

## Bostik Sanitiser Information for Customers

In response to the COVID-19 pandemic, on 28 March 2020, the Therapeutic Goods Administration (**TGA**) excluded specified hand sanitisers from requiring TGA approval for both hospital settings and households, provided they:

- (1) only contain particular ingredients in particular quantities in the final formulation; and
- (2) comply with certain manufacturing, advertising and labelling conditions.

The specific ingredients, quantities and manufacturing, advertising and labelling conditions are defined in the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020 (Determination)*. A copy of the relevant sections of the Determination are attached in Annexure A.

Bostik is pleased to confirm that the ingredients and quantities used in its Bostik Hospital Grade Hand Sanitiser (**Bostik Formulation**) comply with the TGA Determination, as follows:

Determination	Bostik Formulation
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)	<i>Ethanol 80% v/v (pharmacopoeial grade) with 5ppm denatonium benzoate</i>
Purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process	<i>Purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process</i>
Glycerol 1.45% v/v (pharmacopoeial grade or food standard grade)	<i>Glycerin 1.45% v/v (pharmacopoeial grade)</i>
Hydrogen peroxide 0.125% v/v (pharmacopoeial grade)	<i>Hydrogen peroxide 0.125% v/v (pharmacopoeial grade)</i>
and does not contain any other active or inactive ingredients, including colours, fragrances or emollients	<i>Does not contain any other ingredients</i>

Bostik further confirms that the Bostik Formulation is manufactured under sanitary conditions in our Thomastown manufacturing facility in Australia using equipment that is well maintained and fit for purpose, as required by the Determination.

## Annexure A

### 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.

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

Note: See section 5.

<b>Specified goods that are excluded goods when used, advertised, or presented for supply in a particular way</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>Specified goods</b>	<b>Use, advertising or presentation</b>
1	<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) 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);</p> <p style="margin-left: 20px;">(ii) purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process;</p> <p style="margin-left: 20px;">(iii) glycerol 1.45% v/v (pharmacopoeial grade or food standard 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 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;</p> <p>(ba) the purified water specified in subparagraph (a)(ii) is used as soon as practicable following purification to maintain the acceptable chemical</p>	<p>when:</p> <p>(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:</p> <p style="margin-left: 20px;">(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;</p> <p style="margin-left: 20px;">(ii) the labels may include a batch number;</p> <p style="margin-left: 20px;">(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;</p> <p style="margin-left: 20px;">(iv) the labels may state that the formulation of the goods is based on the handrub formulation of the World Health Organization;</p> <p style="margin-left: 20px;">(v) the labels may include any caution, warning or other marking that relates to the safe use, transportation or storage of the goods;</p> <p style="margin-left: 20px;">(vi) the labels may be printed in colour;</p> <p style="margin-left: 20px;">(vii) the front and back labels</p>

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| <p>quality, and the acceptable microbiological quality, of the water;</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), (ba) and (c)</p> | <p>may be combined into a single label or may otherwise be co-located on the goods; and</p> <p>(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</p> <p>(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:</p> <ul style="list-style-type: none"><li>(i) an advertisement in relation to the goods may include information as to where the goods may be purchased;</li><li>(ii) an advertisement in relation to the goods may include price information</li></ul> |
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