

The Therapeutic Goods Administration (TGA) has excluded certain hand sanitisers from regulatory requirements to help urgently meet the surge in demand during the pandemic. In Australia, hand sanitisers are regulated as cosmetics or therapeutic goods depending on their ingredients and claims. Unless excluded by the TGA, hand sanitisers will generally be considered therapeutic goods if they:

- claim to kill specific organisms; or
- are intended for use in clinics or hospitals.

What hand sanitisers are excluded?

From 28 March 2020, hand sanitisers do not need to be included in the Australian Register of Therapeutic Goods (ARTG) provided they meet the following requirements:

1. Permitted ingredients

Contain only the following ingredients and not any other ingredient:

- Ethanol 80% v/v (pharmacopoeial or food standard grade) or isopropyl alcohol 75% v/v (pharmacopoeial grade) in an aqueous solution;
- Sterile distilled water or boiled cold water;
- Glycerol 1.45% V/v (pharmacopoeial grade); and
- Hydrogen peroxide 0.125% V/v (pharmacopoeial grade).

2. Manufacturing

Comply with the following manufacturing requirements:

- Testing The Alcohol Concentration Of Each Batch;
- Manufacturing Under Sanitary Conditions Using Well Maintained And Fit For Purpose Equipment; And
- Keeping Adequate Manufacturing Records.

3. Packaging

Use only the prescribed label on packaging and advertising, with the option of including a company logo.

But wait...

While such hand sanitisers may be advertised and sold without TGA regulation, they are still consumer goods that must comply with the Australian Consumer Law.

Next steps

Businesses that intend to rely on the exclusion should take care to ensure the hand sanitisers they manufacture or import into Australia satisfy the above requirements. It is important to keep up to date with the regulatory landscape as the continued need for the exclusion may be reassessed once the supply issues resolve.

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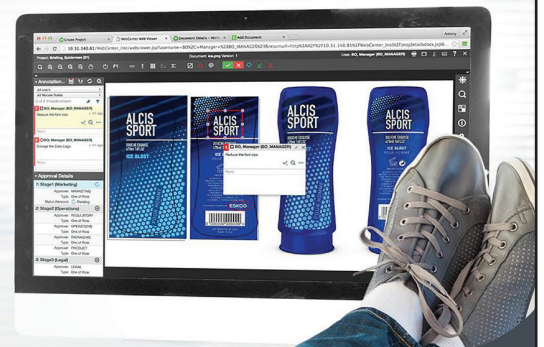
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