Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020

made under section 7AA of the

Therapeutic Goods Act 1989

Compilation No. 2

Compilation date: 6 May 2020

Includes amendments up to: F2020L00551

Prepared by the Department of Health, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* that shows the text of the law as amended and in force on 6 May 2020 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary

1 Name

This instrument is the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020.*

3 Authority

This instrument is made under section 7AA of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

(a) advertise;
(b) batch;
(c) British Pharmacopoeia;
(d) default standard;
(e) European Pharmacopoeia;
(f) label;
(g) supply; and
(h) United States Pharmacopoeia-National Formulary.

In this instrument:

acceptable microbiological quality, in relation to water, means a microbial count that is less than 100 colony forming units per mL.

Act means the *Therapeutic Goods Act 1989*.

food standard grade means compliance with an applicable standard in the Food Chemicals Codex, as in force or existing at the commencement of this instrument.

Note: The Food Chemicals Codex is available online at: www.foodchemicalscodex.org.

other purification process, in relation to water, means a process, such as reverse osmosis, that meets the following requirements:

(a) the process is validated to produce and distribute water that is of acceptable chemical quality and acceptable microbiological quality; and
(b) regular microbiological testing of the water is undertaken, including sampling at the point of use, using one of the following methods:
    (i) filtration of a suitable sample size through a membrane of nominal pore size not greater than 0.45 µm, using R2A agar and incubating on a single plate at 30-35°C for not less than 5 days; or
    (ii) filtration of a suitable sample size through a membrane of nominal pore size not greater than 0.45 µm, using R2A agar and incubating on separate plates at 35-37°C and 20-22°C for not less than 5 days.

pharmacopoeial grade means compliance with an applicable default standard.

Note: The default standards are the British Pharmacopoeia, European Pharmacopoeia and the United States Pharmacopoeia-National Formulary.

Part 2—Excluded goods

5 Excluded goods

For subsection 7AA(2) of the Act, the goods specified in column 2 of an item of the table in Schedule 1, when used, advertised, or presented for supply in a way specified in column 3 of that item, are excluded goods for the purposes of the Act.

Part 3—Application, saving and transitional provisions

6 Transitional provision

(1) In this section:

Amendment Determination means the *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020*.

commencement date means the day on which the Amendment Determination commences.

Former Determination means the *Therapeutic Goods (Excluded Goods—Hand Sanitiser) Determination 2020*, as in force immediately before the commencement date.

transition period means the period beginning on the commencement date and ending on 30 June 2020.

(2) Despite the amendments made by the Amendment Determination, the Former Determination continues to apply for the duration of the transition period in relation to the manufacture and supply of goods specified in items 1 and 2 of the table in Schedule 1 to the Former Determination.

Schedule 1—Specified goods used, advertised, or presented for supply in a particular way

Note: See section 5.

Specified goods that are excluded goods when used, advertised, or presented for supply in a particular way

Column 1	Column 2	Column 3
Item	**Specified goods**	**Use, advertising or presentation**
1	hand sanitiser in relation to which all of the following paragraphs apply: (a) the final formulation of the hand sanitiser contains only the following ingredients: (i) ethanol 80% v/v (pharmacopoeial grade or food standard grade) in an aqueous solution that may contain a denaturant such as denatonium benzoate (NLT 5ppm), sucrose octaacetate (0.12%w/v) or tertiary butyl alcohol (0.25%v/v); (ii) purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process; (iii) glycerol 1.45% v/v (pharmacopoeial grade or food standard grade); (iv) hydrogen peroxide 0.125% v/v (pharmacopoeial grade); and does not contain any other active or inactive ingredients, including colours, fragrances or emollients; (b) the concentration of ethanol specified in subparagraph (a)(i) is verified by the manufacturer testing samples of each batch of the final formulation of the hand sanitiser using gas chromatography, alcoholmeter, hydrometer, or other chemical analysis of equivalent or greater accuracy; (ba) the purified water specified in subparagraph (a)(ii) is used as soon as practicable following purification to maintain the acceptable chemical	when: (a) presented for supply with the front and back labels set out in Part 1 of Schedule 2 attached to the goods, and not presented for supply in any other way, with the following exceptions: (i) the labels may include a business name or logo of the manufacturer or supplier, and a trade name for the goods, neither of which may suggest or imply that the goods have been recommended or approved by or on behalf of a government or government authority; (ii) the labels may include a batch number; (iii) the labels may include an expiry date, which must not be more than 36 months after the completion of the manufacture of the goods; (iv) the labels may state that the formulation of the goods is based on the handrub formulation of the World Health Organization; (v) the labels may include any caution, warning or other marking that relates to the safe use, transportation or storage of the goods; (vi) the labels may be printed in colour; (vii) the front and back labels

	quality, and the acceptable microbiological quality, of the water; (c) the hand sanitiser is manufactured under sanitary conditions using equipment that is well maintained and fit for purpose; (d) records relating to the manufacture of the hand sanitiser are kept by the manufacturer in relation to each of the matters specified in paragraphs (a), (b), (ba) and (c)	may be combined into a single label or may otherwise be co-located on the goods; and (b) not presented for supply in a way that is likely to result in the goods being mistaken for or confused with food or beverages; and (c) advertised in a manner that is consistent with the matters specified in paragraph (a) and not advertised in any other way with the following exceptions: (i) an advertisement in relation to the goods may include information as to where the goods may be purchased; (ii) an advertisement in relation to the goods may include price information
2	hand sanitiser in relation to which all of the following paragraphs apply: (a) the final formulation of the hand sanitiser contains only the following ingredients: (i) isopropyl alcohol 75% v/v (pharmacopoeial grade) in an aqueous solution; (ii) purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process; (iii) glycerol 1.45% v/v (pharmacopoeial grade or food standard grade); (iv) hydrogen peroxide 0.125% v/v (pharmacopoeial grade); and does not contain any other active or inactive ingredients, including colours, fragrances or emollients; (b) the concentration of isopropyl alcohol specified in subparagraph (a)(i) is verified by the manufacturer testing samples of each batch of the final formulation of the hand sanitiser using gas chromatography, alcoholmeter, hydrometer, or other chemical analysis	when: (a) presented for supply with the front and back labels set out in Part 2 of Schedule 2 attached to the goods, and not presented for supply in any other way, with the following exceptions: (i) the labels may include a business name or logo of the manufacturer or supplier, and a trade name for the goods, neither of which may suggest or imply that the goods have been recommended or approved by or on behalf of a government or government authority; (ii) the labels may include a batch number; (iii) the labels may include an expiry date, which must not be more than 36 months after the completion of the manufacture of the goods; (iv) the labels may state that the formulation of the goods is based on the handrub formulation of the World

	of equivalent or greater accuracy; (ba) the purified water specified in subparagraph (a)(ii) is used as soon as practicable following purification to maintain the acceptable chemical quality, and the acceptable microbiological quality, of the water; (c) the hand sanitiser is manufactured under sanitary conditions using equipment that is well maintained and fit for purpose; (d) records relating to the manufacture of the hand sanitiser are kept by the manufacturer in relation to each of the matters specified in paragraphs (a), (b), (ba) and (c)	Health Organization; (v) the labels may include any caution, warning or other marking that relates to the safe use, transportation or storage of the goods; (vi) the labels may be printed in colour; (vii) the front and back labels may be combined into a single label or may otherwise be co-located on the goods; and (b) not presented for supply in a way that is likely to result in the goods being mistaken for or confused with food or beverages; and (c) advertised in a manner that is consistent with the matters specified in paragraph (a) and not advertised in any other way with the following exceptions: (i) an advertisement in relation to the goods may include information as to where the goods may be purchased; (ii) an advertisement in relation to the goods may include price information

Schedule 2—Labels

Part 1—Ethanol hand sanitiser

Note: See item 1 of Schedule 1.

1 Front label

Ethanol hand sanitiser 80%

Hand rub [optional text: suitable for use in medical and health services]

DO NOT DRINK

[Insert volume of the product in mLs]

[Insert name of the manufacturer or supplier]

[Insert contact details of the manufacturer or supplier]

2 Back label

Contains:

Ethanol 80% v/v, water, glycerol and hydrogen peroxide.

[Insert name of denaturant used, if applicable]

Use:

Antiseptic hand rub when soap and water are not available.

Directions for use:

Apply sufficient amount of product on hands to cover all surfaces.

Rub hands together until dry.

Warnings:

For external use only. Flammable. Keep away from heat or flame.

Keep out of eyes, ears and mouth.

Discontinue use if skin irritation or rash occurs.

Keep out of reach of children.

Poisons Information Centre 13 11 26.

Store below 30 °C.

Date of manufacture: [Insert dd mm yyyy]

Part 2—Isopropyl alcohol hand sanitiser

Note: See item 2 of Schedule 1.

1 Front label

Isopropyl alcohol hand sanitiser 75%

Hand rub [optional text: suitable for use in medical and health services]

DO NOT DRINK

[Insert volume of the product in mLs]

[Insert name of the manufacturer or supplier]

[Insert contact details of the manufacturer or supplier]

2 Back label

Contains:

Isopropyl alcohol 75% v/v, water, glycerol and hydrogen peroxide.

Use:

Antiseptic hand rub when soap and water are not available.

Directions for use:

Apply sufficient amount of product on hands to cover all surfaces.

Rub hands together until dry.

Warnings:

For external use only. Flammable. Keep away from heat or flame.

Keep out of eyes, ears and mouth.

Discontinue use if skin irritation or rash occurs.

Keep out of reach of children.

Poisons Information Centre 13 11 26.

Store below 30 °C.

Date of manufacture: [Insert dd mm yyyy]

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020	27 Mar 2020 (F2020L00340)	28 Mar 2020	—
Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination 2020	31 Mar 2020 (F2020L00359)	1 Apr 2020	—
Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020	5 May 2020 (F2020L00551)	6 May 2020	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
Part 1 heading	ad F2020L00551
s 2	rep LA s 48D
s 4	am F2020L00359, F2020L00551
Part 2	
Part 2 heading	ad F2020L00551
Part 3	
Part 3	ad F2020L00551
Schedule 1	
Schedule 1	am F2020L00551
Schedule 2	
Schedule 2	am F2020L00359
	rs F2020L00551