

Hazardous Substances and New Organisms Act 1996

Pharmaceutical Active Ingredients Group Standard 2010

Pursuant to section 96B of the Hazardous Substances and New Organisms Act 1996 (**the Act**), the Environmental Risk Management Authority, on application by Douglas Pharmaceuticals Limited, issues this Group Standard.

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1 Title

Pharmaceutical Active Ingredients Group Standard 2010

HSNO Approval Number

The HSNO Approval Number for this Group Standard is **HSRxxxxxx**.

2 Commencement

This Group Standard comes into force on **insert date** and applies to substances under section 96B(2)(a), (b) and (c) of the Act.

3 Interpretation

- (1) In this Group Standard, unless the context otherwise requires, words and phrases shall have the meanings given to them in Schedule 2.
- (2) In this Group Standard, references to a hazardous property of a substance being equivalent to a specified HSNO hazard classification, means a reference to the specified hazard classification as set out in the Hazardous Substances (Classification) Regulations 2001.

4 Scope of Group Standard

Substances covered by Group Standard

- (1) This Group Standard applies to any substance destined solely for use as a pharmaceutical active ingredient in a pharmaceutical product, whether imported or manufactured, and where that pharmaceutical active ingredient meets the minimum degrees of hazard as set out in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.
- (a) A substance referred to in subclause (1) must have one or more of the following (but only the following) hazards:
 - (b) a flammable liquid with a flashpoint of less than 23°C and an initial boiling point of greater than 35°C, HSNO 3.1B classification;
 - (c) a flammable liquid with a flashpoint of greater than 23°C and less than or equal to 60°C, HSNO 3.1C classification;
 - (d) a flammable liquid with a flashpoint of greater than 60°C and less than or equal to 93°C, HSNO 3.1D classification;
 - (e) a flammable solid with low hazard, HSNO 4.1.1B classification;
 - (f) an oxidising solid or liquid with low hazard, HSNO 5.1.1C classification;
 - (g) acute toxicity, HSNO 6.1A, 6.1B, 6.1C, 6.1D, 6.1E classifications;
 - (h) skin irritancy, HSNO 6.3A or 6.3B classification;
 - (i) eye irritancy, HSNO 6.4A classification;
 - (j) respiratory sensitisation, HSNO 6.5A classification;
 - (k) contact sensitisation, HSNO 6.5B classification;
 - (l) mutagenicity, HSNO 6.6A or 6.6B classifications;
 - (m) carcinogenicity, HSNO 6.7A or 6.7B classifications;
 - (n) reproductive toxicity, HSNO 6.8A, 6.8B or 6.8C classifications;
 - (o) target organ toxicity, HSNO 6.9A or 6.9B classifications;
 - (p) metallic corrosivity, HSNO 8.1A classification;
 - (q) skin corrosivity, HSNO 8.2A, 8.2B or 8.2C classifications;
 - (r) eye corrosivity, HSNO 8.3A classification;
 - (s) ecotoxicity, HSNO class 9.

Substances excluded from Group Standard

- (2) This Group Standard excludes any substance that—
- (a) is not a pharmaceutical active ingredient of a medicine that has been assessed and approved for use in New Zealand by the Ministry of Health, in Europe by the European Medicines Agency, in Australia by the Therapeutic Goods Administration, in Japan by the Pharmaceutical and Food Safety Bureau (PFBS) or the United States by the Food and Drug Administration (US FDA); or
 - (b) is an excipient ingredient in a pharmaceutical product; or
 - (c) is not listed on the Inventory of Chemicals, unless clause 26 of Schedule 1 is complied with.

5 Conditions of Group Standard

The obligations and restrictions set out in Schedules 1 and 2 to the Group Standard apply to the substances by way of conditions.

Schedule 1

Conditions of Group Standard

Part 1

Information Requirements

1 General information

- (1) Any information provided or required to be made available or supplied under this Part (Information Requirements) must be readily understandable and if provided in words (whether written or oral) be in the English language. Where written information is provided, it must also be legible and durable.
- (2) Any information provided must not include any statement, expression, device, trade name or description that—
 - (a) contradicts or modifies any expression required by this Group Standard to be on the label; or
 - (b) is false or misleading in relation to the safety of the substance or any of its ingredients; or
 - (c) misrepresents the composition of the substance; or
 - (d) misrepresents any property of the substance, including information that suggests the substance belongs to a class or sub-class that it does not in fact belong to.

2 Labelling

Duties of suppliers

- (1) A person must not sell or supply a substance to another person unless the substance is labelled in accordance with this clause.

Hazard information required on each label

- (2) A label must provide the following general information about a substance:
 - (a) the product name; and
 - (b) enough information to enable the New Zealand importer, supplier or manufacturer to be contacted, either in person or by telephone; or
 - (c) be accompanied with transportation documentation that meets the IATA/Land Transport/Sea Transport Legislative requirements; and
 - (d) in the case of a HSNO class 6 or HSNO class 8 substance, a 24 hour emergency telephone number.

- (3) A label must provide the following hazard information about the substance:
- (a) where a substance is a flammable liquid, the pictogram, signal word and hazard statements for flammable liquids, where relevant, to appear on the main label—
 - (i) the pictogram for flammable liquids in the case of a HSNO 3.1B or 3.1C substance; and
 - (ii) the **applicable** signal word, either—
 - (I) ‘**danger**’ in the case of a HSNO 3.1B substance; or
 - (II) ‘**warning**’ in the case of a HSNO 3.1C or 3.1D substance, unless the substance is a HSNO 6.1A, 6.1B, 6.1C, 6.5A, 6.6A, 6.7A, 6.8A, 6.9A, 8.2A, 8.2B, 8.2C or 8.3A substance in which case the signal word ‘**danger**’ is required; and
 - (iii) the applicable hazard statement, either—
 - (I) ‘**highly flammable liquid and vapour**’ in the case of a HSNO 3.1B substance; or
 - (II) ‘**flammable liquid and vapour**’ in the case of a HSNO 3.1C substance; or
 - (III) ‘**combustible liquid**’ in the case of a HSNO 3.1D substance; and
 - (b) where a substance is a flammable solid, the pictogram, signal word and hazard statement for HSNO 4.1.1B substances to appear on the main label—
 - (i) the relevant pictogram for a HSNO class 4 substance as depicted in Table 1 of the document, Labelling of Hazardous Substances: Hazard and Precautionary Information published by the Authority, July 2006; and
 - (ii) the applicable signal word—
 - (I) ‘**warning**’ unless the substance is a HSNO 6.1A, 6.1B, 6.1C, 6.5A, 6.6A, 6.7A, 6.8A, 6.9A, 8.2A, 8.2B, 8.2C or 8.3A substance in which case the signal word ‘**danger**’ is required; and
 - (II) the hazard statement ‘**flammable solid**’; and
 - (c) where a substance is an oxidiser, the pictogram, signal word and hazard statements for HSNO 5.1.1C substances to appear on the main label—
 - (i) the pictogram for a HSNO 5.1.1C substance; and
 - (ii) the applicable signal word—
 - (I) ‘**warning**’ unless the substance is a HSNO 6.1A, 6.1B, 6.1C, 6.5A, 6.6A, 6.7A, 6.8A, 6.9A, 8.2A, 8.2B, 8.2C or 8.3A substance in which case the signal word ‘**danger**’ is required; and
 - (II) the oxidising hazard statement ‘**may intensify fire; oxidizer**’; and

- (d) where a substance is an acutely toxic, the pictogram, signal word and hazard statements for acutely toxic substances to appear on the main label—
- (i) the applicable pictogram for acute toxicity; and
 - (ii) the applicable signal word, either—
 - (I) ‘**danger**’ in the case of a HSNO 6.1A, 6.1B or 6.1C substance; or
 - (II) ‘**warning**’ in the case of a HSNO 6.1D or 6.1E unless the substance is a HSNO 3.1B, 6.5A, 6.6A, 6.7A, 6.8A, 6.9A, 8.2A, 8.2B, 8.2C or 8.3A substance in which case the signal word ‘**danger**’ is required; and
 - (iii) the applicable acute toxicity hazard statement(s), depending on the route for toxicity—
 - (I) for a HSNO 6.1A (oral) substance, ‘**fatal if swallowed**’
 - (II) for a HSNO 6.1B (oral) substance, ‘**fatal if swallowed**’
 - (III) for a HSNO 6.1C (oral) substance, ‘**toxic if swallowed**’
 - (IV) for a HSNO 6.1D (oral) substance, ‘**harmful if swallowed**’
 - (V) for a HSNO 6.1E (oral) substance, ‘**may be harmful if swallowed**’
 - (VI) for a HSNO 6.1A (dermal) substance, ‘**fatal in contact with skin**’
 - (VII) for a HSNO 6.1B (dermal) substance, ‘**fatal in contact with skin**’
 - (VIII) for a HSNO 6.1C (dermal) substance, ‘**toxic in contact with skin**’
 - (IX) for a HSNO 6.1D (dermal) substance, ‘**harmful in contact with skin**’
 - (X) for a HSNO 6.1E (dermal) substance, ‘**may be harmful in contact with skin**’
 - (XI) for a HSNO 6.1A (inhalation) substance, ‘**fatal if inhaled**’
 - (XII) for a HSNO 6.1B (inhalation) substance, ‘**fatal if inhaled**’
 - (XIII) for a HSNO 6.1C (inhalation) substance, ‘**toxic if inhaled**’
 - (XIV) for a HSNO 6.1D (inhalation) substance, ‘**harmful if inhaled**’
 - (XV) for a HSNO 6.1E (inhalation) substance, ‘**may be harmful if inhaled**’; and
- (e) where a substance is carcinogenic, the pictogram and relevant hazard statement for carcinogenic substances to appear on the main label—
- (i) the pictogram for carcinogens; and

- (ii) the applicable signal word, either—
 - (I) ‘**danger**’ in the case of a HSNO 6.7A substance; or
 - (II) ‘**warning**’ in the case of a HSNO 6.7B substance, unless the substance is a HSNO 3.1B, 6.1A, 6.1B, 6.1C, 6.5A, 6.6A, 6.8A, 6.9A, 8.2A, 8.2B, 8.2C or 8.3A substance in which case the signal word ‘**danger**’ is required; and
- (iii) the applicable carcinogenic hazard statement, either—
 - (I) ‘**may cause cancer**’, <state the route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>, in the case of a 6.7A substance; or
 - (II) ‘**suspected of causing cancer**’, <state the route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>, in the case of a 6.7B substance; and
- (f) where a substance is corrosive, the pictogram, signal word and hazard statements for corrosive substances to appear on the main label—
 - (i) the pictogram for corrosivity; and
 - (ii) the applicable signal word, either—
 - (I) ‘**danger**’ in the case of a HSNO 8.2A, 8.2B, 8.2C, or 8.3A substance; or
 - (II) ‘**warning**’ in the case of a HSNO 8.1A substance, unless the substance is a HSNO 3.1B, 6.1A, 6.1B, 6.1C, 6.5A, 6.6A, 6.7A, 6.8A, 6.9A, 8.2A, 8.2B, 8.2C or 8.3A substance in which case the signal word ‘**danger**’ is required; and
 - (iii) the applicable hazard statement, either—
 - (I) ‘**may be corrosive to metals**’ in the case of a 8.1A substance; or
 - (II) ‘**causes severe skin burns and eye damage**’ in the case of a HSNO 8.2A, 8.2B or 8.2C substance; or
 - (III) ‘**causes serious eye damage**’ in the case of a HSNO 8.3A substance if the substance is not also a HSNO 8.2 substance.
- (g) where a substance has any of the hazards permitted under clause 4(2) of this Group Standard (Scope of Group Standard), the corresponding pictograms and hazard statements as listed in Tables 1 and 2 of the document Labelling of Hazardous Substances: Hazard and Precautionary Information published by the Authority, July 2006 must appear on the label, subject to the principles of precedence as set out in the above-named document; and
- (h) for all hazards, the label must provide the applicable precautionary (prevention, storage and response) statements as listed in Tables 3 to 5 of the document Labelling of Hazardous Substances: Hazard and Precautionary Information published by the Authority, July 2006.

- (4) A single indication may be used if it is capable of conveying two or more of the items of hazard identification required by subclause (3).

Disposal information required on each label

- (5) A label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with clause 22 of this schedule, which may also include any method of disposal that must be avoided.

Identification of components on label

- (6) Subject to subclause (7), a label must provide—
- (a) the common or chemical name and concentration of every ingredient that would independently of any other ingredient, give the substance a HSNO 6.1A, 6.1B, 6.1C, 6.5, 6.6, 6.7, 6.8, 6.9, 8.2 or 8.3 classification; and
 - (b) the name of every ingredient (other than an ingredient referred to in subclause (a)) that would, independently of any other ingredient, give the substance a HSNO 6.1D classification, and the concentration of the ingredient that would contribute the most to the classification.
- (7) In the case of a HSNO 6.5, 6.6, 6.7, 6.8, 6.9 classifications, the identification of any component on the label is only required if the concentration of the component is at or above the concentration specified in **Table 1**.

Table 1. Concentration values triggering identification of components on label

HSNO Classification	Cut-off, %
6.5A, 6.5B, 6.6A	0.1
6.6B	1
6.8A, 6.8C	0.3
6.8B	3
6.9A, 6.9B	10

- (8) For the purposes of complying with subclause (6)—
- (a) a generic name may be used to identify a group of ingredients in accordance with the provisions of regulation 26 of the Hazardous Substances (Identification) Regulations 2001; and
 - (b) the concentration of an ingredient in a substance may be stated as a range in accordance with the provisions of regulation 27 of the Hazardous Substances (Identification) Regulations 2001.

Multiple Packages

- (9) Where a substance is labelled in compliance with subclauses (1) to (8), but some or all of the required information is obscured by outer packaging, the outer packaging of the substance must bear the labelling or marking required by—
- (a) Subclauses (3)(a) to (g); or
 - (b) the Land Transport Rule; or

- (c) the Civil Aviation Rule; or
- (d) the Maritime Rule.

Exemption from specific labelling requirements for ecotoxic substances

- (10) For a substance with an ecotoxic hazard of—
 - (a) HSNO 9.1C or 9.1D classification, the corresponding hazard statement required by subclause (3)(g) is not required;
 - (b) HSNO 9.2, 9.3, or 9.4 classification, the corresponding pictogram, and hazard prevention and response statements required by subclauses (3)(g) and (h) are not required.

Exemption from labelling requirements for small packages

- (11) When a substance is contained in a package with a capacity of 5 L or 5 kg or less, the label for that package does not need to provide the following information:
 - (a) any pictogram required by subclauses (3)(a) to (g); and
 - (b) the signal word, hazard and response statements for any HSNO class 9 hazards, as required by subclauses (3)(g) and (h).

Exemption from specific labelling requirements for imported and exported packages

- (12) Where a substance has been imported into New Zealand in a closed package or in a freight container (and for any reasonable period after it arrives that is necessary to arrange compliance with the requirements of subclauses (1) to (8)), and where that substance is being carried from the place of importation to the destination stated in its importation documentation without having been removed from that package or container, subclauses (1) to (8) are complied with if the package or container concerned complies with the requirements of—
 - (a) subclauses (3)(a) to (3)(g); or
 - (b) the Land Transport Rule; or
 - (c) the Civil Aviation Rule; or
 - (d) the Maritime Rule.
- (13) Where a substance is exported from New Zealand, subclauses (1) to (8) are complied with if the substance is labelled or marked as required by—
 - (a) subclauses (3)(a) to (3)(g); or
 - (b) the Land Transport Rule; or
 - (c) the Civil Aviation Rule; or
 - (d) the Maritime Rule.

Alternative compliance measures for labelling

- (14) The requirements of subclauses (1) to (13) do not need to be met if a substance complies with—
- (a) the relevant identification provisions in the Hazardous Substances (Identification) Regulations 2001, the Hazardous Substances (Emergency Management) Regulations 2001, and the Hazardous Substances (Disposal) Regulations 2001; or
 - (b) a code of practice approved by the Authority under section 78 of the Act that specifies requirements equivalent to those set out in subclauses (1) to (13); or
 - (c) the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and the requirements of subclause (2); or
 - (d) the relevant current labelling requirements of Australia, USA, Canada, the European Union or any other country as approved by the Authority, as if the substances were for sale or supply in those countries, and the requirements of subclause (2).

Substances transported in bulk

- (15) Where a substance is transported in bulk, subclauses (1) to (8) do not apply provided the substance is transported in compliance with—
- (a) the Land Transport Rule; or
 - (b) the Civil Aviation Rule; or
 - (c) the Maritime Rule.
- (16) For the purposes of subclause (15), “bulk” means—
- (a) a liquid substance in a container of an undivided quantity exceeding **450 L**; or
 - (b) a solid substance in a container in an undivided quantity exceeding **400 kg**.

3 Safety data sheets

- (1) A person, when selling or supplying a substance shall provide a safety data sheet for the substance supplied to the recipient:
- (a) the first time the substance is supplied to the place of work; and
 - (b) they have not previously supplied a safety data sheet for that substance to the recipient.
- (2) The Person in Charge must ensure that:
- (a) in each place of work where the substance is stored or used, that every person handling the substance has access to a safety data sheet for that substance; and

- (b) the safety data sheet must be available to a person handling the substance within 10 minutes, and be readily understandable by any fully trained worker required to have access to it.
- (3) A person who manufactures or supplies a substance in New Zealand or imports a substance into New Zealand must, if asked to do so by any person in charge of a place of work where a substance is stored or used, give that person the required safety data sheet.
- (4) Information required on a safety data sheet must be provided under the following general headings in the order listed below, and must include the information referred to under those headings:
- (a) **Identification of the substance and supplier—**
 - (i) product name; and
 - (ii) recommended uses; and
 - (iii) name of the supplier, New Zealand contact details including an emergency contact;
 - (b) **Hazards identification—**
 - (i) a description of the hazards of the substance, which may include its HSNO hazard classification; and
 - (ii) hazard information, including signal words, hazard statement(s) and precautionary statement(s);
 - (c) **Composition/information on ingredients—**
 - (i) in the case of single component substances, their chemical identity, including common names and synonyms, CAS number and any impurities that are themselves hazardous; or
 - (ii) in the case of substances that are mixtures, the chemical identity of each hazardous ingredient, their CAS numbers and their concentration ranges;
 - (d) **First aid measures—**
 - (i) first aid instructions according to each relevant route of exposure; and
 - (ii) if medical attention is required, and its urgency; and
 - (iii) information on the most important symptoms and effects, acute and delayed from exposure;
 - (e) **Fire fighting measures—**
 - (i) information on the appropriate type of extinguishers or fire-fighting agents, including extinguishers that may not be appropriate for a particular situation; and
 - (ii) any advice on hazards that may arise from combustion products; and

- (iii) precautions for fire fighters and protective clothing requirements;
- (f) **Accidental release measures—**
 - (i) advice on protective clothing requirements and emergency procedures; and
 - (ii) any environmental precautions from accidental spills and release; and
 - (iii) advice on how to contain and clean up a spill or release;
- (g) **Handling and storage—**
 - (i) precautions for safe handling; and
 - (ii) conditions for safe storage, including any incompatibilities;
- (h) **Exposure controls/personal protection—**
 - (i) exposure limits set for the substance or any of its components, or in their absence, relevant overseas exposure limits; and
 - (ii) engineering controls; and
 - (iii) individual protection measures, including personal protective equipment;
- (i) **Physical and chemical properties—**
 - (i) a description of relevant physical and chemical properties for the substance, including units of measurement and reference conditions where appropriate; and
 - (ii) where necessary for interpretation of data reported, the method of determination;
- (j) **Stability and reactivity—**
 - (i) an indication of the chemical stability of the substance under normal and anticipated storage and handling conditions; and
 - (ii) a list of conditions to avoid to prevent a hazardous situation; and
 - (iii) information on incompatible substances or materials;
- (k) **Toxicological information—**
 - (i) a full description of the toxicological (health) effects, including the symptoms or signs of injury or ill health associated with each likely route of exposure; and
 - (ii) the dose, concentration or conditions of exposure likely to cause injury or ill health; and
 - (iii) a summary of the data used to identify the health effects;

- (l) **Ecological information—**
 - (i) ecotoxicity; and
 - (ii) persistence and degradability; and
 - (iii) mobility;
 - (m) **Disposal considerations—**
 - (i) disposal methods, including disposal of packaging; and
 - (ii) special precautions to be taken during disposal; and
 - (iii) any method of disposal that should not be used;
 - (n) **Transport information—**

If relevant,

 - (i) the UN number; and
 - (ii) the proper shipping name; and
 - (iii) the UN Dangerous Goods class and subsidiary risk; and
 - (iv) the UN Packing Group;
 - (o) **Regulatory information—**
 - (i) HSNO approval number and/or title of the Group Standard; and
 - (ii) information on the conditions of the Group Standard, and any other regulatory requirements;
 - (p) **Other information—**
 - (i) date of preparation or revision of the safety data sheet; and
 - (ii) a key/legend to abbreviations and acronyms used.
- (5) Where a substance is being transported, a safety data sheet is not required if:
- (a) there is in the vehicle concerned documentation complying with the Land Transport Rule whilst being transported by land; or
 - (b) there is in the ship concerned documentation complying with the Maritime Rule whilst being transported by sea; or
 - (c) there is in the aircraft concerned documentation complying with the Civil Aviation Rule whilst being transported by air.

Part 2 Site and Storage

4 Compliance with site and storage requirements

- (1) Any location at which a substance is manufactured or stored in quantities that exceed those set out in Table 2 must comply with the relevant conditions as set out in the relevant site and storage document, published by the Authority as appropriate to the material's hazards.
- (2) The relevant site and storage documents are—
 - (a) for flammable liquids, *Site and Storage Conditions for Class 3.1 Flammable Liquids, July 2006*;
 - (b) for flammable solids, *Site and Storage Conditions Class 4 Substances, July 2006*;
 - (c) for oxidising substances, *Site and Storage Conditions for Class 5.1.1 Oxidising Substances and Class 5.2 Organic Peroxides, July 2006*;
 - (d) for all other substances, *Site and Storage Conditions for Toxic, Corrosive and Ecotoxic Substances, July 2006*.

Table 2. Trigger quantities beyond which site and storage conditions apply

	Trigger Quantity	
Location and transit depot test certification for HSNO 3.1B substances	100 L	(closed containers greater than 5 L)
	250 L	(closed containers up to and including 5 L)
	50 L	(open containers)
Location and transit depot test certification for HSNO 3.1C substances	500 L	(closed containers greater than 5 L)
	1,500 L	(closed containers up to and including 5 L)
	250 L	(open containers)
Location and transit depot test certification for HSNO 4.1.1B substances	100 kg	(closed containers)
	100 kg	(open containers)
Location and transit depot test certification for HSNO 5.1.1C substances	1000 L / 1000 kg	(closed containers)
	100 L / 100 kg	(open containers)
Hazardous atmosphere zone for HSNO 3.1B or 3.1C substances	100 L	(closed containers)
	25 L	(decanting)
	5 L	(open occasionally)
	1 L	(open containers in continuous use)
Fire extinguishers	250 L	(for a HSNO 3.1B substance)
	500 L	(for a HSNO 3.1C or 3.1D substance)
	500 kg	(for a HSNO 4.1.1B substance)
	500 L or 500 kg	(for a HSNO 5.1.1C substance)

	Trigger Quantity	
Response plans and secondary containment	100 L or 100 kg	(for a HSNO 6.1A, 6.1B, 6.1C, 8.2A, 9.1A substance)
	1,000 L or 1,000 kg	(for a HSNO 3.1B, 6.1D, 6.5A, 6.5B, 6.7A, 8.2B, 9.1B or 9.1C substance)
	5,000 L or 5,000 kg	(for a HSNO 5.1.1C substance)
	10,000 L or 10,000 kg	(for all other substances)
Signage	50 L or 50 kg	(for a HSNO 6.1A or 8.2A substance)
	100 L or 100 kg	(for a HSNO 9.1A, 9.2A, 9.3A, 9.4A substance)
	250 kg or 250 L	(for a HSNO 3.1B, 6.1B or 8.2B substance)
	1,000 L or 1,000 kg	(for a HSNO 3.1C, 4.1.1B, 5.1.1C, 6.1C, 8.1A, 8.2C, 8.3A, 9.1B, 9.1C, 9.2B, 9.2C, 9.3B, 9.4B, or 9.4C substance)
	10,000 L or 10,000 kg	(for all other substances)

- (3) The trigger quantities referred to in Table 2 must take into account any other hazardous substance that is present at that location.

Stationary container systems

- (4) Any stationary container system that contains, or is intended to contain, a substance must comply, to the extent applicable, with the controls for stationary container systems as set out in Parts 1 to 19 of Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004, notwithstanding clause 1(1) of that Schedule.

Part 3

Approved Handler

5 Approved handler requirement for HSNO 3.1B substances

When present in quantities greater than 250 L (when in containers greater than 5 L) or 500 L (when in containers up to and including 5 L), a HSNO 3.1B substance must be—

- (a) under the personal control of an approved handler who holds a current test certificate to manage HSNO class 3 substances; or
- (b) secured so that a person cannot gain access to the substance without tools, keys, or any other device used for operating locks.

6 Approved handler requirement for HSNO 5.1.1C substances

When present in quantities greater than 1000 L or 1000 kg, a HSNO 5.1.1C substance must be—

- (a) under the personal control of an approved handler who holds a current test certificate to manage HSNO class 5 substances; or
- (b) secured so that a person cannot gain access to the substance without tools, keys, or any other device used for operating locks.

7 Approved handler requirement for HSNO 6.1A-C substances

When present in any amount, a HSNO 6.1A-6.1C substance must be—

- (a) under the personal control of an approved handler who holds a current test certificate to manage HSNO class 6 substances; or
- (b) secured so that a person cannot gain access to the substance without tools, keys, or any other device used for operating locks.

8 Approved handler requirement for HSNO 6.7A substances

When present in quantities greater than 10 L or 10 kg, a HSNO 6.7A substance must be—

- (a) under the personal control of an approved handler who holds a current test certificate to manage HSNO class 6 substances; or
- (b) secured so that a person cannot gain access to the substance without tools, keys, or any other device used for operating locks.

9 Approved handler requirement for HSNO 8.2A substances

When present in any amount, a HSNO 8.2A substance must be—

- (a) under the personal control of an approved handler who holds a current test certificate to manage HSNO class 8 substances; or
- (b) secured so that a person cannot gain access to the substance without tools, keys, or any other device used for operating locks.

10 Exemptions to approved handler requirements

Despite clauses 5-10 of this Schedule, a substance may be handled by a person who is not an approved handler if—

- (a) an approved handler is present at the place where the substance is being handled; and
- (b) an approved handler has provided guidance to the person in respect of the handling; and
- (c) an approved handler is available at all times to provide assistance, if necessary, to the person while the substance is being handled by the person.

11 Exception to approved handler requirement for transportation of packaged substances

- (1) The approved handler requirement is deemed to be complied with if—
 - (a) in the case of a substance being transported on land—

- (i) in the case of a substance being transported by rail, the person who drives the rail vehicle that is transporting the substance is fully trained in accordance with an approved safety system under section 6D of the Transport Services Licensing Act 1989 or a safety system which is referred to in an approved safety case under the Railways Act 2005; and
 - (ii) in every other case, the person who drives, loads, or unloads the vehicle that is transporting the substance—
 - (I) for hire or reward, or in quantities which exceed those set out in Schedule 1 of the Land Transport Rule, has a current dangerous goods endorsement on his or her driver licence; or
 - (II) in every other case, the Land Transport Rule is complied with; or
 - (b) in the case of a substance being transported by sea, one of the following is complied with:
 - (I) Maritime Rule; or
 - (II) International Maritime Dangerous Goods Code; or
 - (c) in the case of a substance being transported by air, the Civil Aviation Rule is complied with.
- (2) Subclause (1)(a)—
- (a) does not apply to a tank wagon or a transportable container to which the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 applies; but
 - (b) despite paragraph (a), does apply to an intermediate bulk container that complies with Chapter 6.5 of the UN Model Regulations.
- (3) Subclause (1)(c)—
- (a) applies to pilots, aircrew, and airline ground personnel loading and handling substances within an aerodrome; but
 - (b) does not apply to the storage and handling of a substance in any place that is not within an aerodrome, or within an aerodrome by non-airline ground personnel.

12 Tracking requirement for 6.1A and 6.1B substances

The location and movement of a HSNO 6.1A or 6.1B substance must comply with the Hazardous Substances (Tracking) Regulations 2001.

Part 4 Licenses

13 Manufacturing Site Requirements

- (1) A pharmaceutical active ingredient may only be provided for use to:

- (a) a company holding a current licence to manufacture medicine issued in accordance with the Medicines Act 1981; or
 - (b) a company with an Exempt Laboratory Code of Practice that identifies the written policies and procedures adhered to by the company that ensures effective chemical management during all processes involving chemicals, during the lifecycle of these chemicals until their incorporation into a medicinal product.
- (2) The Licence to Manufacture Medicine held by the company in subclause (1) must include—
- (a) conditions and approved classes of medicine covering the chemical properties of the pharmaceutical active ingredient; and
 - (b) conditions requiring the company to manufacture, pack, label and sell medicines in accordance with the Medicines Act 1981 and Medicines Regulations 1984; and
 - (c) the specific classes approved by the Ministry of Health, including at least one of the following:
 - (i) Class a: Antibiotics and preparations of antibiotics;
 - (ii) Class d: Hormones and steroid preparations;
 - (iii) Class e: Preparations, other than vitamins that have a dose of 5 mg or less per dose unit.
 - (iv) Class f: Antineoplastic agents and immunosuppressant agents, other than steroid preparations.
 - (v) Class g: Other medicines.

Part 5 Packaging

14 General packaging requirements

Every person who packs a substance must—

- (a) select packaging that when filled and closed—
 - (i) does not leak any substance under normal working conditions; and
 - (ii) maintains its ability to retain its contents, if part of the contents are removed and the package resealed; and
 - (iii) does not react with a substance in any way as to weaken the package; and
- (b) ensure that, if a substance is being packed into a package that has previously contained another substance—
 - (i) both substances are compatible; or

- (ii) all practicable steps are taken to remove all residues of the original substance.

15 Specific packaging requirements for 5.1.1C substances

Packaging for a HSNO 5.1.1 substance must, when closed, exclude any other substance that may cause the substance to spontaneously combust.

16 Compliance with UN Packing Group requirements

- (1) Where allowed for by the UN Model Regulations, large packaging may be used to contain a substance if it has been constructed, marked, and tested as a large package as provided in Chapter 6.6 of the UN Model Regulations.
- (2) When a substance is packaged in quantities less than or equal to 450 L or 400 kg, the packaging must comply with the requirements of—
 - (a) UN Packing Group I for any HSNO 6.1A or 8.2A substance; or
 - (b) UN Packing Group II for a HSNO 3.1B, 6.1B and/or 8.2B substance; or
 - (c) UN Packing Group III for a HSNO 3.1C, 4.1.1B, 5.1.1C, 6.1C, 8.1A, 8.2C, 8.3A, 9.1A or 9.1B substance.
 - (d) Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 for all other substances.

Variation to UN Packing Group II requirements

- (3) Despite subclause (2)(b), a HSNO 3.1B substance may, as a minimum, be packaged in packaging that complies with—
 - (a) UN Packing Group III criteria if it is a viscous substance that conforms with paragraphs 32.3.1.7 and 32.4.2 of the UN Manual of Tests and Criteria; or
 - (b) Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 when—
 - (i) in quantities less than or equal to **1 L**; or
 - (ii) in quantities less than or equal to **5 L**, where specifically provided for by the UN Model Regulations.
- (4) Despite subclause (2)(b), a HSNO 6.1B or 8.2B substance may, as a minimum, be packaged in packaging that complies with Schedule 4 of the Hazardous Substance (Packaging) Regulations 2001 when—
 - (a) in quantities less than or equal to **0.1 L** or **0.5 kg** for a HSNO 6.1B substance; or
 - (b) in quantities less than or equal to **0.5 L** or **1 kg** for a HSNO 8.2B substance

Variation to UN Packing Group III requirements

- (5) Despite subclause (2)(c), a substance required to comply with UN Packing Group III requirements may, as a minimum, be packaged in packaging that complies with Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 when—
- (a) in quantities less than or equal to **5 L** for a HSNO 3.1C substance; or
 - (b) in quantities less than or equal to **450 L** if it is a viscous substance that conforms with paragraphs 2.3.2.5 of the UN Model Regulations for a HSNO 3.1C substance, providing it is not also a HSNO 8.2C substance.
 - (c) in quantities less than or equal to **5 L** or **5 kg** for a HSNO 5.1.1C, 8.2C, 8.3A, 9.1A or 9.1B substance.
 - (d) in quantities of less than or equal to **5 L** or **5 kg** for a HSNO 6.1C substance.
 - (e) in quantities of less than or equal to **3 kg** for a HSNO 4.1.1B substance.
 - (f) in quantities of less than or equal to **5 L** or **5 kg** for a HSNO 9.1A or 9.1B substance.

Marking of Packaging

- (6) No manufacturer or importer of packaging designed and constructed for use with a substance may mark the packaging as specified in paragraphs 6.1.2 and 6.1.3 of the UN Model Regulations unless—
- (a) the markings comply with the corresponding elements of those paragraphs, including the codes for packaging type, UN Packing Group, and the UN packaging symbol; and
 - (b) the codes marked for UN Packing Group II or UN Packing Group III are marked on packaging that complies with the tests set out in Schedule 2 or Schedule 3 respectively of the Hazardous Substances (Packaging) Regulations 2001; and
 - (c) the design of the packaging has also been test certified as complying with the tests set out in Schedule 2 or Schedule 3 respectively of the Hazardous Substances (Packaging) Regulations 2001.
- (7) Subclause (6) does not apply to a substance that is not required to be packaged in UN Packing Group II or UN Packing Group III.

Part 6
Equipment

17 Personal protective equipment

- (1) A person who handles a hazardous substance in a place of work must use protective clothing or protective equipment that is designed, constructed, and operated to ensure that the person—
- (a) does not come into contact with the substance; and

- (b) is not exposed to a concentration of the substance that is greater than the workplace exposure standard for the substance, or any component of the substance.
- (2) Subclause (1) does not apply to a substance that is contained in a closed package that complies with the requirements of Part 5 (Packaging).
- (3) The supervisor of a place of work must ensure that protective clothing or protective equipment used to handle a substance is accompanied by documentation containing information specifying—
 - (a) the circumstances in which the clothing or equipment may be used; and
 - (b) the requirements for maintaining the clothing or equipment.
- (4) In subclause (3)(a), “circumstances” include, if relevant, the presence of other substances, and the temperatures and pressures in or at which the clothing or equipment may be used.

Additional protective clothing requirements for HSNO 5.1.1C substances

- (5) Protective clothing or equipment must be used at any time when a HSNO 5.1.1C substance is expected, or likely, to—
 - (a) come into contact with an ignition source or an incompatible substance or material, or
 - (b) be exposed to a greater temperature than the limit specified in clause 5(2) of the document entitled Site and Storage Conditions for Class 5.1.1 Oxidising Substances and Class 5.2 Organic Peroxides published by the Authority, 2006.
- (6) The protective clothing or equipment referred to in subclause (5) must—
 - (a) be designed, constructed, and operated to—
 - (i) prevent the substance making direct contact with the wearer or user; and
 - (ii) prevent the wearer or user being exposed to more than the level of heat radiation specified in clause 14(2) of the document entitled Site and Storage Conditions for Class 5.1.1 Oxidising Substances and Class 5.2 Organic Peroxides published by the Authority, 2006; and
 - (b) be designed and constructed of materials that, in the circumstances in which the substance is being used or handled—
 - (i) cannot be degraded, attacked, or combusted by the substance; or
 - (ii) are resistant to such degradation, attack, or combustion for the time specified by the supplier of the equipment or clothing.
- (7) The documentation referred to in subclause (3) must be available to a person handling the substance within 10 minutes, and be readily understandable by any fully trained worker required to have access to it.

18 Equipment used to handle a substance

- (1) The person in charge of a substance must ensure that equipment used to handle the substance—
 - (a) retains the substance, without leakage at all temperatures and pressure for which the equipment is intended to be used; and
 - (b) dispenses or applies the substance, without leakage, at a rate and in a manner that the equipment is designed for.
- (2) The equipment must be accompanied by documentation containing information about the use and maintenance of the equipment to enable the equipment to be used and maintained in a manner that complies with subclause (1).

Additional equipment requirements for HSNO 5.1.1C substances

- (3) The person in charge must ensure that any equipment or clothing that is directly used to handle a HSNO 5.1.1C substance is designed, constructed and operated in such a way that—
 - (a) the substance does not make direct contact with any incompatible substance or material; and
 - (b) the substance does not accumulate in or on the equipment or clothing beyond any accumulation that is directly associated with its intended design and use, as indicated in the documentation provided under subclause (2); and
 - (c) the substance is not exposed to sufficient energy to cause combustion or its chemical decomposition, unless the contact or exposure is intended or anticipated, in which case, the conditions of clauses 17(5) and 17(6) of this schedule must be met; and
 - (d) in the circumstances in which the substance is being used or handled, the equipment or clothing cannot be degraded, attacked, or combusted by the substance, or are resistant to such degradation, attack, or combustion for the time specified by the supplier of the equipment and clothing.
- (4) In relation to the circumstances described in subclause (3)(d), relevant matters include the range of temperatures and pressures and the presence of other substances likely to be encountered when used as described in the documentation referred to in subclause (2).
- (5) The documentation referred to in subclause (2) must meet the location and presentation requirements for documentation specified in clause 3(2)(b) of this schedule.

Part 7 Transportation

19 Fire extinguishers

Where a motor vehicle is transporting a HSNO 3.1B, 3.1C, 3.1D, 4.1.1B, or 5.1.1C substance in quantities greater than those listed in Table 3, there must be present, in or on the vehicle, the number of fire extinguishers listed in Table 3.

Table 3. Trigger quantities for provision of fire extinguishers in vehicles

	Trigger Quantity	No of fire extinguishers
3.1B	250 L	2
3.1C, 3.1D	500 L	2
4.1.1B	500 kg	2
5.1.1C	500 L or 500 kg	2

20 Passenger service vehicle restrictions

- (1) When a substance is carried on a passenger service vehicle, the substance must—
- (a) be packaged in a sealed container; and
 - (b) not exceed—
 - (i) **1 L** per package for a HSNO 3.1B substance; or
 - (ii) **10 L** per package for a HSNO 3.1C or 3.1D substance; or
 - (iii) **3 kg** per package for a HSNO 4.1.1B substance; or
 - (iv) **1 kg** per package for a HSNO 5.1.1C substance; or
 - (v) **0.1 L** or **0.5 kg** for a HSNO 6.1B, 6.5A or 6.5B substance; or
 - (vi) **1 L** or **3 kg** per package for a HSNO 6.1C, 6.3A or 6.4A substance; or
 - (vii) **10 L** or **10 kg** per package for a HSNO 6.1D, 6.1E or 6.3B substance; or
 - (viii) **0.5L** or **1 kg** for a HSNO 8.2B substance; or
 - (ix) **1 L** or **2 kg** per package for a HSNO 8.2C or 8.3A substance; or
 - (x) **2.5 L** or **5 kg** per package for all other substances.
- (2) No HSNO 6.1A or 8.2A substance may be transported on passenger service vehicles.

21 Tank Wagons and Transportable Containers

Tank wagons and transportable containers of any capacity used to carry a substance must comply with the Hazardous Substances (Tanks Wagons and Transportable Containers) Regulations 2004.

Part 8 Disposal

22 Disposal of substance

- (1) This clause does not apply to a substance that is intended for recycling.

Disposal requirements for HSNO 3.1 and HSNO 4.1.1B substances

- (2) A HSNO 3.1B, 3.1C, 3.1D or 4.1.1B substance may be disposed of by—
- (a) exporting the substance from New Zealand as waste; or
 - (b) treating the substance so that it is no longer a hazardous substance.
- (3) In subclause 2(b), “treating the substance” does not include depositing the substance in a sewage facility but does include—
- (a) burning in an incineration facility, provided—
 - (i) the burning is managed to the performance requirements of regulation 6(3)(b) of the Hazardous Substances (Disposal) Regulations 2001 in relation to blast pressure, heat radiation and access by persons; and
 - (ii) the burning operation does not exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its component(s); or
 - (b) depositing the substance in a landfill provided the landfill is managed to ensure that—
 - (i) the substance will not at any time come into contact with an explosive or oxidising substance (HSNO class 1 or 5); and
 - (ii) there is no ignition source in the vicinity of the disposal site that is capable of igniting the substance; and
 - (iii) were the substance to ignite, no person or place where a person may legally be, would be exposed to more blast overpressure or heat radiation than that described in regulation 6(3)(b) of the Hazardous Substances (Disposal) Regulations 2001; and
 - (iv) the concentration of the substance in any discharge from the landfill does not, after reasonable mixing, exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its component(s).

Disposal requirements for non-flammable substances, non-oxidising substances and non-aerosols

- (4) A substance must be disposed of by—
- (a) exporting the substance from New Zealand as waste; or
 - (b) treating the substance so that it is no longer a hazardous substance; or
 - (c) discharging the substance into the environment so that, after reasonable mixing, the concentration of the substance in an environmental medium does not exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its component(s).

- (5) In subclause 4(b), “treating the substance” includes depositing the substance in a landfill, incinerator or sewage facility providing—
- (a) the landfill, incinerator or sewage facility renders the substance non-hazardous by a means other than dilution; or
 - (b) the concentration of the substance in any discharge from the landfill, incinerator or sewage facility does not, after reasonable mixing, exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its component(s).
- (6) Notwithstanding subclause (4)(c), if the substance or one or more of its components is bioaccumulative and not rapidly degradable the substance must be treated before discharge into the environment to reduce the percentage by volume of the substance in the discharge to 1% or less.
- (7) A substance with no ecotoxic (HSNO class 9) hazard may be discharged into the environment without complying with subclause (4)(c) if it is rapidly degradable and the products of degradation are not hazardous.

Disposal requirements for HSNO 5.1.1C substances

- (8) A HSNO 5.1.1C substance must be disposed of by—
- (a) exporting the substance from New Zealand as waste; or
 - (b) treating the substance so that it is not longer a hazardous substance.
- (9) In subclause 8(b), “treating the substance” does not include depositing the substance in a sewage facility, but does include—
- (a) detonation, deflagration, or controlled combustion, provided the detonation, deflagration or controlled combustion is managed to the performance requirements of regulation 7(3)(b) of the Hazardous Substances (Disposal) Regulations 2001 in relation to blast pressure, heat radiation and access by persons; or
 - (b) depositing the substance in a landfill provided the landfill is managed to ensure that—
 - (i) the substance will not at any time come into contact with an explosive or flammable substance (equivalent to HSNO class 1, 2, 3, or 4); and
 - (ii) there is no ignition source in the vicinity of the disposal site that is capable of igniting the substance; and
 - (iii) if the substance were to combust, or cause or contribute to combustion, no person or place where a person may legally be would be exposed to more blast overpressure or heat radiation than that described in regulation 7(3)(b) of the Hazardous Substances (Disposal) Regulations 2001; and
 - (iv) the concentration of the substance in any discharge from the landfill does not, after reasonable mixing, exceed any relevant tolerable exposure limit and/or environmental exposure limit set for the substance or any of its components.

23 Disposal of packaging

- (1) The conditions of subclauses (2) and (3) apply to a package that—
 - (a) contained a substance; and
 - (b) was in direct contact with the substance; and
 - (c) is no longer to be used to contain the substance and is intended for disposal.
- (2) A package must—
 - (a) be rendered incapable of containing any substance; and
 - (b) be disposed of in a manner that is consistent with that of the substance it contained, taking into account the nature and type of the packaging.
- (3) Notwithstanding subclause (2), a package may be reused or recycled if—
 - (a) it has been treated to remove any residual contents of the substance; or
 - (b) the residual contents of the package have been rendered non-hazardous.

Part 9 Exposure Limits

24 Compliance with exposure limits

- (1) Exposure limits are adopted for a substance or component(s) of a substance (as the case may be) to the extent (if at all) that they are set out on the register of exposure limits.
- (2) In the case of WES values, where a WES value does not exist on the register of exposure limits but is listed in the document referred to in subclause (3), the value or values specified in that document shall apply to the substance or any component of the substance.
- (3) The document referred to in subclause (2) is the document entitled “Workplace Exposure Standards”, published by the Occupational Safety and Health Service, Department of Labour January 2002, ISBN 0-477-03660-0.

Part 10 Other Matters

25 Assigning a product to a Group Standard

- (1) The manufacturer or importer of a substance who determines, or is otherwise independently advised, that the substance complies with clause 4 of this Group Standard (Scope of Group Standard) must keep a record of that determination or advice and have that record available for inspection.

- (2) The record must contain sufficient information to allow for independent verification that the substance complies with clause 4 of this Group Standard (Scope of Group Standard).

Part 11 Notification to the Authority

26 Inventory of Chemicals

- (1) Where a substance is imported into, or manufactured in, New Zealand as a pharmaceutical active ingredient, and that substance is, or contains, a hazardous chemical that is not listed on the Inventory of Chemicals, then the importer or manufacturer of the substance must at the time they first import or manufacture the substance, notify the Authority in writing of—
- (a) the name of the substance; and
 - (b) the HSNO approval number and/or title of this Group Standard; and
 - (c) the name and CAS number of the chemical not listed on the Inventory of Chemicals that is present in the substance; and
 - (d) the concentration of that chemical in the substance; and
 - (e) the hazardous properties of the chemical, including the provision of the relevant hazard data used to assign the substance to the Group Standard; and
 - (f) the proposed use of the substance as a pharmaceutical active ingredient.
- (2) Where a substance has been notified to the Authority under subclause (1), then that substance may not be used for any purpose other than in a pharmaceutical product.

27 Record of assignment to Group Standard

Where a substance is assigned to this Group Standard, then the importer or manufacturer of the substance must at the time they first import or manufacture the substance, notify the Authority in writing of—

- (a) the name of the pharmaceutical active ingredient; and
- (b) the name and CAS number of the pharmaceutical active chemical; and
- (c) the concentration of that chemical in the substance; and
- (d) the hazardous properties of the chemical; and
- (e) the proposed use of the substance as a pharmaceutical active ingredient.

Schedule 2 Interpretation

Approved handler means a person who holds a current test certificate certifying that they have met the requirements of the Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001 as an approved handler in relation to one or more hazard classifications or hazardous substances

CAS number means Chemical Abstract Services Registry number

Civil Aviation Rule means the Civil Aviation Rule - Part 92 - Carriage of Dangerous Goods made under the Civil Aviation Act 1990

Compatible means that the substance:

- (a) is chemically inert if brought into contact with any other substance for the range of temperatures and pressures at which the substances are brought into contact; or
- (b) if it is chemically reactive when brought into contact with any other substance, it does not:
 - (i) cause combustion; or
 - (ii) generate an explosion; or
 - (iii) generate a new hazardous substance of a different class, subclass or category

Condition means any obligation or restriction imposed upon a substance by a Group Standard

Excipient ingredient means a component of a formulated pharmaceutical active ingredient that is not pharmaceutically active and used to deliver the pharmaceutical active chemical to the patient.

Exposure limit means an environmental exposure limit (EEL), a tolerable exposure limit (TEL), or a workplace exposure standard (WES) as those terms are defined in section 77B(6) of the Act

Inventory of Chemicals means an inventory kept and maintained by the Authority, of chemicals known to be present in New Zealand

Land Transport Rule means the Land Transport Rule 45001/1: Dangerous Goods 205 made under the *Land Transport Act 1998*

Large packaging means packaging consisting of an outer packaging that contains articles or inner packaging, and that—

- (a) is designed for mechanical handling; and
- (b) can contain a net mass of contents of more than **400 kg** or has a capacity of more than **450 L**; but

- (a) has a volume of **3 m³** or less

Main label means, where there are two or more labels on a container or a label is divided into two or more portions:

- (a) that label or portion of the label on which the name of the product is most prominently shown and which is primarily designed to attract attention; or
- (b) where the name of the product is equally prominent on two or more labels or portions of a label, each of those labels or portions of the label on which the name of the product is equally prominent

Maritime Rule means the Maritime Rule: Part 24A – Carriage of Cargoes – Dangerous Goods made under the Maritime Transport Act 1994

Medicine is defined in the Medicines Act 1981 to mean—

- (a) any substance or article, other than a medical device, that is manufactured, imported, sold, or supplied wholly or principally—
 - (i) for administering to one or more human beings for a therapeutic purpose; or
 - (ii) for use as an ingredient in the preparation of any substance or article that is to be administered to one or more human beings for a therapeutic purpose, where it is so used—
 - (I) in a pharmacy or a hospital; or
 - (II) by a practitioner, or registered midwife, or designated prescriber, or in accordance with a standing order; or
 - (III) in the course of any business that consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies; or
 - (iii) for use as a pregnancy test;
- (b) But does not include—
 - (i) substances used in dental surgery for filling dental cavities; or
 - (ii) bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilising the dressing; or
 - (iii) any radioactive material within the meaning of section 2(1) of the Radiation Protection Act 1965; or
 - (iv) any animal food in which a medicine is incorporated; or
 - (v) any animal remedy; or

- (vi) any other substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a medicine for the purposes of this Act

Package, packaging, inner packaging and outer packaging have the same meanings as in regulation 3 of the Hazardous Substances (Packaging) Regulations 2001

Passenger service vehicle has the same meaning as in the Public Transport Management Act 2008 to mean—

- (a) means a vehicle used or available for use in a passenger service for the carriage of passengers; but
- (b) does not include—
 - (i) a vehicle designed or adapted to carry 12 or fewer persons (including the driver) provided by one of the passengers being carried; or
 - (ii) a vehicle specified as an exempt passenger service vehicle in the regulations or the rules

Person in charge in relation to a place, a hazardous substance location, a transit depot, or a place of work, means a person who is—

- (a) the owner, lessee, sublessee, occupier, or person in possession of the place, location, or depot, or any part of it; or
- (b) any other person who, at the relevant time, is in effective control or possession of the relevant part of the place, location, or depot

Pharmaceutical Active Chemical is a single component chemical that has a pharmaceutical activity in a Pharmaceutical Product

Pharmaceutical Active Ingredient is a substance included in a written formulation followed to manufacture a medicine or pharmaceutical product. The pharmaceutical active ingredient may be a single component pharmaceutical active chemical, or a formulated substance containing a pharmaceutical active chemical and excipient ingredients

Pharmaceutical Product means a formulated product containing a pharmaceutical active ingredient, approved for use in New Zealand as a medicine by the Ministry of Health, in Europe by the European Medicines Agency, in Australia by the Therapeutic Goods Administration, in Japan by the Pharmaceutical and Food Safety Bureau (PFSB) or the United States by the Food and Drug Administration (US FDA)

Pictogram means a graphical composition intended to convey specific information, in accordance with either—

- (a) the relevant pictograms contained in Annex 1 of the first revised edition of *The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, published in 2005 by the United Nations (as reproduced in Table 1 of *Labelling of Hazardous Substances: Hazard*

and Precautionary Information published by the Authority, July 2006);
or

- (b) where a hazard class and/or category specified in (a) is covered as a pictogram under the UN Model Regulations, the assigned corresponding pictogram as defined in paragraph 5.2.2 of the UN Model Regulations (as reproduced in Table 1 of *Labelling of Hazardous Substances: Hazard and Precautionary Information* published by the Authority, July 2006)

Place of work has the same meaning as in section 2(1) and (3) of the Health and Safety in Employment Act 1992

Register of exposure limits means the register of exposure limits for substances with toxic or ecotoxic properties kept and maintained by the Authority pursuant to section 20A of the Act

Substance means any Pharmaceutical Active Ingredient that is within the scope of clause 4 of this Group Standard (Scope of Group Standard)

Therapeutic purpose is defined in the Medicines Act 1981 to mean —

- (a) treating or preventing disease; or
- (b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or
- (c) effecting contraception; or
- (d) inducing anaesthesia; or
- (e) altering the shape, structure, size, or weight of the human body; or
- (f) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or
- (g) cleaning, soaking, or lubricating contact lenses.

UN Manual of Tests and Criteria means the fourth revised edition of the *Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria*, published in 2003 by the United Nations

UN Model Regulations means the 14th revised edition of the Recommendations on the Transport of Dangerous Goods Model Regulations, published in 2005 by the United Nations

UN Packing Group relates to a standard of packaging that indicates the level of hazard inherent to dangerous goods defined by the United Nations. Packing Group I indicates high danger; Packing Group II, medium danger; Packing Group III, low danger

Explanatory note

This note is not part of the Group Standard, but is intended to provide guidance to users of the Group Standard.

- (1) Clause 4 of this Group Standard (Scope of Group Standard) sets out the parameters that determine whether a substance is covered by this Group Standard. It is the responsibility of the manufacturer or importer of a substance to determine whether the substance complies with these parameters. The means of complying may not necessarily require product testing as this may be achieved in a variety of ways, for example, an analysis of the constituent components' hazards. For more information contact ERMA New Zealand.
- (2) Codes of practice that have been approved by ERMA New Zealand are a means of complying with the conditions of this Group Standard. A list of approved codes is available from the ERMA New Zealand web site.
- (3) This Group Standard covers pharmaceutical active ingredients (which may be a single component pharmaceutically active chemical or a formulated substance containing a pharmaceutically active chemical and non-active excipient components) used to manufacture registered medicines under the Medicines Act 1981 (or equivalent overseas recognised registration body) or products intended for the treatment of medical conditions as defined under the Medicines Act 1981 where registration is required.
- (4) The Australian and New Zealand Government have signed an agreement to establish a joint regulatory scheme for therapeutic products. This scheme will regulate medicines (including complimentary medicines) and medical devices. When this scheme comes into force, further guidance will be provided on the boundaries between this Group Standard and the requirements that will be established under the joint regulatory scheme.

Availability and publication of Group Standard and Reference Materials

- (5) This Group Standard, and any materials incorporated into it by reference that are published by ERMA New Zealand may be—
 - (a) viewed on the ERMA New Zealand web site; or
 - (b) inspected free of charge during normal business hours at the ERMA New Zealand office; or
 - (c) purchased from ERMA New Zealand, Public Awareness Group, Email publicationinfo@ermanz.govt.nz.
- (6) Any regulations incorporated by reference into a Group Standard may be—
 - (a) inspected free of charge during normal business hours at the ERMA New Zealand office; or
 - (b) purchased from Bennetts at <http://www.bennetts.co.nz/legislation.htm>; or
 - (c) viewed at <http://www.legislation.govt.nz>.

- (7) Any materials incorporated by reference into a Group Standard that are published by the United Nations may be—
- (a) inspected free of charge during normal business hours at the ERMA New Zealand office; or
 - (b) viewed on or ordered from the UN website, <http://www.unece.org/trans/danger/publi/order.htm>; or
 - (c) ordered from the New Zealand distributor: Legislation Direct, PO Box 12 418, Wellington, Ph 0064 4 495 2882, Fax 0064 4 495 2880, Email ldorders@legislationdirect.co.nz, or <http://www.legislationdirect.co.nz>.
- (8) Any materials incorporated by reference into a Group Standard that are published by Standards New Zealand or Standards Australia may be—
- (a) inspected free of charge during normal business hours at the ERMA New Zealand office; or
 - (b) ordered from Standards New Zealand, Ph 0800 735 656, Fax 0064 4 498 5994, Email snz@standards.co.nz or <http://www.standards.co.nz/purchase-standards/default.htm> or, in the case of Australian standards, from SAI Global Limited, Ph 00612 8206 6010, Fax 00612 8206 6020 or Email sales@sai-global.com as appropriate.
- (9) Any materials incorporated by reference into a Group Standard that are published by any other party or organisation may be inspected free of charge during normal business hours at the ERMA New Zealand office.

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