Reprint
as at 1 December 2017

Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001

(SR 2001/112)

Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001: revoked, on 1 December 2017, by regulation 4(1) of the Hazardous Substances (Health and Safety Reform Revocations) Regulations 2017 (LI 2017/233).

Silvia Cartwright, Governor-General

Order in Council

At Wellington this 28th day of May 2001

Present:
Her Excellency the Governor-General in Council

Pursuant to sections 74(b) and 75(1)(g) of the Hazardous Substances and New Organisms Act 1996, Her Excellency the Governor-General, acting on the advice and with the consent of the Executive Council, makes the following regulations (given on the recommendation of the Minister for the Environment made in accordance with section 141(1) of that Act).

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Note

Changes authorised by subpart 2 of Part 2 of the Legislation Act 2012 have been made in this official reprint.

Note 4 at the end of this reprint provides a list of the amendments incorporated.

These regulations are administered by the Ministry for the Environment.

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Regulations

1 Title

These regulations are the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.

2 Commencement

These regulations come into force on 2 July 2001.

3 Interpretation

In these regulations, unless the context otherwise requires,—

Act means the Hazardous Substances and New Organisms Act 1996

ASTM, when followed by letters and numbers, means the document identified by those letters and numbers that is published by the American Society for Testing and Materials

data includes values that are directly measured, calculated, or estimated for any of the measures given

deflagrate, in relation to a substance that is initiated or ignited, means the production in that substance of a chemical reaction that proceeds through, or along the surface of, the substance at subsonic velocity, where that chemical reaction,—

(a) results in the steady production of hot gases at high pressures; and

(b) if the substance is sufficiently confined, results in an increase in pressure, rate of reaction, and temperature that may produce a detonation of the substance

detonate, in relation to a substance that is initiated, means the production in that substance of a chemical reaction that proceeds through that substance at supersonic velocity, resulting in the production of heat and a supersonic shock wave through the surrounding medium

gas means a substance that—

(a) is completely gaseous at 20°C and at 101.3 kPa absolute pressure; or

(b) has a vapour pressure of more than 300 kPa absolute pressure at 50°C

ISO means the International Standards Organisation; and—

(a) **ISO 9328 (II): 1991** means the ISO Standard called Steel plates and strips for pressure purposes—technical delivery conditions, Part II; and

(b) **ISO 10156: 1996** means the ISO Standard called Gases and gas mixtures—determination of fire potential and oxidising ability for the selection of cylinder valve outlets

liquid means—

(a) a substance with a melting point of less than or equal to 20°C at 101.3 kPa absolute pressure; or

(b) a viscous substance, without a defined melting point, if—

(i) more than the quantity of the substance specified in ASTM D 4359–90, called Test method for determining whether a material is a liquid or a solid, collects on a watch glass when tested in the manner specified in that test; or

(ii) a penetrometer penetrates into the substance the distance defined in the test for determining fluidity prescribed in Appendix A.3 of the European Agreement concerning the *International Carriage of Dangerous Goods by Road (ADR)*, published in 1994 by the United Nations, when the method specified in that test is followed

pyrotechnic effect, in relation to a substance that is initiated, means the production in that substance of a self-sustaining exothermic chemical reaction resulting in heat, sound, light, gas, smoke, or motion, or a combination of these

solid means a substance that is neither a liquid nor a gas

Test Series, when followed by a letter or number, means 1 or more tests as prescribed in the UN Manual of Tests and Criteria

UN Manual of Tests and Criteria means the third revised edition of the *Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria,* published in 1999 by the United Nations (New York and Geneva)

UN Model Regulations means the 11th revised edition of the *Recommendations on the Transport of Dangerous Goods Model Regulations*, published in 1999 by the United Nations (New York and Geneva).

4 Substances not considered hazardous

(1) A substance is not hazardous for the purposes of the Act unless it meets the minimum degrees of hazard for at least 1 of the intrinsic hazardous substance properties specified in regulation 7.

(2) This regulation is subject to regulations 5, 6, and 6A.

Regulation 4(2): replaced, on 18 July 2013, by section 110(1) of the Psychoactive Substances Act 2013 (2013 No 53).

5 Medicines

(1) A medicine is not hazardous for the purposes of the Act unless Parts 13, 14, or 15 of the Act apply.

(2) Despite subclause (1), a new medicine must be treated as hazardous if it meets any of the minimum degrees of hazard prescribed in these regulations and—

(a) it is a substance to which section 3(1)(b)(i) of the Medicines Act 1981 applies; or

(b) an application is made to register that medicine as a trade name product under the Agricultural Compounds and Veterinary Medicines Act 1997.

(3) In this regulation,—

medicine has the same meaning as in section 3(1) of the Medicines Act 1981, except that it does not include a gas contained at a pressure greater than 170 kPa in a container larger than 100 mL, at any time after that gas becomes so contained and before the time the gas is first administered to a person for a therapeutic purpose

new medicine means—

(a) any medicine that has not been generally available in New Zealand—

(i) before the commencement of the Medicines Act 1981; or

(ii) at any time during the period of 5 years immediately before the date on which it is proposed to become so available:

(b) any medicine that, immediately before the commencement of Part 2 of the Medicines Act 1981, was a therapeutic drug to which section 12 of the Food and Drug Act 1969 applied, and in respect of the sale or distri-

bution of which the Minister of Health had not given his or her consent under that section:

(c) any medicine that becomes a medicine for the first time after the commencement of the Medicines Act 1981:

(d) any medicine that is referred to the Minister of Health under section 24(5) of the Medicines Act 1981.

Regulation 5(2)(a): amended, on 1 July 2014, by section 49 of the Medicines Amendment Act 2013 (2013 No 141).

6 Food

(1) A food is not hazardous for the purposes of the Act unless Parts 13, 14, or 15 of the Act apply.

(2) In this regulation,—

food has the same meaning as in section 9 of the Food Act 2014, except that it does not include a food additive if that food additive has not been mixed with or added to any other food or drink

food additive means a substance added to food and regulated under an adopted joint food standard as defined in the Food Act 2014.

Regulation 6(2) **food**: amended, on 1 March 2016, by section 447 of the Food Act 2014 (2014 No 32).

Regulation 6(2) **food additive**: replaced, on 1 March 2016, by section 447 of the Food Act 2014 (2014 No 32).

6A Psychoactive substances

(1) A psychoactive substance is not hazardous for the purposes of the Act if—

(a) the substance is an approved product; or

(b) the substance—

(i) meets the minimum degree of hazard specified in clause 2(1)(s) of Schedule 4; and

(ii) only meets the minimum degree of hazard specified in clause 2(1)(s) of Schedule 4 because of its psychoactive properties; and

(iii) does not meet any other minimum degree of hazard of the intrinsic hazardous substance properties specified in regulation 7.

(2) In this regulation,—

approved product has the same meaning as in section 8 of the Psychoactive Substances Act 2013

psychoactive substance has the same meaning as in section 9 of the Psychoactive Substances Act 2013.

Regulation 6A: inserted, on 18 July 2013, by section 110(1) of the Psychoactive Substances Act 2013 (2013 No 53).

7 Minimum degrees of hazard

(1) The minimum degrees of hazard for substances with explosive properties are the degrees of hazard specified in Schedule 1.

(2) The minimum degrees of hazard for substances with flammable properties are the degrees of hazard specified in Schedule 2.

(3) The minimum degrees of hazard for substances with oxidising properties are the degrees of hazard specified in Schedule 3.

(4) The minimum degrees of hazard for substances with toxic properties are the degrees of hazard specified in Schedule 4.

(5) The minimum degrees of hazard for substances with corrosive properties are the degrees of hazard specified in Schedule 5.

(6) The minimum degrees of hazard for substances with ecotoxic properties are the degrees of hazard specified in Schedule 6.

Schedule 1
Minimum degrees of hazard for substances with explosive properties

r 7(1)

1 Minimum degrees of hazard for substances other than manufactured articles

A substance (other than a manufactured article) with explosive properties is not hazardous for the purpose of the Act unless—

(a) the substance is listed as class 1 in the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations; or

(b) the substance propagates a detonation in accordance with paragraph 12.4.1.4 of the UN Manual of Tests and Criteria when tested as prescribed by Test Series 2 type (a) in paragraph 12.4 of that manual; or

(c) the substance propagates a detonation in accordance with paragraph 12.5.1.4 of the UN Manual of Tests and Criteria when tested as prescribed by Test Series 2 type (b) in paragraph 12.5 of that manual; or

(d) the substance produces a pressure rise from 690 to 2070 kPa gauge pressure or more, as determined in accordance with paragraph 12.6.1.4 of the UN Manual of Tests and Criteria, when tested as prescribed by Test Series 2 type (c) in paragraph 12.6 of that manual; or

(e) the substance is specifically manufactured to detonate, deflagrate, or produce a pyrotechnic effect.

2 Minimum degrees of hazard for manufactured articles

A manufactured article containing, incorporating, or including a hazardous substance with explosive properties is not hazardous for the purposes of the Act unless—

(a) the article is listed as class 1 in the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations; or

(b) the article produces some effect of projection, fire, smoke, heat, or loud noise external to the article when tested as a stack of articles as prescribed in Test Series 6 type (c) in paragraph 16.6 of the UN Manual of Tests and Criteria.

Schedule 2
Minimum degrees of hazard for substances with flammable properties

r 7(2)

1 Interpretation

In this schedule, unless the context otherwise requires,—

flammable ingredient means a substance that meets 1 or more of the minimum degrees of hazard for a flammable gas, a flammable liquid, or a flammable solid, or any combination of them

flammable range—

(a) means the range between 2 ratios of gas or vapour to air, the lower of which contains too much air, and the upper of which contains too little air, to support combustion; and

(b) includes a minimal range effectively equivalent to a single value

flashpoint means the lowest temperature at which a flammable liquid, when tested in a closed cup flash point test, gives off vapour that ignites

SADT means self-accelerating decomposition temperature, being the lowest temperature at which self-accelerating decomposition of the substance occurs in the packaging in which it is tested when tested as prescribed in Test Series H in section 28 of the UN Manual of Tests and Criteria.

2 Minimum degrees of hazard

(1) A substance with flammable properties is not hazardous for the purposes of the Act unless—

(a) the substance is a gas or a gas mixture that is sufficiently flammable to be capable of ignition when mixed with air in a proportion within a flammable range at 20°C and at a pressure of 101.3 kPa absolute; or

(b) the substance—

(i) is or contains a gas compressed, liquefied, or dissolved under pressure (with or without a liquid, paste, or powder); and

(ii) is packed under pressure in a way that is designed to be released—

(A) as solid or liquid particles in suspension in a gas; or

(B) as a foam, paste, or powder; or

(C) in a liquid state; or

(D) in a gaseous state; and

(iii) comprises 45% or more by mass of flammable ingredients; or

(c) the substance is a liquid that has a flash point of less than or equal to 93°C; or

(d) the substance—

(i) is described in paragraph 2.4.2.4 of the UN Model Regulations as being an explosive substance that has been dissolved or suspended in water or other liquid substances to form a homogeneous mixture in order to suppress its explosive properties; or

(ii) is listed in paragraph 2.3.1.4 of the UN Model Regulations with one of the serial numbers UN 1204, UN 2059, UN 3064, or UN 3343; or

(iii) is listed in the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations as having a class, division, or subsidiary risk of liquid desensitised explosive; or

(e) the substance is a solid that meets the criteria specified in paragraph 33.2.1.4.4 of the UN Manual of Tests and Criteria when tested in accordance with the test method for readily combustible solids as prescribed in Test Series N.1 in paragraph 33.2.1.4 of that manual; or

(f) the substance is a solid that—

(i) is listed in the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations; and

(ii) has one of the serial numbers UN 1331, UN 1343, UN 1944, UN 1945, or UN 2254; or

(g) the substance—

(i) has an SADT of less than or equal to 75°C in a quantity of 50 kg and a heat of decomposition greater than 300 joules per gram; or

(ii) is listed in paragraph 2.4.2.3.2.3 of the UN Model Regulations as having a class, division, or subsidiary risk of self-reactive; or

(h) the substance—

(i) meets 1 or more of the minimum degrees of hazard for substances with explosive properties specified in Schedule 1; and

(ii) has been desensitised to the extent that it would, when tested as prescribed in Test Series 6 type (c) in paragraph 16.6 of the UN Manual of Tests and Criteria, not show a projection, fire, smoke, heat, or noise effect external to the substance itself; or

(i) the substance—

(i) is described in paragraph 2.4.2.4 of the UN Model Regulations as being an explosive substance that has been wetted with water or alcohols or diluted with other substances to form a homogeneous mixture in order to suppress its explosive properties; or

(ii) is listed in paragraph 2.4.2.4 of the UN Model Regulations; or

(iii) is listed in the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations as having a class, division, or subsidiary risk of a solid desensitised explosive; or

(j) the substance—

(i) is a solid in powder form that, when tested as prescribed in Test Series N.2 in paragraph 33.3.1.4 of the UN Manual of Tests and Criteria, ignites in one of the tests; or

(ii) is a liquid that, when tested in as prescribed in Test Series N.3 in paragraph 33.3.1.5 of the UN Manual of Tests and Criteria, ignites in the first part of the test (paragraph 33.3.1.5.3.1) or ignites or chars the filter paper in the second part of the test (paragraph 33.3.1.5.3.2); or

(iii) is a solid that, when tested as prescribed in Test Series N.4 in paragraph 33.3.1.6 of the UN Manual of Tests and Criteria, gives a positive result in a test using a 100 mm sample cube at 140°C; or

(k) the substance, when tested as prescribed in Test Series N.5 in paragraph 33.4.1.4 of the UN Manual of Tests and Criteria, reacts with water at ambient temperatures to produce a gas that ignites spontaneously; or

(l) the substance, when tested as prescribed in Test Series N.5 in paragraph 33.4.1.4 of the UN Manual of Tests and Criteria, reacts with water at ambient temperatures to produce a flammable gas at a rate greater than or equal to 1 litre per kilogram of substance per hour.

(2) When tested in accordance with any of subclause (1)(e), (g), (h), (j)(i), (j)(iii), (k), or (l), a substance must be—

(a) in the finest particle form in which that substance is reasonably capable of being used or rendered; or

(b) if it is likely or known that more than 10% of the mass of the substance will crumble into a finer particle form, in that finer form.

Schedule 3
Minimum degrees of hazard for substances with oxidising properties

r 7(3)

1 Interpretation

In this schedule, unless the context otherwise requires,—

organic peroxide means a substance containing 1 or more chemical compounds that—

(a) contains the bivalent oxygen [-0-0-] structure; and

(b) may be considered as a derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical; and

(c) may cause or contribute to combustion by the release of chemical energy or compounds that may cause or contribute to fire, explosion, or chemical decomposition

oxidising substance means a substance that, while not necessarily combustible in itself, may cause or contribute to the combustion of other substances or materials.

2 Minimum degrees of hazard

(1) A substance with oxidising properties is not hazardous for the purposes of the Act unless—

(a) the substance is listed in the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations as having a class, division, or subsidiary risk of 5.1 (oxidising substances); or

(b) the substance is a solid that—

(i) is an oxidising substance; and

(ii) when mixed with dried cellulose, either spontaneously ignites or shows a mean burning time equal to or faster than the mean burning time of a 3:7 reference mixture by mass of potassium bromate and cellulose under the same conditions when the mixture is tested in accordance with the test method for oxidising solids as prescribed in Test Series O.1 in paragraph 34.4.1 of the UN Manual of Tests and Criteria; or

(c) the substance is a liquid that—

(i) is an oxidising substance; and

(ii) when mixed with dried cellulose, either spontaneously ignites or shows a mean pressure rise time that is equal to or faster than the mean pressure rise time of the reference mixture of 65% aqueous nitric acid solution and cellulose under the same conditions when that solution is tested in accordance with the test method for oxi-

dising liquids as prescribed in Test Series O.2 in paragraph 34.4.2 of the UN Manual of Tests and Criteria; or

(d) the substance is a gas that—

(i) is an oxidising substance; and

(ii) will cause or contribute to combustion at a faster rate than air when tested in accordance with the test method for determining the oxidising power of gases and gas mixtures as prescribed in ISO 10156:1996; or

(e) the substance is listed in—

(i) paragraph 2.5.3.2.4 of the UN Model Regulations as an organic peroxide; or

(ii) the Dangerous Goods List in Chapter 3.2 of the UN Model Regulations as having a class or division of 5.2 (organic peroxides); or

(f) the substance—

(i) is an organic peroxide or contains organic peroxides; and

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

(g) the substance—

(i) is an organic peroxide or contains organic peroxides; and

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

(2) If a substance is a mixture and is made up of 1 or more chemical elements or compounds, any one of which meets 1 or more of the minimum degrees of hazard specified in subclause (1)(b), (c), (f), or (g), then the mixture is hazardous for the purposes of the Act unless it can be shown that the exact mixture itself does not meet any of the minimum degrees of hazard specified in subclause (1).

(3) When tested in accordance with subclause (1)(b), a substance must be—

(a) in the finest particle form in which that substance is reasonably capable of being used or rendered; or

(b) if it is likely or known that more than 10% of the mass of the substance will crumble into a finer particle form, in that finer form.

(4) For the purposes of subclause (1)(f) and (g), the available oxygen content as a percentage by mass must be determined in accordance with the following formula:

$$O\% = 16 \Sigma (n_i [c_i/m_i])$$

where—

O% is the percentage of available oxygen content to be determined

Σ is the symbol for summation where there is more than 1 organic peroxide

n_i is the number of peroxygen groups per molecule of each organic peroxide

c_i is the percentage concentration by mass of each organic peroxide

m_i is the molecular mass of each organic peroxide.

Schedule 4
Minimum degrees of hazard for substances with toxic properties

r 7(4)

1 Interpretation

In this schedule, unless the context otherwise requires,—

developmental effect, in relation to an organism, includes structural abnormality, altered growth, functional deficiency, or interference with the normal development of an organism (including the death of a developing organism), that is—

(a) manifested at any point in the organism's life span; and

(b) caused by—

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

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

dust and mist, in relation to a substance in the atmosphere, means that 90% of the substance is in the form of particles with a aerodynamic diameter of less than 10 microns

expert means—

(a) a member of a scientific committee set up by an international, national, or professional scientific body to review scientific data; or

(b) a person considered by his or her scientific peers to be an expert in the relevant field of scientific study

genotoxic effect means alterations to the structure, information content, or segregation of DNA, including—

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

(b) temporary non-physiological alterations to its replication

LD_{50} means the median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals

mean Draize score,—

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

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

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

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

mutagenic effect means a permanent change in the amount or structure of the genetic material in a cell, being a permanent change that is—

(a) manifested at the phenotypic level; or

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

reliable information means information that is derived from—

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

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

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

reproductive effect includes—

(a) interference with reproductive ability or capacity, including alteration to the male or female reproductive system; or

(b) an effect on the onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, or premature reproductive senescence; or

(c) an effect on or through lactation; or

(d) modifications in other functions that are dependent on the integrity of the reproductive system

sensitisation means an immunologically mediated response where, after exposure to a substance to which an organism or human being has been previously exposed, the organism or human being is, or 1 or more organs in an organism or human being are, more readily and adversely affected by that substance

significant adverse biological effect means a toxicologically significant change in an organ or in an animal observed during the study where the probability that the change is different from any recognised background history of change or from the value in a recognised unexposed control organ or animal group in the test animal strain is greater than 0.95 (equivalent to P (probability) of 0.05 or less)

valid, in relation to a study, means—

(a) the design of the study methodology accurately reflects the matters the study seeks to measure; and

(b) the study findings can be extrapolated from the sample used in the study to a broader population.

2 Minimum degrees of hazard

(1) A substance with toxic properties is not hazardous for the purposes of the Act unless—

(a) data for the substance indicates an LD_{50} of 5 000 milligrams or less of the substance per kilogram of bodyweight as a result of acute exposure of animals to the substance by oral or dermal routes; or

(b) data for the substance indicate any mortality, as a result of acute exposure of animals by—

(i) oral or dermal routes to 2 000 milligrams or less of the substance per kilogram of bodyweight; or

(ii) the inhalation route to—

(A) 5 000 parts or less of the substance per million in air, if the substance is a gas; or

(B) 20 milligrams or less of the substance per litre of air, if the substance is a vapour; or

(C) 5 milligrams or less of the substance per litre of air, if the substance is a dust or mist; or

(c) clinical signs (other than diarrhoea, piloerection, or an ungroomed appearance) indicate to an expert a significant adverse biological effect as a result of acute exposure of animals by—

(i) oral or dermal routes to 2 000 milligrams or less of the substance per kilogram of bodyweight; or

(ii) the inhalation route to—

(A) 5 000 parts or less of the substance per million in air, if the substance is a gas; or

(B) 20 milligrams or less of the substance per litre of air, if the substance is a vapour; or

(C) 5 milligrams or less of the substance per litre of air, if the substance is a dust or mist; or

(d) reliable information for the substance, including reliable information from animal studies other than those from which LD_{50} data was obtained, where exposure was by a route other than oral, dermal, or inhalation, indicates to an expert the potential for significant acute toxic effects in humans after exposure to the substance; or

(e) data for the substance, in the opinion of an expert, indicates evidence in humans of significant acute toxic effects as a result of exposure to the substance; or

(f) data for the substance indicates a mean Draize score of 1.5 or more for either of the skin irritation effects known as erythema or oedema, as a result of exposure to the substance; or

(g) data for the substance indicates a mean Draize score of 1 or more for either of the eye irritation effects known as corneal opacity or iritis, as a result of exposure to the substance; or

(h) data for the substance indicates a mean Draize score of 2 or more for either of the eye irritation effects known as conjunctival redness or chemosis, as a result of exposure to the substance; or

(i) data for the substance indicates positive evidence of respiratory sensitisation in animals as a result of exposure to the substance; or

(j) data for the substance indicates positive evidence of sensitisation by skin contact in animals as a result of exposure to the substance of either—

(i) 30% or more sensitisation response in an adjuvant type test method; or

(ii) 15% or more sensitisation response in a non-adjuvant type test method; or

(k) data for the substance, in the opinion of an expert, indicates evidence in humans of specific respiratory hypersensitivity (including asthma, rhinitis, and alveolitis) as a result of exposure to the substance; or

(l) data for the substance, in the opinion of an expert, indicates evidence in humans of sensitisation by skin contact as a result of exposure to the substance; or

(m) data for the substance indicates evidence of mutagenic effects as a result of mammalian *in vivo* exposure to the substance; or

(n) data for the substance indicates evidence of—

(i) genotoxic effects as a result of mammalian *in vivo* exposure to the substance; and

(ii) mutagenic effects as a result of *in vitro* exposure to the substance; or

(o) data for the substance indicates evidence of mutagenic effects as a result of *in vitro* exposure of mammalian cells to the substance and the substance has a structure–activity relationship to known germ cell mutagens, where—

(i) **structure–activity relationship** means a significant correlative relationship between the chemical structure of the substance and the chemical structure of a known germ cell mutagen; and

(ii) the relationship relates to that germ cell mutagen activity; or

(p) reliable information for the substance indicates to an expert that exposure to the substance causes the development of cancer or an increase in the incidence of benign or malignant tumours in an organ or an organism; or

(q) reliable information for the substance indicates to an expert that exposure to the substance causes an adverse reproductive effect; or

(r) reliable information for the substance indicates to an expert that exposure to the substance causes an adverse developmental effect; or

(s) data for the substance indicates, in the opinion of an expert, evidence of a significant adverse biological effect or a significant toxic effect (other than an effect referred to in any of paragraphs (a) to (r)) on the function or morphology of an organ, or on the biochemistry or haematology of an organism or human being as a result of exposure to the substance and, in the case of a significant adverse biological effect, the change is relevant to human health.

(2) A substance is not required to be tested in accordance with subclause (1)(a) if the substance—

(a) has been tested in accordance with subclause (1)(b); and

(b) does not meet the minimum degree of hazard specified in subclause (1)(b).

Schedule 5
Minimum degrees of hazard for substances with corrosive properties

r 7(5)

1 Interpretation

In this schedule, unless the context otherwise requires, **mean Draize score**, in relation to acute eye irritation tests, means the mean value in at least 2 of 3 tested animals from Draize grades measured at intervals of 24 hours, 48 hours, and 72 hours after instillation of the substance.

2 Minimum degrees of hazard

A substance with corrosive properties is not hazardous for the purposes of the Act unless—

(a) the substance corrodes, at a rate exceeding 6.25 millimetres per year at a test temperature of 55°C,—

(i) steel type P235 (ISO 9328 (II):1991); or

(ii) steel type SAE 1020 (Society of Automotive Engineers); or

(iii) non-clad aluminium types SAE 7075-T6 or AZ5GU-T6; or

(b) data for the substance indicates that the substance has a pH level of 2 or less, or 11.5 or more; or

(c) data for the substance indicates destruction of dermal tissue, being visible necrosis through the epidermis and into the dermis, as a result of exposure to the substance, that has not fully reversed within an observation period of 14 days; or

(d) data for the substance indicates destruction of ocular tissue, being adverse effects on the cornea, iris, or conjunctiva, as a result of exposure to the substance, that has not fully reversed within an observation period of 21 days; or

(e) data for the substance indicates a mean Draize score of 3 or more for the eye irritation effect known as corneal opacity, as a result of exposure to the substance; or

(f) data for the substance indicates a mean Draize score of 1.5 or more for the eye irritation effect known as iritis, as a result of exposure to the substance.

Schedule 6
Minimum degrees of hazard for substances with ecotoxic properties

r 7(6)

1 Interpretation

In this schedule, unless the context otherwise requires,—

BCF means bioconcentration factor, being the steady state concentration of a substance in an aquatic organism divided by the concentration of the substance in the surrounding water

bioaccumulative, in relation to a substance, means the substance has a BCF greater than or equal to 500 or, if BCF data is not available, a log K_{ow} greater than or equal to 4; and, for the purposes of this definition, measured log K_{ow} values take precedence over estimated values

biocidal action, in relation to a substance, means the substance causes mortality, inhibited growth, or inhibited reproduction in an organism

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

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

EC_{50} means the median effect concentration, being a statistically derived concentration of a substance that can be expected to cause—

(a) an adverse effect in 50% of organisms; or

(b) a 50% reduction in growth or in the growth rate of organisms

K_{ow} means the steady state ratio of the solubility of a substance in n-octanol to the solubility of that substance in water

LC_{50} means the median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of organisms exposed for a specified time

LD_{50} means a median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of organisms

LOEC means the lowest observed effect concentration, being the lowest concentration of a substance that produces a significant ecotoxic effect in an organism or in an organism population

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

NOEC means the no observed effect concentration, being the highest concentration of a substance that does not produce a significant ecotoxic effect in an organism or in an organism population

rapidly degradable, in relation to a substance in water, means that—

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

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

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

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

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

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

significant ecotoxic effect means an ecotoxicologically significant change in an organism or in an organism population observed during the study where the probability that the change is different from any recognised background history of change or from the value in a recognised unexposed control organism population is greater than 0.95 (equivalent to P (probability) of 0.05 or less).

2 Minimum degrees of hazard

(1) A substance with ecotoxic properties is not hazardous for the purposes of the Act unless—

(a) the substance is ecotoxic to aquatic organisms because—

(i) data for the substance indicates that the fish LC_{50} is 100 milligrams or less of the substance per litre of water over a 96-hour exposure period, as a result of exposure to the substance; or

(ii) data for the substance indicates that the crustacean EC_{50} is 100 milligrams or less of the substance per litre of water over a 48-hour exposure period, as a result of exposure to the substance; or

(iii) data for the substance indicates that the algal or other aquatic plant EC_{50} is 100 milligrams or less of the substance per litre of water over a 72-hour or 96-hour exposure period, as a result of exposure to the substance; or

(iv) data for the substance indicates that the chronic fish NOEC, or chronic crustacean NOEC, or algal or other aquatic plant chronic NOEC, is 1 milligram or less of the substance per litre of water, as a result of exposure to the substance; or

(v) in the absence of the NOEC data prescribed in subparagraph (iv) data for the substance indicates that it is not rapidly degradable and is bioaccumulative; or

(b) the substance is ecotoxic to soil organisms because—

(i) data for the substance indicates that a plant or soil invertebrate EC_{50} is 100 milligrams or less of the substance per kilogram of dry weight of soil over a 14-day exposure period, as a result of exposure to the substance; or

(ii) data for the substance indicates a 25% reduction in microbial respiration or microbial nitrification at 100 milligrams or less of the substance per kilogram of dry weight of soil after a 28-day exposure period, as a result of exposure to the substance; or

(c) the substance is ecotoxic to terrestrial vertebrates because—

(i) data for the substance indicates an acute avian or mammalian oral or dermal LD_{50} of 2 000 milligrams or less of the substance per kilogram of body weight, as a result of exposure to the substance; or

(ii) data for the substance indicates an acute avian or mammalian LC_{50} of 5 000 parts or less of the substance per million in the diet, as a result of exposure to the substance; or

(iii) data for the substance indicates a chronic avian or mammalian MATC of 100 parts or less of the substance per million in the diet, as a result of exposure to the substance; or

(d) the substance is ecotoxic to terrestrial invertebrates because data for the substance indicates an acute oral or contact LD_{50} of 25 micrograms or less of the substance per terrestrial invertebrate, as a result of exposure to the substance; or

(e) the substance is designed for biocidal action.

(2) A substance referred to in subclause (1)(e) is not hazardous for the purposes of this schedule if—

(a) the substance is designed for biocidal action against a virus, protozoan, bacterium, or an internal organism in humans or in other vertebrates; and

(b) the substance does not meet any of the minimum degrees of hazard specified in subclause (1)(a) to (d).

Martin Bell,
for Clerk of the Executive Council.

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Reprints notes

1 General

This is a reprint of the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 that incorporates all the amendments to those regulations as at the date of the last amendment to them.

2 Legal status

Reprints are presumed to correctly state, as at the date of the reprint, the law enacted by the principal enactment and by any amendments to that enactment. Section 18 of the Legislation Act 2012 provides that this reprint, published in electronic form, has the status of an official version under section 17 of that Act. A printed version of the reprint produced directly from this official electronic version also has official status.

3 Editorial and format changes

Editorial and format changes to reprints are made using the powers under sections 24 to 26 of the Legislation Act 2012. See also http://www.pco.parliament.govt.nz/editorial-conventions/.

4 Amendments incorporated in this reprint

Hazardous Substances (Health and Safety Reform Revocations) Regulations 2017 (LI 2017/233): regulation 4(1)

Food Act 2014 (2014 No 32): section 447

Medicines Amendment Act 2013 (2013 No 141): section 49

Psychoactive Substances Act 2013 (2013 No 53): section 110(1)

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