Pharmaceutical Active Ingredients Group Standard 2017 – HSR100425

GROUP STANDARD
UNDER THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996
Pharmaceutical Active Ingredients Group Standard 2017

Pursuant to clause 5 of Schedule 7 of the Hazardous Substances and New Organisms Act 1996 (the Act), the Environmental Protection Authority has reviewed and, for the purpose of updating, reissues this Group Standard.

Table of Contents

1. Name of Group Standard ................................................................................ 1
2. Commencement .............................................................................................. 1
3. Interpretation ................................................................................................... 1
4. Scope of Group Standard ............................................................................... 1
5. Conditions of Group Standard ....................................................................... 2

Schedule 1: Conditions of Group Standard ........................................................... 3

Part 1 - Compliance with EPA Notices ................................................................ 3
1. Labelling and advertising ............................................................................... 3
2. Safety Data Sheets .......................................................................................... 3
3. Packaging ........................................................................................................ 3
4. Disposal ........................................................................................................... 3
5. Restrictions on supply, storage and use ...................................................... 3

Part 2 - Notification to the Authority ................................................................. 4
6. Inventory of Chemicals ................................................................................... 4
7. Notification of assignment to group standard .............................................. 4

Part 3 - Other Matters ........................................................................................... 5
8. Assigning a substance to a group standard .................................................. 5

Schedule 2: Interpretation ....................................................................................... 6
Explanatory note ...................................................................................................... 7
1. **Name of Group Standard**
Pharmaceutical Active Ingredients Group Standard 2017

**HSNO Approval Number**
The HSNO Approval Number for this Group Standard is HSR100425.

2. **Commencement**
This Group Standard comes into force on 1 December 2017.

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. Any words or phrases that are used but not defined in this Group Standard but that are defined in the Act have the same meaning as the Act.
   (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) Notice 2017.

4. **Scope of Group Standard**

   **Substances covered by Group Standard**
   (1) This Group Standard applies to hazardous substances under section 96B(2)(a), (b) and (c) of the Act.
   (2) Subject to clause 4(3), this Group Standard applies to a substance that—
      (a) is 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) Notice 2017; and
      (b) is 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 (PFSB) or the United States by the Food and Drug Administration (US FDA); and
      (c) has one or more of the following (but only the following) hazards:
         (i) 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;
         (ii) a flammable liquid with a flashpoint of greater than 23°C and less than or equal to 60°C, HSNO 3.1C classification;
         (iii) a flammable liquid with a flashpoint of greater than 60°C and less than or equal to 93°C, HSNO 3.1D classification;
         (iv) a flammable solid with low hazard, HSNO 4.1.1B classification;
         (v) an oxidising solid or liquid with low hazard, HSNO 5.1.1C classification;
         (vi) acute toxicity, HSNO 6.1A, 6.1B, 6.1C, 6.1D, 6.1E classifications;
(vii) HSNO 6.1E (aspiration hazard) classification;
(viii) skin irritancy, HSNO 6.3A or 6.3B classification;
(ix) eye irritancy, HSNO 6.4A classification;
(x) respiratory sensitisation, HSNO 6.5A classification;
(xi) contact sensitisation, HSNO 6.5B classification;
(xii) mutagenicity, HSNO 6.6A or 6.6B classifications;
(xiii) carcinogenicity, HSNO 6.7A or 6.7B classifications;
(xiv) reproductive toxicity, HSNO 6.8A, 6.8B or 6.8C classifications;
(xv) target organ toxicity, HSNO 6.9A or 6.9B classifications;
(xvi) metallic corrosivity, HSNO 8.1A classification;
(xvii) skin corrosivity, HSNO 8.2A, 8.2B or 8.2C classifications;
(xviii) eye corrosivity, HSNO 8.3A classification;
(xix) ecotoxicity, HSNO class 9.

Substances excluded from Group Standard

(3) This Group Standard does not apply to a substance that is an excipient ingredient.

(4) This Group Standard excludes any substance if it contains—
   (a) asbestos; or
   (b) a chemical that:
      (i) is a persistent organic pollutant within the definition in section 2 of the Act; or
      (ii) exhibits the characteristics of a persistent organic pollutant as set out in paragraph 1 of Annex D to Schedule 1AA of the Act.

5. Conditions of Group Standard

The conditions that specify the obligations and restrictions for substances covered by this Group Standard are set out in Schedule 1.

Advisory Note: In addition to requirements specified in this document, people who are undertaking work in a workplace involving hazardous substances covered by this Group Standard have obligations under the Health and Safety at Work Act 2015.
Schedule 1: Conditions of Group Standard

Part 1 - Compliance with EPA Notices

1. Labelling and advertising
   Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Labelling) Notice 2017.

2. Safety Data Sheets
   Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Safety Data Sheet) Notice 2017.

3. Packaging
   Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Packaging) Notice 2017.

4. Disposal
   Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Disposal) Notice 2017.

5. Restrictions on supply, storage and use
   (1) Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Hazardous Property Controls) Notice 2017.
   (2) In addition, 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 that complies with subclause (3); or
      (b) a company with a 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.
   (3) The licence to manufacture medicine held by the company in subclause (2)(a) 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 2 - Notification to the Authority

6. Inventory of Chemicals
(1) When a substance is imported into, or manufactured in, New Zealand as a pharmaceutical active ingredient, the importer or manufacturer must ensure that all hazardous chemicals contained in the substance are listed on the Inventory of Chemicals.
(2) If that substance contains a hazardous substance 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 the 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.
(3) Where a substance has been notified to the Authority under subclause (2), then that substance may not be used for any purpose other than in a pharmaceutical product.

7. Notification 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.
Part 3 - Other Matters

8. Assigning a substance to a group standard

(1) If an importer or manufacturer considers that this Group Standard applies to the importation or manufacture of a substance, then the importer or manufacturer is responsible for assigning the substance to this Group Standard.

(2) In order to assign the substance to this Group Standard, the importer or manufacturer must—

   (a) ensure that the substance complies with clause 4 of this Group Standard (Scope of Group Standard); and

   (b) keep a record of how it was determined the substance complies with clause 4 of this Group Standard.

(3) The importer or manufacturer must—

   (a) ensure that the record contains sufficient information to allow for independent verification that the substance complies with clause 4 of this Group Standard (Scope of Group Standard); and

   (b) have that record available for inspection.
Schedule 2: Interpretation

**asbestos** has the same meaning as in the Health and Safety at Work (Asbestos) Regulations 2016 but does not include substances that contain naturally occurring traces of asbestos

**CAS number** means Chemical Abstract Services Registry number

**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 is used to deliver the pharmaceutical active chemical to the patient

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

**medicine** has the same meaning as in clause 5(3) of the Hazardous Substances (Minimum Degrees of Hazard) Notice 2017

**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)

**substance** means any pharmaceutical active ingredient that is within the scope of clause 4 of this Group Standard (Scope of Group Standard)

**workplace** has the same meaning as in the Health and Safety at Work Act 2015
Explanatory note

This note is not part of the group standard but is intended to provide guidance to users of the group standard.

(1) Under the Act, section 96E(3) provides that a hazardous substance to which section 96B(2)(a) applies is deemed to have been approved by the Authority under section 29.

(2) Any transitional measures that were in this Group Standard immediately prior to 1 December 2017 but have expired have not been included in this reissued Group Standard.

(3) All amendments made under section 96B to the Group Standard since it was first issued that are still in force have been incorporated into this reissued Group Standard.

(4) In addition to requirements specified in this document, people who are undertaking work in a workplace involving hazardous substances covered by this Group Standard have obligations under the Health and Safety at Work Act 2015.

(5) A person relying on this Group Standard will have four years (until 1 December 2021) to comply with the Labelling, Safety Data Sheet and Packaging Notices. Within that time, a person may comply with the equivalent conditions in the Group Standard in force immediately before 1 December 2017. All other aspects of this Group Standard apply from 1 December 2017.