

Coronavirus COVID-19

WHS requirements for alcohol-based hand sanitisers in response to COVID-19

This fact sheet is for businesses who may have recently become involved in the manufacture or supply of hand sanitisers during the COVID-19 pandemic.

Alcohol-based hand sanitisers (hand sanitisers), and some of their ingredients, are hazardous chemicals. For example, hand sanitisers may contain ethanol and isopropanol, which are flammable liquids and can also cause severe eye irritation, and hydrogen peroxide which is an oxidiser and is corrosive to the skin and eyes

The following information is a summary of the work health and safety (WHS) requirements when manufacturing, importing, supplying, handling or storing hand sanitisers in response to COVID-19.

NOTE: If you are not currently equipped to manufacture, store or handle flammable liquids and oxidising chemicals, we strongly recommend that you seek expert advice from a suitably qualified and experienced industry consultant or other expert <u>before</u> you start working with these chemicals.

Manufacturing or importing hand sanitisers

Under the model WHS laws, there are specific requirements for businesses that manufacture or import hazardous chemicals (such as hand sanitisers), including businesses that re-package or re-label a hazardous chemical with their own product name.

If you are a manufacturer or importer of hand sanitiser, you must:

- > ensure, so far as is reasonably practicable, the product is without risks to health and safety, and
- correctly classify the product, and based on that classification, prepare correct labels and a safety data sheet (SDS) for the product.

You must also manage the risks to health and safety when handling and storing hand sanitiser.



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If you are manufacturing or importing hand sanitiser in response to the COVID-19 pandemic, you are exempt from the usual Therapeutic Goods Administration (TGA) licensing requirements for the duration of the COVID-19 pandemic, provided your hand sanitiser meets the requirement of the <u>Therapeutic Goods (Excluded Goods – Hand Sanitisers) Determination 2020</u>. Hand sanitisers that meet these requirements can be prepared by following the <u>World Health Organisation's (WHO) instructions</u>.

Labels for use on 'TGA excluded' hand sanitisers can also be found in the *Therapeutic Goods (Excluded Goods – Hand Sanitisers) Determination 2020.*

A <u>free safety data sheet</u> for 'TGA excluded' hand sanitisers has also been produced by the company UL.

If you are manufacturing or importing hand sanitiser that is not covered by the TGA exclusion (because they are not manufactured in accordance with the WHO instructions), you need to meet the requirements set out below.

Classes of hand sanitisers

In response to the high demand for hand sanitisers during the COVID-19 pandemic, the TGA has developed three classes for hand sanitisers. These are:

- 1. **General consumer products** which are classified as cosmetics and include hand sanitisers, or antibacterial skin preparations. These are not regulated by the TGA.
- Therapeutic Goods which are antibacterial hand hygiene products that require evaluation from the TGA and inclusion in the Australian Register of Therapeutic Goods (ARTG).
- 3. **Products with one of two specific formulations** these types of hand sanitisers are excluded from the TGA regulations during the COVID-19 pandemic. However, they must be made following a strict formula based on advice from the WHO.

More information about the TGA's classification of hand sanitisers can be found on their website.

Labelling hand sanitisers

Labelling hand sanitisers classed as General consumer products (cosmetics)

These products should be labelled in accordance with the Australian Competition and Consumers Commission's <u>mandatory standard for cosmetics labelling</u>. There are no WHS laws regarding how to label cosmetics and toiletries packaged for consumers.

If you want to import or manufacture cosmetic products or cosmetic ingredients for commercial purposes, you may also need to register your business with the National Industrial Notification and Assessment Scheme (NICNAS). Further information can be found on the <u>NICNAS website</u>.









Labelling hand sanitisers classed as Therapeutic Goods

Under the model WHS Regulations, you must label Therapeutic Goods as per the TGA's <u>labelling and packaging requirements</u>, provided they are in a form intended for:

- a patient or consumer
- therapeutic purposes.

Therapeutic Goods hand sanitisers that are to be used in a clinic or hospital (including aged care facilities) must be labelled in accordance with the <u>TGA requirements</u>.

When not in these forms, you must label products as per the WHS laws for <u>labelling chemicals</u>. For example, if you are storing a Therapeutic Goods hand sanitiser in a 200 litre container before repackaging it into smaller containers, you would apply WHS labelling to the 200 litre container.

Labelling hand sanitisers that are currently excluded from the TGA regulations

If you are a manufacturer or importer of TGA excluded hand sanitisers, you must ensure those products are labelled with the labels set out in the <u>Therapeutic Goods (Excluded Goods – Hand</u> <u>Sanitisers) Determination 2020</u>.

SDS for hand sanitisers

Manufacturers and importers of hand sanitisers must ensure that an SDS is available for their product, regardless of the class of the hand sanitiser. SDS are documents that provide critical information about hazardous chemicals, including:

- > the chemical's identity and ingredients
- > health and physical hazards
- > first aid and firefighting methods
- > safe handling and storage procedures, and
- > disposal considerations.

More information can be found on the Safe Work Australia Safety data sheets webpage.

In response to the COVID-19 pandemic, UL is making SDS for TGA excluded hand sanitisers freely available to manufacturers and importers. More information can be found <u>on their website</u>.

If you wish to produce your own SDS, see the <u>model Code of Practice: Preparation of safety data</u> <u>sheets for hazardous chemicals</u> for more information.

Supplying hand sanitisers

Suppliers of hand sanitiser must:

- Make sure, so far as is reasonably practicable, that products they supply are without risks to health and safety.
- Provide <u>SDS</u> with the products.

A supplier is anyone who supplies a hand sanitiser that may be used at a workplace. This includes intermediaries in the supply chain such as distributors, on-sellers and wholesalers.





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If you are a supplier you must not supply hand sanitiser to workplaces if you know, or ought reasonably to know that the products are not correctly labelled (see above).

There are also restrictions on the age of workers who can supply flammable liquids such as hand sanitisers, workers undertaking this task must be at least 16 years of age.

Handling and storing hazardous chemicals

Handling and storing flammable liquids such as hand sanitiser and ethanol

As hand sanitisers and their ingredients (such as ethanol) are highly flammable, manufacturers and importers must consider the risk of fire when using, manufacturing and storing these chemicals and take appropriate steps to reduce the risk of fire.

This includes:

- minimising the amount of flammable and combustible substances that are kept at the workplace by law these must be kept at the lowest practicable quantity for the workplace.
- identifying and separating sources of fuel, oxygen and ignition sources
- ensuing that ignition sources are not introduced into areas where flammable liquids are used or stored, or where flammable vapours may accumulate, and
- ensuring there is appropriate fire-fighting and fire protection equipment in case of an emergency, and that staff are trained in how to use them and how to respond in an emergency.

More information can be found in Chapters 3.4 and 4.2 of the <u>model Code of Practice: Managing</u> the risks of hazardous chemicals in the workplace and the Guide: <u>Managing risks of storing</u> chemicals in the workplace.

Handling and storing oxidisers such as hydrogen peroxide

Oxidisers such as hydrogen peroxide can react violently with many common chemicals, especially flammable materials. Common chemicals that are incompatible with oxidisers include flammable liquids (such as ethanol and isopropanol), organic materials (such as wood, paper, cellulose products), fuels, oils and solvents (such as mineral turpentine and methylated spirits) and other organic (carbon-based) chemicals.

As the WHO's formula for hand sanitisers includes both flammable liquids and oxidisers, take care to ensure these chemicals are not mixed in a way might cause a fire or dangerous chemical reaction. In the WHO's instructions, the hydrogen peroxide used in the manufacture of hand sanitisers should be only 3%, which is unlikely to cause a dangerous reaction. If hydrogen peroxide is being stored on site for use in manufacturing hand sanitisers, either keep it diluted or separate from stores of flammable and combustible materials, including ethanol.

You should assess any situation where an oxidiser could come into contact with other chemicals. This includes any containers and other equipment used when handling or transferring the chemicals. Oxidisers should be handled in compatible containers and with compatible equipment to avoid a dangerous reaction occurring. Since oxidisers provide oxygen to fires and other chemical reactions, oxidisers can cause a fire or explosion even if they are handled under an inert atmosphere like nitrogen.





Further information can be found in Appendix J of the <u>model Code of Practice: Managing the</u> risks of hazardous chemicals in the workplace and the Guide: <u>Managing risks of storing</u> chemicals in the workplace.

Hazardous chemical registers

A hazardous chemicals register is a list of hazardous chemicals at a workplace. It must include the current SDS for each of the chemicals listed.

If your business uses, stores or handles hazardous chemicals (such as ethanol, isopropanol and hydrogen peroxide) you must prepare a register and keep it up-to-date so workers can easily find information about those chemicals.

All hazardous chemicals that are stored, handled or used at a workplace must be listed on the register except where they are:

- > in-transit, or
- > consumer products.

Consumer products are those that are packed primarily for use by a household consumer and are used in a way and quantity that is consistent with normal household use.

More information about hazardous chemical registers, including a template for preparing your own register, can be found on the <u>Registers, manifests and placards web page.</u>

Storing larger quantities of flammable liquids or oxidisers

While any business which uses, stores or handles hazardous chemicals needs to keep a hazardous chemical register; the placard and manifest requirements described below only apply if you store more than the threshold quantity of hazardous chemicals.

For hand sanitisers and their flammable ingredients (Category 2 flammable liquids), the threshold quantities are:

- > Placarding quantity: 250 litres
- > Manifest quantity: 2,500 litres

For hydrogen peroxide, the threshold quantities are:

- > Placarding quantity: 50 litres or kilograms
- > Manifest quantity: 500 litres or kilograms

NOTE: If hydrogen peroxide is stored in a diluted form, a greater volume can be stored before placards and manifests are required.

A placard is a special type of sign displayed at a workplace to warn about the large stores of hazardous chemicals kept there, while a manifest is a written document that contains information about the quantity, classification and locations of the hazardous chemicals at the workplace. Both placards and manifests contain vital information for use by emergency services in the event of an incident.

More information about the placarding and manifest requirements can be found on the <u>Registers</u>, <u>manifests and placards web page</u>.

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Safe Work Australia resources

- > Model Code of Practice: Managing risks of hazardous chemicals in the workplace
- > Guide: <u>Managing risks of storing chemicals in the workplace</u>.

NOTE: this is a summary of the model WHS requirements for hazardous chemicals. Contact your <u>WHS regulator</u> for further advice about your duties.

