustion of other substances or material;
- **organic peroxides**, being substances which contain the bivalent oxygen [-0-0-] structure and may be considered as derivatives of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

5.3 Oxidising threshold technical description

a) Oxidising substances not organic peroxides (Subclasses 5.1.1 and 5.1.2)

A substance is an oxidising substance if either:

(i) The substance is listed in the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations, as having a classification, division or subsidiary risk of an oxidising substance (UN Division 5.1);

or

(ii) For a solid, if when tested in the form in which it is generally available, it is found that the test mixture of the substance with dried cellulose either spontaneously ignites or shows a mean burn time equal to or faster than that of the 3:7 reference mixture by mass of potassium bromate and cellulose when tested under the same conditions as described in the standard test. The standard test is that prescribed for oxidising solids in Test Series O.1 in paragraph 34.4.1 of the *UN Manual of Tests and Criteria*.

(Note: The physical form of the substance presented for testing should also be considered. The substance should be tested in the finest particle form in which it is reasonably capable of being used or rendered. Where it is likely or known that more than 10% of the mass of the substance will crumble into a finer particle form, then the substance should be prepared and tested using that finer form);

or

(iii) For a liquid, if when tested by mixing with dried cellulose it is found the mixture either spontaneously ignites or shows a mean pressure rise time that is equal to or faster than the mean pressure rise time of the 1:1 reference mixture, by mass, of 65% aqueous nitric acid and cellulose when tested under the same conditions as described in the

standard test. The standard test is that prescribed for oxidising liquids in Test Series O.2 in paragraph 34.4.2 of the *UN Manual of Tests and Criteria*;

or

(iv) For a gas, if when tested the substance will cause or contribute to combustion at a faster rate than air does, when tested in accordance with the test method for determining the oxidising power of gases or gas mixtures as prescribed in ISO 10156:1996 – Gases and gas mixtures – determination of fire potential and oxidising ability for the selection of cylinder valve outlets.

(b) Organic peroxides (Subclass 5.2)

An organic peroxide is an substance with oxidising properties if any of the following conditions apply:

either

(i) The substance is listed in paragraph 2.5.3.2.4 of the *UN Model Regulations* as an organic peroxide or is listed in the Dangerous Goods List in Chapter 3.2 of the *UN Model Regulations* as having a class or division of an organic peroxide (Division 5.2);

or

(ii) the substances provides more than 1% available oxygen from the organic peroxides, when containing not more than 1% hydrogen peroxide by mass;

or

(i) the substance provides more than 0.5% available oxygen from the organic peroxides, when containing not less than 1% and not more than 7% hydrogen peroxide by mass.

Definition of 'available oxygen' content

For an organic peroxide, the available oxygen content as a percent (%) by mass is determined according to the following formula:

$$\% = 16 \times \sum_i n_i \times \frac{c_i}{m_i}$$

Where:

n_i	=	number of peroxygen groups per molecule of organic peroxide $_i$
c_i	=	concentration (mass %) of organic peroxide $_i$
m_i	=	molecular mass of organic peroxide $_i$
x	=	multiplication symbol
$\sum$	=	symbol for summation where there is more than one organic peroxide

This formula calculates the availability of oxygen as a percent by mass. The '*i*' is a mathematical expression to allow for adding up the available oxygen for each component in a mixture. Mixtures of different organic peroxides with or without hydrogen peroxide are common.

5.4 Notes on the oxidising thresholds

(a) Threshold tests for substances with oxidising properties

The approach taken to defining tests and criteria for thresholds for oxidising substances is to specify the specific testing procedures based on those in the *UN Manual of Tests and Criteria* and to provide that substances listed in the *UN Model Regulations* be included. The latter is to minimise any possible need for re-testing of substances already accepted as having an oxidising property. This approach has been taken because there appear to be no other recognised procedures in common usage. Similarly, for gases the criterion used is a single test procedure laid out in ISO 10156:1996.

(b) Mixture rule

If the substance is a mixture and any of the constituent chemical elements or compounds in the mixture meet any of the criteria in Sections 5.3(a)(ii) and (iii) and 5.3(b)(ii) and (iii) above, then the mixture (ie as it is imported or manufactured) is deemed to be hazardous unless it can be shown that the exact mixture itself does not meet any of the criteria set out in Section 5.3 above.

(c) Screening procedures for substances which may be oxidising substances

Organic compounds do not need to be considered against the criteria for oxidising substances if they do not contain oxygen, fluorine or chlorine, or if these elements are present in the compound but are chemically bonded only to carbon or hydrogen.

Inorganic substances do not need to be considered against the criteria for oxidising substances if they do not contain any oxygen or halogen atoms.

(d) Organic peroxides

Some organic peroxide formulations:

- may under increased temperature evolve oxygen and thus depress the temperature at which other flammable materials may ignite;
- can form peroxides when left to ‘stand” that are unstable, and may be explosive exposure to light/air eg diethyl ether.

We expect consideration of the stability of a substance will consider information on such hazards.

5.5 Oxidising Property Classification

For substances with an oxidising property, classification generally follows the degree to which these effects are observed to occur when the substance is tested. The classification systems for oxidising substances and organic peroxides are generally consistent with those given in the UN Model Regulations, with the test criteria being those contained in the *UN Manual of Tests and Criteria*.

Oxidising substances are divided into subclass 5.1.1, for solids and liquids, subclass 5.1.2 for gases, and subclass 5.2 for organic peroxides. Each subclass is divided into several categories representing different degrees of hazard, except in the case of subclass 5.1.2 where there is only one category.

An oxidising substance or organic peroxide is classified as having a particular hazard classification if it meets the criteria set out in the table in Schedule 3 of the *Hazardous Substances (Classification) Regulations* for that hazard classification.

The classification systems for oxidising substances and for organic peroxides are summarised in the following table.

Degree of Hazard	Nature of Oxidising Hazard		
	Oxidisers (liquids/solids) 5.1.1	**Oxidising Gases[1] 5.1.2**	**Organic Peroxides[2] 5.2**
A	5.1.1A (equivalent to UN PG I)	5.1.2A Promotes combustion at a greater rate than air does	5.2A
B	5.1.1B (equivalent to UN PG II)		5.2B
C	5.1.1C (equivalent to UN PGIII)		5.2C
D			5.2D
E			5.2E
F			5.2F
G			5.2G

[1] Gas means a substance that: (a) has a vapour pressure > 300 kPa at 50°C, or (b) is completely gaseous at 20°C and a standard pressure of 101.3 kPa.

[2] Generally equivalent to the classification system for UN Class 5.2, as contained in the UN Model Regulations, 11th Revised Edition.

Note that in the case of Subclass 5.2 (organic peroxides), if a substance does not meet the criteria for a 5.2A, 5.2B, or 5.2C hazard classification, then a 5.2D classification applies unless sufficient data are provided that show that the substance meets the criteria for hazard classifications 5.2E, 5.2F or 5.2G. With respect to the criteria in the *Hazardous Substances (Classification) Regulations* for Subclass 5.2, Test Series A, B, C, D, E, F and G refer to the tests for self-reactive substances and organic peroxides in Sections 21, 22, 23, 24, 25, 26 and 27, respectively, of the *UN Manual of Tests and Criteria*.

6. Substances with Corrosive Properties

6.1 Corrosive properties

The HSNO legislation defines 3 sub-classes under the corrosive property as follows:

(a) Subclass 8.1 – Substances corrosive to metals

(b) Subclass 8.2 – Substances corrosive to dermal tissue

(c) Subclass 8.3 – Substances corrosive to ocular tissue

A substance that exerts a corrosive action only on non-metallic materials and which does not meet either of the criteria for (a), (b) or (c) above, is not above the threshold for corrosive properties.

6.2 Corrosive thresholds

A substance is above the threshold for a corrosive property if any one or more of the following conditions described in a), b), or c) below are met.

a) Metallic corrosive

A substance is above the threshold for the corrosive property if it corrodes specified steel or aluminium surfaces at a rate exceeding 6.25 mm a year at a test temperature of 55ºC.

Interpretations

Specified steel: Steel type P235 (ISO 9328 (II) : 1991), SAE 1020 steel.

Specified aluminium: aluminium, non-clad types 7075-T6 or AZ5GU-T6

b) Skin corrosive

A substance is above the threshold as a biological corrosive to the skin if:

i) the pH of the substance is ≤ 2 or ≥ 11.5; or

ii) the substance causes irreversible destruction of the skin after exposure to the substance for greater than 1 hour but not more than 4 hours, within an observation period of up to 14 days in greater than or equal to 33% of test animals.

c) Eye corrosive

A substance is above the threshold as a biological corrosive to the skin if:

i) the pH of the substance is ≤ 2 or ≥ 11.5; or

ii) the mean Draize score is ≥ 3 for corneal opacity and/or ≥ 1.5 for iritis; or

iii) effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of 21 days.

Interpretations

Irreversible destruction of the skin: visible necrosis through the epidermis.

Mean Draize score: in relation to acute eye irritation tests, is the mean value in at least 2 of 3 tested animals from Draize grades measured at intervals of 24 hours, 48 hours and 72 hours after installation of the substance.

6.3 Classification

It is only necessary for a substance to trigger any one of the above corrosive threshold effects in order for it to be captured by the HSNO Act and to require classification against the HSNO toxicity classification scheme. For example, a substance may be below the skin corrosive thresholds, but be above the eye corrosive threshold and thus require assessment and classification by the ERMA New Zealand.

The HSNO corrosive classification scheme summarised in the following table will be used for substances with corrosive properties that have exceeded a corrosive property threshold level. The threshold levels are essentially the lower cut-off boundaries for the classification schemes.

	Nature of Hazard		
Degree of Hazard	**Metallic corrosive 8.1**	**Skin corrosive 8.2**	**Eye corrosive 8.3**
A	pH less than 2 or greater than 11.5; or Evidence of metallic corrosion of >6.25 mm/year	pH less than 2 or greater than 11.5; or Evidence of irreversible damage within 1 hour following exposure to the substance for ≤ 3 minutes	pH less than 2 or greater than 11.5; or Evidence of irreversible damage; or Draize Grade ≥ 3 for corneal opacity and/or Draize Grade >1.5 for iritis
B		Evidence of irreversible damage within 14 days following exposure to the substance for >3 minutes but not more than 1 hour	
C		Evidence of irreversible damage within 14 days following exposure to the substance for >1 hour but not more than 4 hours	

6.4 Acceptable test methodologies for substances with corrosive properties

These specifications are limited to criteria which permit the use of any data (measured, calculated or estimated) within any guidelines provided by ERMA New Zealand to establish whether a given substance is captured by the threshold.

The following test guidelines would meet the threshold criteria for metallic corrosives:

- United States National Association of Corrosion Engineers (NACE) Standard TM-01-69 (ref. 49CFR 173.240)

- American Society for Testing and Materials (ASTM) standard G-31-72 (extended in 1990)

The following test methodology is deemed to meet the requirements for testing the biological corrosion to skin threshold:

- OECD Test Guideline 404: Acute Dermal Irritation/Corrosion, 1992.

The following test methodology is deemed to meet the requirements for testing the biological corrosion to the eye threshold:

- OECD Test Guideline 405: Acute Eye Irritation/Corrosion, 1992.

However, particularly for mixtures, it is expected that 'mixture rules' for combining information about the components of the mixture and/or estimation techniques will be accepted as a means of establishing whether or not a substance falls above or below the threshold.

It should also be noted that older studies/methods may still provide useful information for the above measure but may pre-date currently accepted Good Laboratory Practice (GLP). It is not envisaged that information derived from these studies would be excluded from consideration.

6.5 Mitigating factors/data interpretation

The *User Guide to HSNO Thresholds and Classifications* outlines mitigating factors that should be considered when interpreting data from various sources. For example, problems associated with testing a substance (or substance as a mixture) or where testing is not necessary for a particular effect.

6.6 Hazard cut-off levels for corrosive effects

The *User Guide to HSNO Thresholds and Classifications* outlines internationally accepted hazard cut-off levels for biologically corrosive effects below which the corrosive effect is unlikely to occur. For example if a substance that can cause skin corrosion when tested according to an acceptable test methodology is present at less than 1%, then the corrosive effect is unlikely to occur. If however, your data shows a skin corrosive below 1%, then the threshold for skin corrosion is still triggered.

6.7 Minimum data sets

The *User Guide to HSNO Thresholds and Classifications* also recognises the actual risk posed by substances in particular circumstances. Different types of hazardous substances present different levels of risk and will therefore require different types and levels of information for consideration of applications for approval. Different levels of information could relate to the quantity, extent, or degree of detail of information, as applicable to the application involved.

This approach is consistent with the ERMA New Zealand publication *User Guide for Making an Application for a Hazardous Substance Approval*.

6.8 Classification of mixtures ('mixture rules')

To assist in the determination of whether a substance, or substance as a mixture, triggers a toxic effect threshold and its subsequent classification, a series of 'mixture rules' are provided in the *User Guide to HSNO Thresholds and Classifications.* These rules are internationally accepted under the Global Harmonisation System (GHS) and follow a stepwise process, based on the type of data available to the applicant for a particular biologically corrosive endpoint, on how to use that information to classify their substance as hazardous or non-hazardous.

For example if the substance has been tested, then it is relatively straightforward to decide if the threshold is triggered or not. If a substance as a mixture has not been directly tested but individual components of the mixture have been, then this data can be used to estimate the likely toxicity of the substance as a mixture.

7. Substances with Toxic Properties

7.1 Toxic Properties

The toxic threshold criteria are derived from the documents of the Advisory Group on Harmonisation of Classification and Labelling (AG-HCL), a subcommittee of the Chemicals Group in the Organisation of Economic Co-operation and Development (OECD) Environment Directorate. These documents form part of the overall Global Harmonisation System (GHS) detailed in Appendix A.

The HSNO legislation defines 8 Subclasses under the toxic property as follows:

a) Subclass 6.1 - Substances which are acutely toxic
b) Subclass 6.3 - Substances which are skin irritants
c) Subclass 6.4 - Substances which are eye irritants
d) Subclass 6.5 - Substances which are sensitisers
e) Subclass 6.6 - Substances which are mutagenic
f) Subclass 6.7 - Substances which are carcinogenic
g) Subclass 6.8 - Substances which are reproductive or developmental toxicants; and
h) Subclass 6.9 - Substances which are target organ systemic toxicants.

Note that Class 6.2 is omitted from the above list as the numbering system used in the Regulations reflects the UNRTDG numbering system. Under the UNRTDG system, Class 6.2 is assigned to infectious substances.

7.2 Toxic thresholds

A substance is above the threshold for toxic effects if it triggers any one of the following threshold levels

a) Acute toxicity

i)	oral or dermal effects	LD_{50} is ≤ 5000 mg substance/kg bodyweight **unless** At or below the respective threshold value, reliable data becomes available from human or animal studies, which indicates a statistically significant acute toxic effect
ii)	oral and dermal effects	LD_{50} is >2000 mg substance/kg bodyweight and any mortality or any clinical signs of a significant adverse biological effect are observed (other than diarrhoea, piloerection or an ungroomed appearance)
iii)	inhalation effects (gases)	LC_{50} is ≤ 5000 ppm in air

iv) inhalation effects (vapours) LC_{50} is ≤ 20 mg substance/l air

v) inhalation effects (dusts or mists LC is ≤ 5 mg substance/l air

b) Skin Irritation

i) the substance exhibits a Draize Grade ≥ 1.5 for either erythema or oedema

c) Eye Irritation

i) the substance exhibits a Draize Grade ≥ 1 for either corneal opacity or iritis or Draize Grade ≥ 2 for either conjunctival redness or chemosis

d) Sensitisation

i) positive sensitisation effects in animals or humans on challenge

e) Mutagenicity

i) positive mutagenic effects following *in* vivo mammalian exposure

ii) positive genotoxic effects following mammalian *in vivo* exposure and mutagenic effects as a result of in vitro exposure to the substance; or

iii) positive evidence of mutagenic effects following *in vitro* exposure of mammalian cells to the substance and the substance has a structure-activity relationship to a known germ cell mutagen.

f) Carcinogenic Effects

Reliable information indicates to an expert that exposure to the substance causes the development of cancer or an increase in the incidence of benign or malignant tumours in an organ or an organism.

g) Reproductive/Developmental Effects

Reliable information indicates to an expert that exposure to the substance causes an adverse reproductive or developmental effect.

h) Target Organ Systemic Effects

Evidence of significant adverse biological effect in the function or morphology of an organ or in the biochemistry or haematology of an organism following exposure to the substance.

7.3 Interpretation of terms

developmental effect

in relation to an organism, includes structural abnormality, altered growth, functional deficiency, or interference with the normal development of the organism, that is manifested at any point in the

organism's life span, and includes the death of a developing organism, and that is caused by:

(a) the exposure of either parent to the substance before conception; or

(b) the exposure of the developing offspring to the substance during prenatal development, postnatal development, or development up to the time of sexual maturation.

genotoxic effect

alterations to the structure, information content, or segregation of DNA, including:

(a) DNA damage caused by interference with its normal replication processes; and

(b) temporary non-physiological alterations to its replication.

LC_{50} (median lethal concentration)

a statistically derived concentration of a substance that can be expected to cause death during exposure or within a fixed time after exposure in 50 per cent of animals exposed for a specified time.

LD_{50} (median lethal dose)

a statistically derived single dose of a substance that can be expected to cause death in 50 per cent of animals when administered by the oral or dermal route.

mean draize score

(a) in relation to acute skin irritation tests, means the mean value in at least 2 of 3 tested animals:

(i) From Draize grades measured at intervals of 24 hours, 48 hours, and 72 hours after the patch is removed; or

(ii) where reactions are delayed, from Draize grades on 3 consecutive days after the onset of dermal reactions.

(b) In relation to acute eye irritation tests, means the mean value in at least 2 of 3 tested animals from Draize grades measured at intervals of 24 hours, 48 hours and 72 hours after the instillation of the substance.

mutagenic effect

a permanent change in the amount or structure of the genetic material in a cell, being a permanent change that is:

(a) manifested at the phenotypic level; or

(b) an underlying DNA modification (including specific base pair changes and chromosomal translocations).

reliable information

information that is derived from:

(a) a valid and relevant animal study conducted in accordance with internationally accepted test guidelines and principles of good laboratory practice: or

(b) an epidemiological study in humans that is statistically sound and has undergone peer review; or

(c) any other study whose relevance and validity can be demonstrated according to internationally accepted criteria and scientific practice.

reproductive effect includes:

(a) interference with reproductive ability or capacity, including alteration to the male or female reproductive system; or
(b) an effect on the onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, or premature reproductive senescence; or
(c) an effect on or through lactation; or
(d) modifications in other functions that are dependent on the integrity of the reproductive system.

sensitisation

an immunologically mediated reaction where, after repeated exposure to a substance, an organism is, or one or more organs in an organism are, more readily and adversely affected by that substance.

significant adverse biological effect: *a toxicologically significant change in an organ or in an organism observed during the treatment period of the study, being a change that is neither transient nor an adaptive response, where the probability that the effect is different from any recognised background history of effect in the test animal strain is greater than 0.95 (equivalent to P (probability) of 0.05 or less).*

Valid in relation to a study

(a) the design of the study methodology accurately reflects the matters the study seeks to measure; and
(b) the study findings can be extrapolated from the sample used in the study to a broader population.

7.4 Classification

It is only necessary for a substance to trigger any one of the above toxic effect thresholds in order for it to be captured by the HSNO Act and to require classification against the HSNO toxicity classification scheme. For example, a substance may be below the acute toxicity thresholds, but be above the skin irritation threshold and thus require assessment and classification by ERMA New Zealand.

The HSNO toxicity classification scheme generally follows the latest approach adopted by the OECD. The classification scheme summarised in the following table will be used for substances with toxic properties that have exceeded a toxic property threshold level. The threshold levels are essentially the lower cut-off boundaries for the classification schemes.

The levels of toxicity given in the table will be used to determine the cut-offs between each step in the relevant classification scheme.

Toxic Property Classification

Category	Nature of Toxic Hazard											
	Acute Toxicity 6.1					Skin Irritant 6.3	Eye Irritant 6.4	Sensitiser (respiratory and contact) 6.5	Carcinogen 6.7	Reproductive/ Developmental 6.8	Mutagen 6.6	Target Organ Systemic 6.9
	Oral LD_{50} mg/kg bw	Dermal LD_{50} mg/kg bw	Gases LC_{50} ppm in air	Vapours LC_{50} mg/L in air	Dusts/ Mists LC_{50} mg/L in air							
A	5	50	100	0.5	0.05	2.3 ≤ Draize Grade ≤4 or data indicates skin inflammation that persists for 14 days after exposure	1≤ Draize Grade <3 for corneal opacity and/or 1≤ Draize Grade <1.5 for iritis and/or Draize Grade ≥ 2 for conjunctival redness and/or Draize Grade ≥ 2 for or conjunctival oedema	Respiratory (induces specific respiratory hypersensitivity in humans or animal data shows potential to cause sensitisation by inhalation in humans)	Known or Presumed Human Carcinogens	Known or presumed human reproductive or developmental toxicant	Known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans	Known or presumed human target organ toxicant
B	50	200	500	2.0	0.5	1.5 ≤ Draize grade <2.3		Contact (induces sensitisation by skin contact in humans or animal data shows potential to cause sensitisation by skin contact in humans)	Suspected Human Carcinogens	Suspected human reproductive or developmental toxicant	Cause concern for man owing to the possibility that they may induce heritable mutations in the germ cells of humans	Suspected human target organ toxicant
C	300	1000	2500	10	1.0					Effects on or via lactation		
D	2000	2000	5000	20	5							
E*	5000											

* Note that there are several criteria identified in the *User Guide to the HSNO Thresholds and Classifications* for assignment to this category.

7.5 Acceptable test methodologies

Data can be measured, calculated or estimated for each toxic effect. The *User Guide to the HSNO Thresholds and Classifications* provides guidance on which test protocols or methods are recognised as acceptable tests to measure a particular toxic effect. In general, data generated from the following test guidelines provide results that met the HSNO threshold requirements:

- OECD Test Guidelines
- US EPA Guidelines
- EC Guidelines.

It should be noted that older studies/methods may still provide useful information about toxic effects but may predate currently accepted Good Laboratory Practice (GLP). Again, it is not envisaged that information obtained from these studies would be excluded from consideration.

7.6 Mitigating factors/data interpretation

The *User Guide to HSNO Thresholds and Classifications* outlines mitigating factors that should be considered when interpreting data from various sources. For example, problems associated with testing a substance (or substance as a mixture) or where testing is not necessary for a particular effect.

7.7 Hazard cut-off levels for toxic effects

The *User Guide to HSNO Thresholds and Classifications* outlines internationally accepted hazard cut-off levels for a toxic effect below which that toxic effect is unlikely to occur. For example if a substance that can cause skin irritation when tested according to an acceptable test methodology is present at less than 1%, then the skin irritation effect is unlikely to occur. If however, your data shows a skin irritant effect below 1%, then the threshold for skin irritation is still triggered.

7.8 Minimum data sets

The *User Guide to Thresholds and Classifications* also recognises the actual risk posed by substances in particular circumstances. Different types of hazardous substances present different levels of risk and will therefore require different types and levels of information for consideration of applications for approval. Different levels of information could relate to the quantity, extent, or degree of detail of information, as applicable to the application involved.

This approach is consistent with the ERMA New Zealand publication *User Guide for Making an Application for a Hazardous Substance Approval*.

7.9 Classification of mixtures ('mixture rules')

To assist in the determination of whether a substance, or substance as a mixture, triggers a toxic effect threshold and its subsequent classification, a series of 'mixture rules' are provided

in the *User Guide to HSNO Thresholds and Classifications.* These rules are internationally accepted under the GHS and follow a stepwise process, based on the type of data available to the applicant for a particular toxic endpoint, on how to use that information to classify their substance as hazardous or non-hazardous.

For example if the substance has been tested, then it is relatively straightforward to decide if the threshold is triggered or not. If a substance as a mixture has not been directly tested but individual components of the mixture have been, then this data can be used to estimate the likely toxicity of the substance as a mixture.

8. Substance with Ecotoxic Properties

8.1 Ecotoxic Properties

The ecotoxic threshold criteria are derived from two sources:

- for aquatic ecotoxicity, the documents of the AG-HCL.
- for terrestrial ecotoxicity, the scheme used by the US EPA.

The terrestrial ecotoxicity (soil environment, terrestrial vertebrate and invertebrate effects) have not been addressed yet as part of the global harmonisation scheme.

The HSNO legislation defines four Subclasses under the ecotoxic property as follows:

(1) Aquatic effects (Subclass 9.1)
(2) Soil effects (Subclass 9.2)
(3) Terrestrial vertebrate effects (Subclass 9.3)
(4) Terrestrial invertebrate effects (Subclass 9.4)

There is also a threshold set for a substance that is used as a biocide. Any substance that triggers this effect is subsequently classified within the appropriate sub-class of ecotoxic effects above.

8.2 Ecotoxic thresholds

A substance triggers the threshold for ecotoxic effects if it is more toxic than any one of the threshold levels in Sections a) to e).

a) Ecotoxic to the aquatic environment

i) Either the acute fish (96 hour) LC_{50} is ≤ 100 mg/l
or
the crustacean (48/96 hour) EC_{50} is ≤ 100 mg/l
or
the algae (72/96 hour) EC_{50} is ≤ 100 mg/l

or

ii) the chronic fish, crustacean or plant no observable effect level (NOEC) is ≤ 1 mg/L.

or

iii) in the absence of NOEC data, the substance is not rapidly degradable or is bioaccumulative.

b) Ecotoxic to the soil environment

i) a plant or soil invertebrate EC_{50} ≤ 100 mg/kg dry weight of soil

or

ii) a 25% reduction of microbial respiration or nitrification at ≤ 100 mg/kg dry weight of soil.

c) Ecotoxic to terrestrial vertebrates

i) an avian or mammalian acute LD_{50} of ≤ 2000 mg/kg body weight or acute LC_{50} of ≤ 5000 ppm diet

or

ii) a chronic avian or mammalian Maximum Acceptable Toxicant Concentration (MATC) ≤ 100 ppm diet.

d) Ecotoxic to beneficial terrestrial invertebrates

A contact or oral LD_{50} of ≤ 25 µg/terrestrial invertebrate

e) Substances designed to cause biocidal action

Any substance designed for a biocidal action, unless
i) the substance is designed for biocidal action against a virus, protozoan, bacterium, or an internal organism in humans or in other vertebrates; and
ii) the substance does not meet any of the thresholds for aquatic, soil, terrestrial vertebrate or terrestrial invertebrate ecotoxicity.

8.3 Interpretation of terms

bioaccumulative *Any substance that has a bioconcentration factor (BCF) greater than or equal to 500, or, if BCF data is not available, a log K_{OW} greater than or equal to 4; and, for the purposes of this definition, where available:*
(a) measured log K_{OW} values take precedence over estimated values; and
(b) measured BCF values take precedence over log K_{OW} values.

biocidal action *intended to cause either mortality, inhibited growth, or inhibited reproduction in any organism.*

BOD_5 *The 5-day biochemical oxygen demand, being the mass of oxygen consumed by micro-organisms during oxidation of the substance in water over a period of 5 days, expressed in units of milligrams of oxygen consumed per milligrams of the substance.*

chronic aquatic ecotoxicity value *The lowest value in units of a milligram of the substance per litre of water from fish, crustacean, algal, or other aquatic plant chronic NOEC data.*

COD *The chemical oxygen demand, being the equivalent mass of oxygen from an oxidising agent, of a strength at least equal to the oxidising strength of potassium permanganate or potassium dichromate, that is consumed during oxidation of the substance in water, expressed in units of milligrams of oxygen consumed per milligram of the substance.*

EC_{50} *A median effect concentration, being a statistically-derived concentration of a substance in water that can be expected to cause-*

(a) an adverse reaction in 50% of organisms exposed for the specified time; or

(b) a 50% reduction in growth or in the growth rate of the organism population exposed for the specific time.

K_{OW} *The steady state ratio of the solubility of a substance in n-octanol to the solubility of that substance in water.*

LC_{50} *A median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals exposed for a specified time.*

NOEC *The no observed effect concentration, being the highest concentration of substance from the most sensitive species for which data is available that does not produce a significant adverse biological effect in an organism or in an organism population.*

Rapidly degradable *In relation to a substance in water, means that:*

(a) 28 days after a solution containing the substance is inoculated with micro-organisms, there is at least –

(i) a 70% reduction in dissolved organic carbon in the solution; or

(ii) a 60% depletion of oxygen in the solution, when compared with the maximum depletion of oxygen that would occur if the substance were completely degraded; or

(iii) a 60% generation of carbon dioxide in the solution, when compared with the maximum generation of carbon dioxide that would occur if the substance were completely degraded; or

(b) if only COD and BOD_5 data is available, the ratio of BOD_5 to COD is greater than or equal to 0.5:1 or

(c) at least 70% of the substance can be degraded biotically or abiotically, in the aquatic environment within 28 days.

Significant adverse biological effect *A toxicologically significant change in an organ or in an organism observed during the treatment period of the study where the probability that the effect is different from any recognised background history of effect in the test animal strain is greater than 0.95 (equivalent of P (probability) of 0.05 or less)*

8.4 Ecotoxic Classifications

In the following table, the levels of toxicity given will be used to determine the cut-offs between each step in the relevant classification scheme. Any substance with values within the ranges given in various steps will fall into the indicated Class.

Category	Nature of Ecotoxic Hazard			
	Aquatic 9.1	**Soil 9.2**	**Terrestrial Vertebrate 9.3**	**Terrestrial Invertebrate 9.4**
A	[1]Acute toxicity ≤ 1.0 mg/L	[3]Soil ecotoxicity value ≤ 1mg/kg	LD_{50} < 50 mg/kg (body weight) and/or LC_{50} (diet) ≤ 500 mg/kg (food)	Invertebrate ecotoxicity value < 2µg/bee
B	1.0 < Acute toxicity ≤ 10mg/L AND Lack of rapid degradability and/or Bioaccumulative (UNLESS: [2]Chronic value > 1.0mg/L, in which case the substance is excluded from this classification step)	1 < Soil ecotoxicity value ≤ 10 mg/kg	50 < LD_{50} ≤ 500 mg/kg (body weight); and/or 500 < LC_{50} (diet) ≤ 1000 mg/kg (food)	2 ≤ invertebrate ecotoxicity value < 11µg/bee
C	10.0< Acute toxicity ≤100mg/L AND Lack of rapid degradability and/or Bioaccumulative (UNLESS: Chronic value > 1.0mg/L, in which case the substance is excluded from this classification step)	10 < Soil ecotoxicity value ≤100mg/kg AND [4]Soil DT_{50} > 30 days	500 < LD_{50} ≤ 2000 mg/kg (body weight); and/or 1000 < LC_{50} (diet) ≤ 5000 mg/kg (food) and/or a chronic MATC <100 ppm in the diet but which does not meet the criteria for 9.3A or 9.3B	11 ≤ invertebrate ecotoxicity value < 25µg/bee
D	**1.0 < Acute toxicity ≤ 100mg/L and not classified in a higher category** OR No acute toxicity and lack of rapid degradability and bioaccumulative and not classified in a higher category OR A substance designed as a biocide and not classified in a higher category	10 < Soil ecotoxicity value ≤100mg/kg AND Soil DT_{50} ≤ 30 days		

[1]Acute toxicity = the lowest value (in mg substance/litre of water) from (i) fish 96 hour exposure LC_{50} data; or (ii) crustacean 48 or 96 hour exposure EC_{50} data; or (iii) algae 72 or 96 hour exposure EC_{50} data

[2]Chronic value = the lowest value (in mg substance/litre of water) from fish, crustacean or algae NOEC (No Observed Effect Concentration) data

[3]Soil ecotoxicity value = the lowest value (in mg substance/kg dry weight of soil) from: (i) plant or soil invertebrate 14 day exposure EC_{50} data; or (ii) data demonstrating a 25% reduction in soil micro-organism respiration or nitrification at the completion of 28 day exposure to the substance.

[4]Soil DT_{50} = Time to reduce original substance soil concentration by 50%

[5]Invertebrate ecotoxicity value = lowest value (in µg substance/terrestrial invertebrate) from contact or oral LD_{50} data 48 hours after exposure.

LOEC = The lowest observed effect concentration, being the lowest concentration of a substance that produces a statistically significant adverse biological effect in an organism or organism population.

MATC = The maximum acceptable toxicant concentration, being the geometric mean of the NOEC and LOEC where the NOEC and LOEC are derived from the same study.

8.5 Acceptable Test Methodologies

Data can be measured, calculated or estimated for each ecotoxic effect. The *User Guide to the HSNO Thresholds and Classifications* provides guidance on which test protocols or methods are recognised as acceptable tests to measure a particular ecotoxic effect. In general, data generated from the following test guidelines provide results that met the HSNO threshold requirements:

- OECD Test Guidelines
- US EPA Guidelines
- EC Guidelines.

It should be noted that older studies/methods may still provide useful information about toxic effects but may predate currently accepted Good Laboratory Practice (GLP). Again, it is not envisaged that information obtained from these studies would be excluded from consideration.

8.6 Mitigating factors/data interpretation

The *User Guide to HSNO Thresholds and Classifications* outlines mitigating factors that should be considered when interpreting data from various sources. For example, problems associated with testing a substance (or substance as a mixture) or where testing is not necessary for a particular effect.

8.7 Hazard cut-off levels for ecotoxic effects

The *User Guide to HSNO Thresholds and Classifications* outlines hazard cut-off levels for an ecotoxic effect below which the ecotoxic effect is unlikely to occur.

8.8 Minimum data sets

The *User Guide to HSNO Thresholds and Classifications* also recognises the actual risk posed by substances in particular circumstances. Different types of hazardous substances present different levels of risk and will therefore require different types and levels of information for consideration of applications for approval. Different levels of information could relate to the quantity, extent, or degree of detail of information, as applicable to the application involved.

This approach is consistent with the ERMA New Zealand publication *User Guide for Making an Application for a Hazardous Substance Approval*.

8.9 Classification of mixtures ('mixture rules')

To assist in the determination of whether a substance, or substance as a mixture, triggers a toxic effect threshold and its subsequent classification, a series of "mixture rules" are provided in the *User Guide to HSNO Thresholds and Classifications.* These rules are internationally accepted under the GHS and follow a stepwise process, based on the type of

data available to the applicant for a particular ecotoxic endpoint, on how to use that information to classify their substance as hazardous or non-hazardous.

For example if the substance has been tested, then it is relatively straightforward to decide if the threshold is triggered or not. If a substance as a mixture has not been directly tested but individual components of the mixture have been, then this data can be used to estimate the likely ecotoxicity of the substance as a mixture.

Appendix 1: Tables of Hazard Classifications

Hazard Classifications for Class 1, 2, 3, 4, and 5 Substances

Property	Explosiveness						Flammability									Capacity to oxidise		
Class	Class 1						Class 2		Class 3		Class 4					Class 5		
Subclass	**1.1** Mass explosion	**1.2** Projection	**1.3** Fire & minor blast	**1.4** No significant hazard	**1.5** Very insensitive	**1.6** Extremely insensitive	**2.1.1** Gases	**2.1.2** Aerosols	**3.1** Liquids	**3.2** Liquid Desensitised explosive	**4.1.1** Readily combustible	**4.1.2** Self reactive	**4.1.3** Solid Desensitised explosive	**4.2** Spontaneously combustible	**4.3** Dangerous when wet	**5.1.1** Liquids /solids	**5.1.2** Gases	**5.2** Organic peroxide
Hazard Classification	1.1A						2.1.1A	2.1.2A	3.1A	3.2A	4.1.1A	4.1.2A	4.1.3A	4.2A	4.3A	5.1.1A	5.1.2A	5.2A
	1.1B	1.2B		1.4B			2.1.1B		3.1B	3.2B	4.1.1B	4.1.2B	4.1.3B	4.2B	4.3B	5.1.1B		5.2B
	1.1C	1.2C	1.3C	1.4C					3.1C	3.2C		4.1.2C	4.1.3C	4.2C	4.3C	5.1.1C		5.2C
	1.1D	1.2D		1.4D	1.5D				3.1D			4.1.2D						5.2D
	1.1E	1.2E		1.4E								4.1.2E						5.2E
	1.1F	1.2F	1.3F	1.4F								4.1.2F						5.2F
	1.1G	1.2G	1.3G	1.4G								4.1.2G						5.2G
		1.2H	1.3H															
	1.1J	1.2J	1.3J															
		1.2K	1.3K															
	1.1L	1.2L	1.3L															
						1.6N												
				1.4S														

Appendix 1 cont. Hazard Classifications for Class 6, 8, and 9 Substances

Property	Toxicity								Corrosiveness			Ecotoxicity			
Class	Class 6								Class 8			Class 9			
Sub-Class	6.1 Acutely toxic	6.3 Skin irritant	6.4 Eye irritant	6.5 Sensitisation	6.6 Mutagen	6.7 Carcinogen	6.8 Reproductive / developmental	6.9 Target organ systemic	8.1 Metallic corrosive	8.2 Skin corrosive	8.3 Eye corrosive	9.1 Aquatic	9.2 Soil	9.3 Terrestrial Vertebrate	9.4 Terrestrial Invertebrate
Hazard Classification	6.1 A	6.3A	6.4A	6.5 A	6.6 A	6.7 A	6.8 A	6.9 A	8.1A	8.2 A	8.3 A	9.1 A	9.2 A	9.3 A	9.4 A
	6.1 B	6.3B		6.5 B	6.6 B	6.7 B	6.8 B	6.9 B		8.2 B		9.1 B	9.2 B	9.3 B	9.4 B
	6.1 C						6.8 C			8.2 C		9.1 C	9.2 C	9.3 C	9.4 C
	6.1 D											9.1 D	9.2 D		
	6.1E														

Appendix 2 Substance Evaluation Sheet

The attached Substance Evaluation Sheet aims to guide you through the process of assessing for each hazardous property whether a substance is hazardous or not and helps you to consider if you have the necessary information. It has been designed so that one sheet is used for each substance. You may copy the sheet, obtain further copies from ERMA New Zealand, or download it from our website. By working through the sheet in conjunction with this guide, you should be able to decide whether your substance is a hazardous substance. Please do not send your evaluation to ERMA New Zealand for validation. ERMA New Zealand will only make determinations in special circumstances[2].

[2] These circumstances include the review of an application made under Part V of the HSNO Act and Regulations made under section 75(1)(g) of the HSNO Act declaring a substance not to be hazardous for the purposes of the Act.

Substance Evaluation Sheet

1. How to Use this Sheet

This sheet is designed to guide you through the process of assessing whether your substance is 'hazardous' under the HSNO Act. It is designed so that one sheet is used per substance and it is intended for use alongside the *User Guide to the HSNO Thresholds and Classifications*.

2. Identity

Substance Name: _____

Substance Composition: _____

If the substance has more than one component, list all the components that make up the substance. Where the CAS Number and/or UN Number is known list this. For substances with components listed as a percentage range, the maximum value should be used when evaluating the properties below.

Component	CAS No	UN No	%(range)

3. Explosive Properties

There are four parts to the explosives threshold that need to be considered:

- Is the substance listed as a Class 1 substance in the United Nations Recommendations for the Transport of Dangerous Goods – Model Regulations (section 3.3a);
- explosiveness and sensitive to stimuli (likelihood of detonating or deflagrating) (section 3.3b);
- a substance or substances designed to detonate, deflagrate or produce a pyrotechnic effect. (section 3.3c).
- external bonfire test for manufactured articles (section 3.3d)

Does the substance have explosive properties?	No ☐ Don't know ☐ Yes ☐
If **Yes**, list properties that exceed threshold:	

4. Flammable Properties

There are 10 possible flammable elements as outlined below:

Is the substance a flammable gas (section 4.3a)?	No ☐	Don't know ☐	Yes ☐
Is the substance a flammable aerosol (section 4.3 b)?	No ☐	Don't know ☐	Yes ☐
Is the substance a flammable liquid (section 4.3c)?	No ☐	Don't know ☐	Yes ☐
Is the substance a liquid desensitised explosive (section 4.3d)?	No ☐	Don't know ☐	Yes ☐
Is the substance a flammable solid (section 4.3e)?	No ☐	Don't know ☐	Yes ☐
Is the substance a solid, which may cause fire through friction (section 4.3e)?	No ☐	Don't know ☐	Yes ☐
Is the substance a self-reactive substance (section 4.3f)?	No ☐	Don't know ☐	Yes ☐
Is the substance a solid desensitised explosive (section 4.3g)?	No ☐	Don't know ☐	Yes ☐
Is the substance a pyrophoric or self-heating substance, liable for spontaneous combustion (section 4.3h)?	No ☐	Don't know ☐	Yes ☐
Does the substance emit a flammable gas upon contact with water (section 4.3i)?	No ☐	Don't know ☐	Yes ☐
If **Yes** to any of the above, list the properties that exceed threshold:			

5. Oxidising Properties

There are three oxidising property elements to be considered.

Does the substance have oxidising properties (section 5.3a(i),(ii), (iii)) and is a solid or a liquid?	No ☐	Don't know ☐	Yes ☐
Does the substance have oxidising properties (section 5.3a(i),(iv)) and is a gas?	No ☐	Don't know ☐	Yes ☐
Is the substance an organic peroxide (section 5.3b)?	No ☐	Don't know ☐	Yes ☐
If **Yes** to any of the above, list the properties that exceed the threshold:			

6. Corrosive Properties

Substances that are biologically corrosive are those that have irreversible skin or eye irritation effects.

Is the substance a metallic corrosive (section 6.2a)?	No ☐	Don't know ☐	Yes ☐
Is the substance corrosive to skin (section 6.2b)?	No ☐	Don't know ☐	Yes ☐
Is the substance corrosive to eyes (section 6.2c)?	No ☐	Don't know ☐	Yes ☐
If **Yes** to any of the above, list the properties that exceed the threshold:			

7. Toxic Properties

The following toxic property elements need to be considered.

Does the substance have acute toxic properties (oral, dermal, inhalation) (section 7.2a)?	No ☐	Don't know ☐	Yes ☐
Does the substance have skin or eye irritation effects (sections 7.2 b) and c))?	No ☐	Don't know ☐	Yes ☐
Does the substance have sensitisation properties (section 7.2d)?	No ☐	Don't know ☐	Yes ☐
Does the substance have mutagenic or genotoxic effects (section 7.2e)?	No ☐	Don't know ☐	Yes ☐
Does the substance have carcinogenic effects (section 7.2 f))?	No ☐	Don't know ☐	Yes ☐
Does the substance have reproductive or developmental effects (section 7.2g)?	No ☐	Don't know ☐	Yes ☐
Does the substance have target organ systemic toxicity effects (section 7.2 h)?	No ☐	Don't know ☐	Yes ☐
If **Yes** to any of the above, list properties and a summary of the relevant data:			

8. Ecotoxic Properties

There are five elements of the threshold for ecotoxic properties that need to be considered.

Is the substance ecotoxic to the aquatic environment (section 8.2 a)?	No	☐	Don't know	☐	Yes ☐
Is the substance ecotoxic to the soil environment (section 8.2 b)?	No	☐	Don't know	☐	Yes ☐
Is the substance ecotoxic to terrestrial vertebrates (section 8.2 c)?	No	☐	Don't know	☐	Yes ☐
Is the substance ecotoxic to terrestrial invertebrates (section 8.2 d)?	No	☐	Don't know	☐	Yes ☐
Is the substance designed for biocidal action (section 8.2 e)?	No	☐	Don't know	☐	Yes ☐
If **Yes** to any of the above, list the properties and a summary of the relevant data:					

9. Evaluation of Uncertainty or Data Gaps

For those properties where 'Don't Know' has been ticked, please list below whether, in your opinion, the substance may exceed a hazardous property threshold. Each 'Don't Know' tick should be explicitly addressed, with reasons to substantiate your conclusion.

(**Note:** It is not sufficient to state that a particular test or study is not required or relevant. An explanation must be provided as to why the particular test or study is not required or relevant.)

10. Assessment of Substance Evaluation

Is the substance (name): a hazardous substance?:	No	☐	Don't know	☐	Yes ☐

We recommend that after completing an evaluation, you thoroughly document your reasons for your decision. You may also wish to obtain expert advice to support this. Please do not send your evaluation to ERMA New Zealand for validation.