



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

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

Dated 1 May 2020

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

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## 1 Name

This instrument is the *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination (No. 2) 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.	

Note: This table relates only to the provisions of this instrument as originally made.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 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## Schedule 1—Amendments

### *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020*

#### 1 Before section 1

Insert:

### Part 1—Preliminary

#### 2 Section 4 (note)

Repeal the note, substitute:

- 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.

#### 3 Section 4

Insert:

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

***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.

#### 4 Before section 5

Insert:

### Part 2—Excluded goods

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## 5 After section 5

Insert:

# 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.

## 6 Schedule 1 (table item 1, column 2, subparagraph (a)(i))

After “solution”, insert “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)”.

## 7 Schedule 1 (table item 1, column 2, subparagraph (a)(ii))

Repeal the subparagraph, substitute:

- (ii) purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process;

## 8 Schedule 1 (table item 1, column 2, subparagraph (a)(iii))

After “grade”, insert “or food standard grade”.

## 9 Schedule 1 (table item 1, column 2, after paragraph (b))

Insert:

- (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;

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**10 Schedule 1 (table item 1, column 2, paragraph (d))**

After “paragraphs (a), (b),”, insert “(ba)”.

**11 Schedule 1 (cell at table item 1, column 3)**

Repeal the cell, substitute:

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 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



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- goods may include information as to where the goods may be purchased;
- (ii) an advertisement in relation to the goods may include price information

**12 Schedule 1 (table item 2, column 2, subparagraph (a)(ii))**

Repeal the subparagraph, substitute:

- (ii) purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process;

**13 Schedule 1 (table item 2, column 2, subparagraph (a)(iii))**

After “grade”, insert “or food standard grade”.

**14 Schedule 1 (table item 2, column 2, after paragraph (b))**

Insert:

- (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;

**15 Schedule 1 (table item 2, column 2, paragraph (d))**

After “paragraphs (a), (b),”, insert “(ba)”.

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## 16 Schedule 1 (cell at table item 2, column 3)

Repeal the cell, substitute:

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 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;

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- (ii) an advertisement in relation to the goods may include price information

## **17 Schedule 2**

Repeal the Schedule, substitute:

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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]

##### **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]



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## 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]

