



Environmental
Protection Authority
Te Mana Rauhi Taiao

Active Ingredients for Use in the Manufacture of Agricultural Compounds Group Standard 2017 – HSR100756



GROUP STANDARD

UNDER THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996

Active Ingredients for Use in the Manufacture of Agricultural Compounds 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.

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1. Name of Group Standard

Active Ingredients for Use in the Manufacture of Agricultural Compounds Group Standard 2017

HSNO Approval Number

The HSNO Approval Number for this Group Standard is HSR100756.

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 in 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) and (c) of the Act.
- (2) This Group Standard applies to any substance imported or manufactured for use as an active ingredient in an agricultural compound.
- (3) A substance referred to in subclause (2) must be a solid or liquid at ambient temperature, and must have one or more of the following (but only the following) hazards:
 - (a) 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;
 - (b) a flammable liquid with a flashpoint of greater than or equal to 23°C and less than or equal to 60°C, HSNO 3.1C classification;
 - (c) a flammable liquid with a flashpoint of greater than 60°C and less than or equal to 93°C, HSNO 3.1D classification;
 - (d) a flammable solid with low hazard, HSNO 4.1.1B classification;
 - (e) an oxidising solid or liquid with low hazard, HSNO 5.1.1C classification;
 - (f) acute toxicity, HSNO 6.1A, 6.1B, 6.1C, 6.1D or 6.1E classification;
 - (g) HSNO 6.1E (aspiration hazard) classification;
 - (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 classification;
 - (m) carcinogenicity, HSNO 6.7A or 6.7B classifications;

- (n) reproductive toxicity, HSNO 6.8A, 6.8B or 6.8C classification;
- (o) target organ toxicity, HSNO 6.9A or 6.9B classification;
- (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

- (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) This Group Standard excludes any substance that is not—
 - (a) an agricultural compound active ingredient that has an approval under section 28A or section 29 of the Act ; or
 - (b) a component of an agricultural compound, where that agricultural compound has an approval under section 28A or section 29 of the Act.
- (6) This Group Standard excludes any substance that has, at any time, been declined approval 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 substance that is an active ingredient for use in vertebrate toxic agents.
- (9) This Group Standard excludes any substance that is an excipient ingredient in an agricultural compound.
- (10) This Group Standard excludes any substance that is a hazardous chemical not listed on the Inventory of Chemicals, unless it is notified to the Authority under condition 6 of Schedule 1.

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 and use

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

Part 2 - Notification to the Authority

6. Inventory of Chemicals

- (1) When a substance is imported into, or manufactured in, New Zealand for use as an active ingredient in an agricultural compound, 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 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 an active ingredient in an agricultural compound.

- (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 an agricultural compound.

7. Specification of active ingredient

- (1) Any person who—
- (a) imports into New Zealand a substance, which that person has not previously manufactured or imported; or
 - (b) had previously imported a substance but has since changed the source of manufacture for that hazardous substance,
- must provide to the Authority in writing the information required by subclauses (3) and (4).
- (2) The information required by subclause (1) must be provided—
- (a) prior to the substance being imported; and
 - (b) in the case of a substance to which subclause (1)(b) applies—
 - (i) each and every time the source of manufacture is changed; and
 - (ii) include equivalent information for the substance that was supplied by the previous source of manufacture, if such information has not previously been provided to the Authority.
- (3) The information to be provided is—
- (a) the name, and address of the manufacturer of the substance, and the address of the site of manufacture;
 - (b) the specification of the substance (as appropriate) including—
 - (i) the full name, including relevant citation, of the national and/or international standard(s) set by an international scientific or regulatory body recognised by the Authority with which the substance complies, and evidence to support this; or
 - (ii) the manufacturer's specifications including purity of the hazardous substance, isomeric ratio where applicable, maximum impurity content and evidence to support these, including details of analytical methods used. Where the substance is produced at more than one manufacturing site, this information must be provided for each site separately;
 - (c) the identity of any impurity, its origin, and the nature of its relationship to the active component when the impurity is present at a concentration of 10g/kg or more;
 - (d) the identity of any impurity that is known to be of toxicological concern, its origin, and the nature of its relationship to the active component.
- (4) Information on an impurity that is required under subclause (3) must include—
- (a) its chemical name;
 - (b) its CAS number (if available);
 - (c) its maximum concentration in the substance; and
 - (d) if the impurity is known to be of toxicological concern, the information provided must state that the impurity is known to be of toxicological concern.

Part 3 - Other Matters

8. Assigning a substance to a group standard

- (1) If an importer or manufacturer relies on this Group Standard as a means of approving 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

active ingredient means the biologically active component used in the formulation of an agricultural compound that conveys the property to the formulated mixture that makes the formulated mixture an agricultural compound. This may include carriers, diluents, stabilisers, stenching agents, emetics and other additives, and any associated impurities arising during the manufacturing process

agricultural compound has the same meaning as in the Agricultural Compounds and Veterinary Medicines Act 1997

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 agricultural compound that is not an active ingredient

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

substance has the same meaning as in the Hazardous Substances and New Organisms Act 1996

vertebrate toxic agent means a substance for the purpose of managing or eradicating vertebrate pests

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.



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