# Veterinary Medicines (Non-dispersive Open System Application) Group Standard 2020

## HSR100759

**GROUP STANDARD**

**UNDER THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996**

Environmental Protection Authority
Te Mana Rauhī Taiao

New Zealand Government

# Veterinary Medicines (Non-dispersive Open System Application) Group Standard 2020

Pursuant to section 96B of the Hazardous Substances and New Organisms Act 1996 (the Act), the Environmental Protection Authority issues this Group Standard.

## Contents

# 1. Name of Group Standard

Veterinary Medicines (Non-dispersive Open System Application) Group Standard 2020

### HSNO Approval Number

The HSNO Approval Number for this Group Standard is HSR100759.

# 2. Commencement

This Group Standard comes into force on 30 April 2021.

# 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 in the Act.

(2) In this Group Standard, reference to a hazard classification means a reference to the specified hazard classification as set out in the Hazardous Substances (Hazard Classification) Notice 2020.

# 4. Scope of Group Standard

### Substances covered by Group Standard

(1) This Group Standard applies to hazardous substances under section 96B(2)(a) and (c) of the Act.

(2) This Group Standard applies to any substance imported or manufactured for use as veterinary medicine and administered using a non-dispersive open system application method.

(3) A substance referred to in subclause (2) may have one or more of the following (but only the following) hazard classifications:

- (a) flammable liquid Category 2, Category 3 or Category 4:
- (b) flammable solid Category 2:
- (c) oxidising liquid Category 3:
- (d) oxidizing solid Category 3:
- (e) acute oral toxicity Category 3 or Category 4:
- (f) acute dermal toxicity Category 3 or Category 4:
- (g) acute inhalation toxicity Category 3 or Category 4:
- (h) skin irritation Category 2:
- (i) serious eye damage Category 1:

(j) eye irritation Category 2:

(k) respiratory sensitisation Category 1:

(l) skin sensitisation Category 1:

(m) germ cell mutagenicity Category 1 or Category 2:

(n) carcinogenicity Category 1 or Category 2:

(o) reproductive toxicity Category 1 or Category 2:

(p) effects on or via lactation:

(q) specific target organ toxicity – single exposure Category 1, Category 2 or Category 3:

(r) specific target organ toxicity – repeated exposure Category 1 or Category 2:

(s) aspiration hazard Category 1:

(t) hazardous to the aquatic environment acute Category 1:

(u) hazardous to the aquatic environment chronic Category 1, Category 2, Category 3 or Category 4:

(v) hazardous to soil organisms:

(w) hazardous to terrestrial vertebrates:

(x) hazardous to terrestrial invertebrates:

(y) designed for biocidal action.

(4) In addition to the requirements of subclause (3), a substance referred to in subclause (2) must be—

(a) packaged as a liquid and—

(i) administered as a liquid: or

(ii) administered as a gas, where the liquid is packaged at a pressure of greater than 170 kPa in a container not larger than 100 mL: or

(b) packaged and administered in a semi-solid or solid physical state.

## Substances excluded from Group Standard

(5) 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.

(6) This Group Standard excludes any substance that—

(a) has, at any time, been declined approval under section 29 of the Act; or

(b) contains a chemical for which further manufacture or importation has, at any time been declined under section 29 of the Act.

(7) For the avoidance of doubt, subclause (6)—

(a) includes substances for which approval has been or is declined following a reassessment under the Act; and

(b) prevents a substance for which approval has ever been declined from falling within the scope of this Group Standard, despite any subsequent approval for that substance that may be applied for and obtained under the Act.

(8) This Group Standard excludes any veterinary medicine that contains a veterinary medicine active ingredient that—

(a) does not have an approval under section 28A or section 29 of the Act: or

(b) is not an ingredient in a veterinary medicine that has an approval under section 28A or section 29 of the Act.

(9) This Group Standard excludes any substance that—

(a) is a finished dose veterinary medicine where:

(i) the packaged weight is equal to or less than 500 g: or

(ii) the packaged volume is equal to or less than 500 mL:

(b) is applied in a dispersive manner:

(c) is applied by a closed system application method.

(10) Subclause (9)(a) does not apply to finished dose veterinary medicines that are—

(a) parasiticides for use on large animals: or

(b) substances that meet the requirements of subclause (4)(a)(ii).

(11) This Group Standard excludes any substance that contains an excipient ingredient that is a CMR that is not listed on the Inventory of Chemicals, unless—

(a) the new CMR excipient is used to completely replace an existing CMR excipient in the substance: and

(b) the new CMR excipient has a lower hazard classification than the existing CMR.

(12) This Group Standard excludes any substance that is a hazardous chemical not listed on the Inventory of Chemicals.

(13) For the purposes of subclause (12), “chemical” means any element or compound in its natural state or obtained by any production process, including any impurities and any additive necessary to preserve the stability of the chemical but excluding any solvent which may be separated without affecting the stability of the chemical or changing its composition.

# 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, in particular, Part 15 Gases under Pressure of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

# Schedule 1: Conditions of Group Standard

## Part 1 - Compliance with EPA Notices

### 1. Labelling and advertising

(1) Subject to subclause (2), substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Labelling) Notice 2017.

(2) Despite clauses 13 and 19 of the Notice, for a substance that is in one or more of the hazard classes hazardous to the aquatic environment or hazardous to the terrestrial environment that is not applied to the animal as a liquid, the corresponding pictogram, and hazard statement, and prevention and response precautionary statements as required by clause 13, and the information required by clause 19 of the Notice, are not required.

(3) In addition, where the substance is available to the general public, the following precautionary statement must appear on the label in the case of a substance which carries an acute toxicity Category 2, Category 3, or Category 4 or skin corrosion Category 1B or 1C or serious eye damage Category 1 classification and that is applied or administered directly to an animal—"**For animal treatment only**".

(4) A person who relies on clauses 31 or 32 of the Hazardous Substances (Labelling) Notice 2017 must still comply with clause 16 of the Notice.

### 2. Safety data sheets

Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Safety Data Sheets) 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. Restriction on supply, storage and use

(1) Subject to subclause (2), substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Hazardous Property Controls) Notice 2017.

(2) Despite clause 13 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, a solid veterinary medicine carrying an acute toxicity Category 3 classification may be supplied to, used in or stored in a place, other than a workplace, provided it is secured while not in use in accordance with clause 25(2)(a) of the Notice.

(3) Despite clause 4(3) (Scope of Group Standard), no substance that is sold or supplied to the general public is permitted to have any of the following hazard classifications—

(a) germ cell mutagenicity Category 1; or

(b) carcinogenicity Category 1.

(c) reproductive toxicity Category 1 classification.

# Part 2 - Notification to the Authority

## 6. Inventory of Chemicals

(1) When a substance is imported into, or manufactured in, New Zealand after 30 June 2006, 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 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 the group standard under which the substance is deemed to have been approved; 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 an excipient in the veterinary medicine.

(3) Where a substance has been notified to the Authority under subclause (2), and that chemical is a veterinary medicine active ingredient, then that chemical may not be used for any purpose other than as a component in a formulated veterinary medicine.

# Part 3 - **Other Matters**

## 7. 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

**Act** means the Hazardous Substances and New Organisms Act 1996

**administration** means dosing of veterinary medicine to an animal

**animal** does not include a human being

**application** means the method of administering the veterinary medicine

**asbestos** has the same meaning as in regulation 3(1) of the Health and Safety at Work (Asbestos) Regulations 2016 but does not include substances that contain naturally occurring traces of asbestos

**biocidal action** has the same meaning as in the Hazardous Substances (Hazard Classification) Notice 2020

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

**closed system application** means administration of a substance using contained and enclosed equipment so that, from the point of withdrawal from the substance packaging until the completion of administration into the target animal, there is no release of the substance—

(a) into the environment or atmosphere: or

(b) onto the person handling the substance

**CMR** means a substance that is a carcinogen, mutagen or reproductive toxicant within the meaning of the GHS

**companion animal** means an animal kept as a pet, including cats, dogs and horses

**condition** means any obligation or restriction imposed upon a substance by a group standard

**dispersive** means application of the substance in a manner that does not allow all of the substance to be applied to, and only applied to, the intended animal

**excipient ingredient** means a component of a formulated substance that is not the veterinary medicine active ingredient, and is used to deliver the veterinary medicine active ingredient to the treated animal

**gas** has the same meaning as in the Hazardous Substances (Hazard Classification) Notice 2020

**GHS** has the same meaning as in the Hazardous Substances (Hazard Classification) Notice 2020

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

**label** has the same meaning as in the Hazardous Substances (Labelling) Notice 2017

**large animal** means farm animals raised in the agricultural setting to produce commodities such as food, fibre, skin and hides, (such as sheep, cattle, goats). Large animal does not include companion, service or working animals

**liquid** has the same meaning as in the Hazardous Substances (Hazard Classification) Notice 2020

**open system application** means administration of a substance in a manner that does not restrict release of the substance—

(a) into the environment or atmosphere: or

(b) onto the person handling the substance

**service or working animal** means an animal that is—

(a) individually trained to carry out specific roles or tasks; and

(b) kept solely or principally to provide a particular service, function or carry out a specific role or task

**solid** has the same meaning as in the Hazardous Substances (Hazard Classification) Notice 2020

**veterinary medicine** has the same meaning as in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997

**veterinary medicine active ingredient** means an ingredient claimed to have the therapeutic benefit when used in a veterinary medicine, and is primarily responsible for the effects that make a formulated product a veterinary medicine

**workplace** has the same meaning as in section 20(1) of 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) All amendments made under section 96B to the Veterinary Medicines (Non-dispersive Open System Application) Group Standard 2017 since it was first issued that were still in force before 30 April 2021 have been incorporated into this Group Standard.

(3) 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.

(4) Each of the Labelling, Safety Data Sheets and Packaging Notices provide that a person relying on this Group Standard will have four years (until 30 April 2025) to comply with the relevant controls under those Notices. Within that time, a person must comply with one of the following:

(a) the relevant controls under the Labelling, Safety Data Sheets and Packaging Notices; or

(b) the equivalent conditions in the Veterinary Medicines (Non-dispersive Open System Application) Group Standard 2017 in force immediately before 30 April 2021; or

(c) the equivalent conditions in the Veterinary Medicines (Non-dispersive Open System Application) Group Standard 2012 in force immediately before 1 December 2017.

All other aspects of this Group Standard apply from 30 April 2021.

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