



Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020

I, Jane Cook, as delegate of the Minister for Health, make the following determination.

Dated 27 March 2020

Dr Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Contents

1 Name.....	1
2 Commencement.....	1
3 Authority.....	1
4 Definitions.....	1
5 Excluded goods.....	2
Schedule 1—Specified goods used, advertised, or presented for supply in a particular way	3
Schedule 2—Labels	5
Part 1—Ethanol hand sanitiser	5
1 Front label.....	5
2 Back label.....	5
Part 2—Isopropyl alcohol hand sanitiser	6
1 Front label.....	6
2 Back label.....	6

1 Name

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

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	28 March 2020

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

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

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

food standard grade means compliance with an applicable standard in the Food Chemicals Codex.

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

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.

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.

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	<p>hand sanitiser in relation to which all of the following paragraphs apply:</p> <ul style="list-style-type: none"> (a) the final formulation of the hand sanitiser contains only the following ingredients: <ul style="list-style-type: none"> (i) ethanol 80% v/v (pharmacopoeial grade or food standard grade) in an aqueous solution; (ii) sterile distilled water or boiled cold water; (iii) glycerol 1.45% v/v (pharmacopoeial grade); (iv) hydrogen peroxide 0.125% v/v (pharmacopoeial grade); <p>and does not contain any other active or inactive ingredients, including colours, fragrances or emollients;</p> (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; (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), and (c) 	<p>when advertised or presented for supply using the front and back labels set out in Part 1 of Schedule 2, and not advertised or presented for supply in any other way, with the following exceptions:</p> <ul style="list-style-type: none"> (a) the labels may include a company logo; (b) the labels may be printed in colour; and (c) the front and back labels may be combined into a single label

2	<p>hand sanitiser in relation to which all of the following paragraphs apply:</p> <p>(a) the final formulation of the hand sanitiser contains only the following ingredients:</p> <p style="margin-left: 20px;">(i) isopropyl alcohol 75% v/v (pharmacopoeial grade) in an aqueous solution;</p> <p style="margin-left: 20px;">(ii) sterile distilled water or boiled cold water;</p> <p style="margin-left: 20px;">(iii) glycerol 1.45% v/v (pharmacopoeial grade);</p> <p style="margin-left: 20px;">(iv) hydrogen peroxide 0.125% v/v (pharmacopoeial grade);</p> <p>and does not contain any other active or inactive ingredients, including colours, fragrances or emollients;</p> <p>(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 of equivalent or greater accuracy;</p> <p>(c) the hand sanitiser is manufactured under sanitary conditions using equipment that is well maintained and fit for purpose;</p> <p>(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), and (c)</p>	<p>when advertised or presented for supply using the front and back labels set out in Part 2 of Schedule 2, and not advertised or presented for supply in any other way, with the following exceptions:</p> <p>(a) the labels may include a company logo;</p> <p>(b) the labels may be printed in colour; and</p> <p>(c) the front and back labels may be combined into a single label</p>
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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]

[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.

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.

Store below 30 °C.

Date of manufacture: 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]

[Insert volume of the product in mLs]

[Insert name 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.

Store below 30 °C.

Date of manufacture: dd mm yyyy

