

Alcohol-Based Hand Sanitiser Manufacturing and Transport Information Sheet

Manufacturing: Workplace health and safety

Alcohol-based hand sanitisers and their main components, ethanol and isopropanol, are flammable liquids. If you are following the Therapeutic Goods Administration (TGA)
<u>Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020 (Cth)</u> then you will also need to handle hydrogen peroxide, a strong oxidising agent. There is a high risk of serious injury or death if these substances are not handled correctly. The Work Health and Safety responsibilities for manufacture of alcohol-based hand sanitisers must be understood to ensure these risks are appropriately mitigated.

If you are not currently equipped to store, handle or manufacture flammable liquids or oxidising agents, it is strongly advised that you seek expert advice to assist you to comply with requirements for storage, manufacturing and handling of flammable liquids and oxidising agents at your site before manufacturing.

All Australian States and Territories have rules regarding safe management of hazardous chemicals including flammable liquids and oxidising agents. Consult your State/Territory legislation or contact your State/Territory regulator for State/Territory specific information.

The <u>Guide for Flammable and Combustible Liquids</u> by the Office of Industrial Relations Queensland provides an overview of the regulatory requirements for safe management of flammable liquids in Queensland. Similar rules exist in all other States and Territories but with some differing requirements.

Hydrogen peroxide is a strong oxidising agent and must be stored separately from other chemicals. Strong oxidising agents can initiate or accelerate the combustion of other materials. This can lead to more dangerous fires and potentially explosions. For detailed information on proper storage and handling of oxidising agents, refer to Australian Standard AS 4326 Storage and Handling of Oxidizing Agents.

Efficacy and public health and safety

For an alcohol-based hand sanitiser to be effective, it must contain between 60-80% (v/v) ethanol, isopropanol or n-propanol, or a combination of two or more of these ingredients to make up the volume of alcohol¹. Products containing alcohols below this concentration are unlikely to be effective; products that are not effective should not be marketed as alcohol-based hand sanitisers. There must be evidence of product efficacy before products are placed on the market regardless of supply chain or regulatory pathway.

The TGA provides a good <u>summary</u> of alcohol-based hand sanitiser regulations, including information on the new excluded goods determination which excludes specified hand sanitiser formulations from TGA regulation, as long as they only contain particular ingredients in particular quantities in the final formulation, and comply with certain manufacturing practices, and advertisement and labelling conditions. Provided that the exact formulation and other

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¹ WHO Guidelines on Hand Hygiene in Health Care, 2009



requirements are followed, this formulation is permitted for use in both healthcare facilities and for consumer use.

Alcohol hand sanitisers containing over 60% ethanol, isopropanol or n-propanol are also classified as a hazardous chemical. Hazardous Chemicals must be packed in a container that:

- (a) is in sound condition;
- (b) will safely contain the chemical for the time the chemical is likely to be packed;
- (c) is made of material that is compatible with, and will not be adversely affected by, the chemical; and
- (d) does not usually contain food or beverages and cannot be mistakenly identified as containing food or beverages².

A Safety Data Sheet (SDS) for the product must also be produced by the manufacturer or importer of the product and supplied as required under the relevant State/Territory regulations.

Transport

An effective alcohol-based hand sanitiser containing minimum 60% ethanol, isopropanol or n-propanol is classified as a flammable liquid and must be transported as Dangerous Goods (DG).

In Australia, the transport of DG is regulated differently depending on the mode of transport.

The <u>Civil Aviation Safety Authority</u> (CASA) regulates the transport of DG by air. The <u>DG</u> <u>transport rules by air</u> require mandatory certified/approved training for individuals that perform specified functions, including any of the following functions:

- pack DG in transport packages,
- mark and label the packages containing DG,
- consign DG packages for transport,
- prepare and issue the DG transport document.

It is an offence for individuals without relevant air DG training to perform any of the duties listed above.

The <u>Australian Maritime Safety Authority</u> (AMSA) regulates the transport of DG by sea. The DG transport rules by sea, <u>Marine Order 41 (Carriage of dangerous goods) 2017 (Cth)</u>, requires mandatory general awareness and task specific training (in accordance with the IMDG Code) for all persons involved in the transport of DG that will be transported by sea.

It is an offence for an employer not to arrange mandatory training for relevant employees involved in transport of DG by sea.

The mandatory training provides instructions on minimisation of transport risks arising from DG, including selection of correct packaging, correct packing methods, marking and labelling of packages and preparation of the DG transport document.

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² See Model Work Health <u>and Safety Regulations</u> Schedule 9, Part 2.

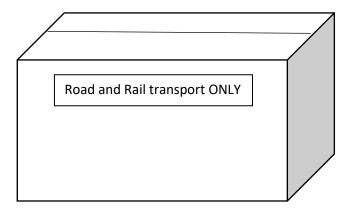


Road and rail transport rules also mandate training of all individuals involved in transport of DG that have responsibility to pack, mark, label, consign and/or transport DG. However, it is not mandatory for training to be delivered via certified/accepted training courses.

The current <u>Australian Code for the Transport of Dangerous Goods by Road and Rail</u> (ADG Code; edition 7.6) contains rules, section 3.4.12, that are relaxed specifically for the transport of personal care products. The definition of personal care products (by inference) includes alcohol-based hand sanitisers in primary packaging size of 1 L or less.

For the reduced requirements in section 3.4.12 to apply, the alcohol-based hand sanitiser must be packed in Limited Quantities³ and packaged in appropriate packaging so that under normal conditions of transport, including handling, there will be no accidental release of the product. As these reduced regulatory requirements only apply to road and rail transport, there should be identification on the package that it cannot be sent by sea or air.

Below is an example of an ethanol hand sanitiser package marking meeting ADG Code 3.4.12 requirements, acceptable only for road and rail transport.



For transport of large quantities of DG, such as ethanol in its raw material form, or final products in containers larger than those permitted for Limited Quantities, Limited Quantities provisions do not apply. Unless you are fully aware of and comply with your regulatory obligations for safe transport of DG, it is best to contact your local DG logistics company.

This information sheet has been written by Accord Australasia with the assistance of:

- Australian Maritime Safety Authority,
- Chemistry Australia,
- Civil Aviation Safety Authority,
- Consumer Health Products Australia,
- Department of Industry, Science, Energy and Resources,
- National Transport Commission,
- Safe Work Australia, and
- WorkSafe Victoria.

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³ For UN1170 Ethanol Solution, the maximum inner packaging quantity allowed is 1 L for packing group II and 5 L for packing group III. Alcohol-based hand sanitiser may be classified as either packing group II or III depending on the flash point of the product. Maximum quantity allowed in rigid outer packaging (e.g. carboard box) is 30kg gross.