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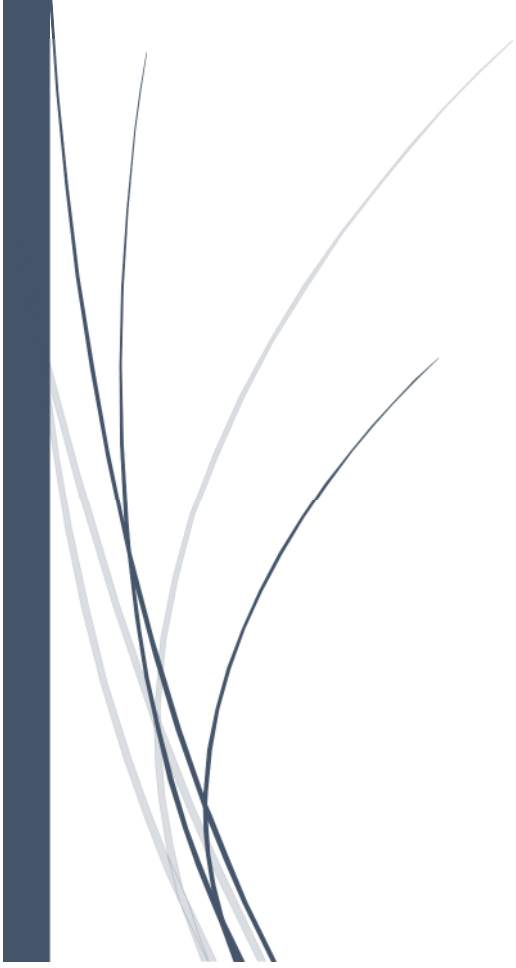
Hand Sanitiser Industry Benchmark

for non-therapeutic goods



accord
hygiene, personal care & specialty products industry

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The Industry Benchmark provided in this document is in addition to legal requirements and does not replace any legal requirements.

Introduction

In recent years, hand sanitisers have become important hand hygiene products utilised broadly by the general public. The hygiene, personal care and specialty chemicals industry recognises that it is vital for consumers to be assured of the efficacy, quality and safety of hand sanitisers regardless of supply chain.

This *Hand Sanitiser Industry Benchmark* sets out the essential requirements to meet consumer expectations on efficacy, quality and safety of non-therapeutic, antibacterial hand sanitisers supplied in Australia, regardless of where the products are manufactured. It is intended to be read by a wide audience, and while jargon is avoided wherever possible, the document does contain references to regulations and technical standards.

This *Hand Sanitiser Industry Benchmark* outlines the:

- Purpose of the document,
- Scope, or the products to which this document applies,
- minimum requirements that ingredients in hand sanitisers must meet for safety and efficacy,
- minimum requirements that the final product must meet for safety and efficacy,
- minimum labelling requirement, over and above the existing regulatory requirements, and
- acceptable claims and the evidence required to support the claims.

In addition, this document contains explanatory notes to guide those that are unfamiliar with the Australian regulation of hand sanitisers and the regulatory boundary between therapeutic and non-therapeutic hand sanitisers in Australia. Notes are also provided for those that may be unfamiliar with quality assurance processes for manufacturing and sourcing. These notes are provided in boxes within the document.

Lastly, this Industry Benchmark reflects the Australian regulatory environment and may not be suitable for use in other jurisdictions.

Purpose

The purpose of this document is to provide an Industry Benchmark for the quality, safety, efficacy and claims of non-therapeutic hand sanitisers. This Industry Benchmark does not replace any existing regulatory obligations but may provide additional information that may assist in meeting existing regulatory obligations.

Scope

This Industry Benchmark applies to 'no-rinse' or 'leave-on' handrubs or hand sanitisers that are excluded therapeutic goods; that is, they are formulated, presented for supply, advertised and used as specified in the *Therapeutic Goods (Excluded Goods) Determination 2018* (EGD 2018) Schedule 2, item 2.

Reference to hand sanitisers from this point on refers only to those products to which this Industry Benchmark applies.

Note:
To paraphrase EGD 2018, antibacterial skin care products that do not contain any substances included in Schedules 2, 3, 4, or 8 to the Poisons Standard are excluded goods when advertised or presented for supply as being active against bacteria and not advertised or presented for supply as being:

a) active against viruses, fungi or other microbial organisms (other than bacteria); or
b) for use in connection with disease, disorders or medical conditions; or
c) active against a named bacterium that is known to be associated with a disease, disorder or medical condition; or
d) for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or
e) for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or
f) for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or
g) for use in connection with a procedure involving venepuncture or delivery of an injection

This Industry Benchmark does not apply to any of the following hand sanitisers:

1. **Products that are 'therapeutic goods'[1],**
2. **Products that are 'excluded goods' complying with the exclusion parameters set out in the *Therapeutic Goods (Excluded Goods – Hand Sanitiser) Determination 2020* (EGD 2020), or**
3. **Rinse-off products i.e. requires rinsing with water after the product is applied.**

Hand sanitisers that are therapeutic goods are regulated by the Therapeutic Goods Administration (TGA): these products must be registered on the Australian Register of Therapeutic Goods (ARTG) and comply with all relevant regulatory requirements as specified by the TGA. Similarly, products that are excluded through the EGD 2020 must meet the specific formulation, use, presentation, advertising and supply requirements detailed in EGD 2020 (but do not require TGA registration).

Hand sanitisers or antibacterial hand wash products that are normally rinsed-off or are required to be rinsed-off are not considered to require a specific benchmark, as they are either low hazard products posing low risk or, if making therapeutic claims, regulated by the TGA.

[1] As defined in the *Therapeutic Goods Act* 1989 (Cth).

Note:
Products within the scope of this Industry Benchmark are regulated as cosmetic products, primarily by the Australian Competition and Consumer Commission (ACCC) for their ingredient labelling, efficacy and safety. The ACCC also prohibits false or misleading representations. The ACCC has a broad range of powers including but not limited to:

- Issuing a **substantiation notice** requiring a person to give information and/or produce documents that could be capable of substantiating or supporting a claim or representation made,
- Issuing an **infringement notice** where it has reasonable grounds to believe that a person has contravened certain consumer protection laws, and
- Issuing a **public warning notice** to alert consumers to a suspected breach of certain provisions of the Australian Consumer Law (ACL).

All ingredients in the product must be disclosed on the label as per the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*.

All ingredients in the product must meet the introduction requirements of the Australian Industrial Chemicals Introduction Scheme (AICIS).

Hand sanitisers must also meet any chemical scheduling controls as detailed in the Poisons Standard and relevant State/Territory poisons regulations unless specifically exempted from labelling and some packaging requirements due to the products being used solely for industrial use. For products solely for industrial use, the workplace hazardous chemicals labelling can be used.

The Excise (Denatured spirits) Determination 2016 (No. 3) prescribes a list of substances required to be used at or above the minimum concentration specified for a sprit to be considered "denatured" for excise tax purposes only. The determination does not take into account any potential public health impacts of the various denaturants, and therefore should not be relied upon as justification of the appropriateness or safety of particular denaturants for use in alcohol-based hand sanitisers.

Under the State/Territory Work Health and Safety (WHS) regulations or Dangerous Goods (DG) Storage and Handling regulations (depending on the State/Territory), a safety data sheet is required for hazardous chemicals and dangerous goods[2].

Products must also meet appropriate regulatory requirements for Trade Measurement and Trade Descriptions.

Any Hand Sanitiser that makes therapeutic claims (as defined under the *Therapeutic Goods Act* 1989 (Cth)), must be registered as a therapeutic good through the TGA, prior to any supply within Australia. Supply of any therapeutic goods which are not registered with the TGA are illegal and non-compliance may attract substantial fines and potential custodial penalties.

[2] For more regulatory information on manufacturing, storage and transport of alcohol-based hand sanitisers, see *"Alcohol-Based Hand Sanitiser Manufacturing and Transport – Information Sheet"*

Definitions

'Antibacterial' means kills or inhibits the growth of bacteria or suppresses the ability of bacteria to reproduce.

'Antiseptic' means a therapeutic good:

a. that is recommended by its manufacturer for:
    i. dermal application; or
    ii. application to the mucous membranes of a person or an animal:
        A. to kill microorganisms; or
        B. to prevent the growth of microorganisms to a level that causes or may cause clinical infection; and
b. that is not represented to be suitable for internal use.

'EDG 2018' means Therapeutic Goods (Excluded Goods) Determination 2018.

'EGD 2020' means Therapeutic Goods (Excluded Goods – Hand Sanitiser) Determination 2020.

'Excluded goods' means goods which might be considered to be therapeutic goods, but which are specifically declared not to be by a determination made by the Secretary of the Department of Health (and therefore not subject to any requirements of the *Therapeutic Goods Act* 1989 (Cth)).

'GHS' means the United Nations Globally Harmonised System of Classification and Labelling of Chemicals.

'Hand sanitiser', for the purposes of this Industry Benchmark, means antibacterial hand preparations that are not normally rinsed-off or are required to be rinsed-off, meeting the exclusion criteria set out in the EGD 2018, Schedule 2, Item 2.

'Label' means a display of printed information:

a. on or attached to the goods; or
b. on or attached to a container or primary pack in which the goods are supplied; or
c. supplied with such a container or pack.

'Microbial' means microorganisms including, but not limited to, bacteria and fungi.

'Poisons Standard' is the legal title of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). It is a Legislative Instrument consisting of decisions regarding the classification of medicines and poisons into Schedules. Scheduling is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison required to protect public health and safety.

'Presentation' means the way in which products are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.

‘Sanitiser’ means an agent that reduces the number of bacterial contaminants.

‘WHO’ means World Health Organization.

‘Young children’ means children aged five years or under.

Safety and Efficacy of hand sanitiser formulations

Safety

Ingredients used in the manufacture of hand sanitisers must be of a suitable grade. The final formulated product must be suitable for frequent dermal application.

> ***Note:***
> The determination of the suitable ingredient grade includes consideration of the impurities present in the ingredient and the risks posed by those impurities in the final product considering its use as a hand sanitiser. Consideration of the suitability of the product for frequent dermal application should also be risk-based and include consideration of the ingredients in the product including the impurity profile and the frequency of use e.g. what is the likely highest frequency of use and is the product safe for use considering that frequency of use.

Efficacy

All hand sanitisers must be efficacious. Product efficacy can be demonstrated in one of two ways:

1. Contains between 60–80% (v/v) alcohol[3]

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 alcohol[4]. The formulation must also contain some water. Other ingredients in the formulation should not significantly degrade the alcohol in the product for the duration of the product's shelf-life.

> ***Note:***
> There is significant evidence, including those compiled in the WHO Guidelines for Hand Hygiene in Healthcare, to support the assumption that a product containing between 60% and 80% alcohol[5] is likely to be efficacious against common bacteria without testing individual formulations.

2. Efficacy testing

The efficacy of hand sanitisers may be demonstrated using appropriate *in vivo* and/or *in vitro* test methodologies.

In vivo test methodologies that may be used include but are not limited to:

- ASTM E2755 - Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults.
- ASTM E2276 - Test Method for Determining the Bacteria-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingerpads of Adults.
- BS EN 1500 - Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements.

[3] Alcohol refers to ethanol, isopropanol, n-propanol or a combination of two or more of these alcohols.
[4] WHO Guidelines on Hand Hygiene in Health Care, 2009
[5] Alcohol refers to ethanol, isopropanol, n-propanol or a combination of two or more of these alcohols.

- EN 12054 - Chemical disinfectants and antiseptics. Products for hygienic and surgical handrub and handwash. Bactericidal activity. Test method and requirements.

The types of in vitro test methodologies that may be used include but are not limited to:

- Time kill study / antibacterial activity test (including suspension tests),
- Carrier test protocol, and
- Germicidal spray test.

Note:
Depending on the test methodology utilised, the acceptable result may be minimum $\log_{10}3$ reduction of bacteria (> 99.9%) on test medium or a 'pass' compared to the test standard e.g. BS EN 1500 require better performance than 60% v/v of the relevant alcohol control.

Product quality management

Premises used for the manufacturing and storage of hand sanitisers must be kept clean and hygienic at all times.

Australian manufacturers and importers must maintain a quality management system for their hand sanitiser operation. Acceptable third-party accredited quality management systems include but are not limited to:

- ISO 9001,
- ISO 13485,
- ISO 22716, and
- *PIC/S Guide to Good Manufacturing Practice for Medicinal Products.*

Note:
The appropriate quality management system will vary depending on the type of operation. For example:

A manufacturing site that manufactures hand sanitisers that are therapeutic goods as well as hand sanitisers that are cosmetic must adhere to the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products* and hold a GMP license.

An importer of fully formulated hand sanitiser may only require an internal quality management system that ensures that the product has been manufactured to the appropriate quality, is safe and efficacious and meets the claims on the label and any other advertising material. This may include appropriate vetting of manufacturer/supplier and an internal or third-party verification process for the imported product.

For manufacturers, it is expected that the quality management system includes processes for verification of raw materials (identity, level of impurities, etc.) used in the manufacturing process as well as testing of final manufactured product to ensure that the final product specifications are met.

Note:
It is expected that all manufacturing sites and warehouses also meet regulatory requirements for safe manufacturing and storage of chemicals. For more regulatory information on manufacturing, storage and

transport of alcohol-based hand sanitisers, see *"Alcohol-Based Hand Sanitiser Manufacturing and Transport – Information Sheet"*

Record keeping

It is the responsibility of the Australian manufacturer or importer to satisfy the quality, safety and efficacy criteria and to keep relevant records to demonstrate these criteria have been met.

Note:
The type and detail of record keeping may vary significantly depending on the business operations.

For example, an Australian manufacturer is expected to keep records relating to the raw materials used in the manufacture of the product (e.g. supplier details, certificate of analysis, quality control records, safety data sheet, etc.) as well as those relating to the hand sanitiser and the manufacturing process (e.g. bill of materials, product specification, stability data, material compatibility, batch testing prior to release for sale, etc.)

An Australian importer with a third-party overseas manufacturer would not be expected to keep records of raw material quality or manufacturing details. However, it is expected that the importer should have ready access to information such as product specification, testing to show that the product meets specification, stability tests, etc.

Where product efficacy is demonstrated using a test methodology, a record of the test result must be kept. Evidence used to support any claims made on the product label or any advertising related to the product must also be recorded.

Where manufacturing is conducted overseas, the Australian operation must be able to access relevant records relating to the hand sanitiser quality, safety and efficacy within a reasonable length of time e.g. two to four weeks.

Record keeping is also an important aspect of a quality management system. All businesses must keep a record of their written standard operating procedures for quality management, as well as evidence that the quality management system is utilised e.g. records specified in the quality management system, internal (and external, if any) audit records, version controls for amendments to the standard operating procedures, etc.

Label and claims

Relating to safety

Hand sanitisers must be packed in a container that:

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

The label should include the following warnings, or words to the following effect:

- 'For external use only' or 'do not swallow';
- 'Discontinue use if skin irritation develops'; and
- 'If ingested, contact the Poisons Information Centre (13 11 26)'[6] or 'If ingested seek immediate medical attention'.

A flammability warning should also be included on the label of alcohol-based hand sanitisers. This may be achieved in one of the following ways:

- in words e.g. 'Flammable' or 'Flammable – keep away from flames' in bold print;
- using the GHS flammable pictogram; or
- using the dangerous goods Class 3 Flammable Liquid hazard label.

Unless the product is supplied solely for industrial use and in a format that cannot be easily removed from premises (e.g. supplied in a refill bag for a dispenser for use in an industrial workplace) the following warning, or words to the effect, should be included on the label:

- 'Keep out of reach of (young) children', '(young) children should not use this product unsupervised', or 'supervise (young) children during use'[7].

> ***Note:***
> When deciding on packaging, labelling or any other presentation aspects of hand sanitisers, care must be taken so that the overall presentation of the product is not mistaken for food or beverage, or appear appealing for ingestion.
>
> Special care must be taken where imagery that may be appealing to children is used. While use by children under adult supervision should be encouraged, the presentation of the product should not encourage misuse by children.

Relating to efficacy

Where the concentration of alcohol is disclosed on the label, it must be accompanied by a unit of measurement, usually % v/v.

[6] The Poisons Information Number in parenthesis is optional.
[7] Words in parenthesis are optional.

Note:
While percentage of volume (= ml/100 ml, abbreviated % v/v) is the most commonly used unit of measurement for the concentration of alcohol, other acceptable measures include percentage of weight (= g/100 g, abbreviated % w/w), or percentage of weight/volume (= g/100 ml, abbreviated % w/v).

The use of terminology such as 'sanitiser' and 'antibacterial' implies efficacy and should be supported by evidence. Log reduction claims e.g. kills '99.9% of bacteria' (a $\log_{10}3$ reduction claim) must not be made unless it can be demonstrated, either through efficacy testing to support the claims or through a weight of evidence approach (literature, similar products, historical evidence, etc.).

Note:
It is expected that if a hand sanitiser with a log reduction claim e.g. 'kills 99.9% of bacteria' is tested in market using an appropriate test methodology reflecting the directions for use of the products, the product would produce the claimed log reduction.

This also means that if efficacy testing is used to demonstrate efficacy, the directions for use should reflect the test criteria that produced the result claimed on the label or any other advertising material.

'Antiseptic' is terminology used for therapeutic goods and should not be used in the presentation of hand sanitisers.

As per the EGD 2018, the hand sanitiser may be advertised or presented for supply as being active against bacteria, but not advertised or presented for supply as being:

a) active against viruses, fungi or other microbial organisms (other than bacteria); or
b) for use in connection with disease, disorders or medical conditions; or
c) active against a named bacterium that is known to be associated with a disease, disorder or medical condition; or
d) for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or
e) for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or
f) for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or
g) for use in connection with a procedure involving venepuncture or delivery of an injection.

Any reference to 'cleaning' must also be substantiated, noting that hand sanitisers do not remove dirt and debris and therefore the only 'cleaning' action performed is the removal of microorganisms.