Australian Government
Department of Health
Therapeutic Goods Administration

OTC medicine monograph: Hand sanitisers

Version 1.0, September 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <https://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines Evaluation /Complementary and OTC Medicines Branch	15/09/2015

Contents

Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of hand sanitisers (hand rubs or hand washes) when applied for as an OTC New Medicine N2 application. Products intended to be used for presurgical hand antisepsis (for disinfection of the hands of theatre staff/surgeons prior to surgery) are not covered by this monograph.

A hand rub is usually formulated as an alcohol-based gel or solution that is intended to be used on hands without the use of water in a hand rubbing procedure.

A hand wash is a detergent-based formulation intended to be used with water in a hand washing procedure.

Proposed medicines must comply with all aspects of the monograph relevant to their strength and dosage form to qualify for evaluation as an N2 application.

This monograph should be read in conjunction with the document Requirements for OTC new medicine N2 applications.

Active substances

This monograph only applies to medicines containing ethanol (CAS No. 64-17-5), isopropyl alcohol (CAS No. 67-63-0), chlorhexidine gluconate (CAS No. 18472-51-0) and triclosan (CAS No. 3380-34-5), either as a single active ingredient product or as a combination of these active ingredients.

Dosage form and strengths

Acceptable dosage forms and strengths are shown in the table below.

Active substance	Dosage forms	Dosage strengths
Ethanol	Lotion, gel or solution formulated as a hand rub	60-95% v/v absolute ethanol
Isopropyl alcohol	Lotion, gel or solution formulated as a hand rub	60-95% v/v
A combination of ethanol and isopropyl alcohol	Lotion, gel or solution formulated as a hand rub	Total alcohol content of 60-95% v/v
Chlorhexidine gluconate	Solution when formulated as a hand wash	1-2% w/v
Combination of ethanol and chlorhexidine gluconate	Lotion, gel or solution formulated as a hand rub	60-95% v/v absolute ethanol with 0.5-2% w/v chlorhexidine gluconate

Active substance	Dosage forms	Dosage strengths
Combination of isopropyl alcohol and chlorhexidine gluconate	Lotion, gel or solution formulated as a hand rub	60-95% v/v isopropyl alcohol with 0.5-2% w/v chlorhexidine gluconate
Triclosan	Solution when formulated as a hand wash	1% w/v

Indications

Therapeutic indications for inclusion in the Australian Register of Therapeutic Goods (ARTG)

For a hand wash preparation, any one or more of the following indications are acceptable, as relevant to the dosage form:

- Antiseptic hand wash
- Hygienic hand wash
- Healthcare personnel antiseptic hand wash

For a hand rub preparation, any one or more of the following indications are acceptable:

- Antiseptic hand rub
- Hygienic hand rub
- Healthcare personnel antiseptic hand rub

Label indications

Any one or more of the following label indications/claims are acceptable, as relevant to the dosage form:

- Antiseptic hand rub/hand wash
- Hygienic hand rub/hand wash
- Healthcare personnel hand rub/hand wash
- Kills germs
- Broad spectrum
- Fast acting (for alcoholic rubs only)

Where the formulation contains excipients such as moisturisers and fragrances, label claims referring to such non-therapeutic attributes are acceptable.

Where the formulation has been tested to meet a particular *in vivo* test, the labels may include a factual statement to the effect that the product meets the requirements of that test.

Hand rubs must not make claims to the effect that the product is suitable for use in food preparation areas or by food handlers. However, claims relating to use by food handlers or in food preparation areas are acceptable for hand wash preparations that require rinsing hands with water.

Directions for use

Directions for use for alcoholic hand rubs should include a statement to the effect that the hands should be washed with soap and water before using the product if the hands are visibly soiled.

The directions for use should be identical to the method of application used when the product was tested for and found to comply with the acceptance criteria specified in the *in vivo* test procedure. For example:

- If a hand wash formulation test involved applying 2mL liquid to wet hands, lathering for 1 minute followed by rinsing, then the directions for use should instruct the user to follow the same procedure*.
- If a hand rub formulation test involved applying 5mL of liquid to the hands, rubbing together and keeping it wet for 30 seconds and allowing it to air dry, then the directions for use should instruct the user to follow the same procedure*.

* **Note:** Since consumers will not be able to measure the volume of the liquid dispensed on their hands, it is recommended that the directions for use either specify the number of pumps that equate to the volume used in testing or alternatively include a direction such as 'deliver sufficient quantity of the liquid to wet the entire hand and to keep it wet for X seconds'.

Labelling

Labelling must comply with all relevant Australian requirements, as detailed in the document Requirements for OTC new medicine N2 applications, including all applicable warning statements.

For all antiseptic preparations containing chlorhexidine gluconate at any concentration, the labels must include the following statements in accordance with the Required Advisory Statements for Medicine Labels:

- Avoid contact with eyes
- If in eyes, rinse well with water
- Mild irritation may occur; stop use if it becomes severe.

In accordance with the labelling requirements of the Poisons Standard, preparations containing more than 1% chlorhexidine must display the following signal word and cautionary statement on the main label:

- The word CAUTION
- The cautionary statement KEEP OUT OF REACH OF CHILDREN

In addition to the above requirements, consult the *Australian Code for the Transport of Dangerous Goods by Road and Rail* for any flammability marking requirement that may apply to alcoholic hand rubs.

Efficacy requirements

The proposed formulation of the product must have been tested to demonstrate satisfactory antimicrobial efficacy by both *in vitro* **and** *in vivo* test methods, as described below. This data should be made available to the TGA if requested.

In vitro tests

In vitro activity of the product must be demonstrated by either of the following *in vitro* tests:

- The European Standard EN13727. This method requires a reduction in viable counts of test organisms (*Escherichia coli* K12 (NCTC 10538), *Pseudomonas aeruginosa* (ATCC 15442), *Enterococcus hirae* (ATCC 10541) and *Staphylococcus aureus* (ATCC 6538)) of ≥ 3 log units under dirty conditions for a hand wash product and ≥ 5 log units under clean conditions for a hand rub product.
- The test method for the evaluation of the effectiveness of an antiseptic hand wash or health-care personnel hand wash described in the FDA Tentative Final Monograph for health-care antiseptic drug products. This method specifies demonstration of *in vitro* activity, using a minimum inhibitory concentration (MIC) test, against a specified range of Gram negative organisms, Gram positive organisms, and yeast organisms. Since the FDA monograph does not specify performance criteria for time-kill testing of health-care antiseptic drug products, antiseptic hand wash and hand rub products are to demonstrate a reduction in viable counts of test organisms that is consistent with EN 13727 requirements (reduction in viable counts of ≥ 5 log units).

In vivo tests

In vivo efficacy must be demonstrated by any of the following methods as relevant:

- The European Standard EN 1499 for hygienic hand washes. This test requires the reduction in transient organisms (*Escherichia coli* K12 (NCTC 10538)) produced by the hand wash to be statistically significantly larger than that produced by a reference hand wash with unmedicated liquid soap.
- The European Standard EN 1500 for hygienic hand rubs. This test requires the reduction in transient organisms (*Escherichia coli* K12 (NCTC 10538)) produced by the hand rub to be not significantly smaller than that produced by a reference hand rub with propran-2-ol 60% v/v.
- The test method for the evaluation of the effectiveness of an antiseptic hand wash/healthcare personnel hand wash described in the FDA Tentative Final Monograph for health-care antiseptic drug products, which is applied to both hand washes and hand rubs. This method is based on ASTM E1174 and uses a glove juice sampling procedure to determine the antimicrobial effectiveness of the hand rub and hand wash products against transient organisms (*Serratia marcescens* (ATCC 14756) or *Escherichia coli* (ATCC 11229)), using ten consecutive hand contaminations/product applications. Products are required to reduce the number of organisms on each hand by ≥ 2 log units within 5 minutes after the first wash and demonstrate a ≥ 3 log reduction on each hand within 5 minutes of the tenth wash.

Quality requirements

In addition to the quality requirements outlined in the document Requirements for OTC new medicine N2 applications, the following specific requirements apply to monograph hand sanitisers.

Finished product specifications

In addition to other requirements specified in the document Requirements for OTC new medicine N2 applications, the finished product specifications must comply, at a minimum, with the relevant set of requirements below.

The medicines must comply with the British Pharmacopoeia, Appendix XVI C. Efficacy of Antimicrobial Preservation or the European Pharmacopoeia, Efficacy of Antimicrobial Preservation.

- Alcoholic hand rubs are deemed to comply with this requirement and are not expected to have been tested for efficacy of antimicrobial preservation during product development.
- Efficacy of antimicrobial preservation of hand wash preparations must have been demonstrated as per Therapeutic Goods Order No 77 Microbiological Standards for Medicines (TGO 77) during product development. However, a preservative efficacy test does not need to be included in the finished product specifications as it is not intended to be used for routine control purposes.

For all preparations, the following tests and limits:

- appearance of the solution
- identification of active ingredient/s
- active ingredient content (90.0-110.0% of the stated amount)
- pH (alcohol based hand-rub preparations that do not contain any excipients other than water are not required to have tests and limits for pH)
- microbiological quality in compliance with TGO 77.

For products containing chlorhexidine gluconate as an active ingredient, the product must also comply with the following test and limit:

- 4-chloroaniline content (not more than 0.3% of the content of chlorhexidine gluconate)

Therapeutic Goods Administration

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