Australian Government
Department of Health
Therapeutic Goods Administration

Guidance on the regulation of exempt disinfectants in Australia

For consultation

December 2018

TGA Health Safety Regulation

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Introduction

This consultation is to seek comments on the consolidation and amendment of TGO 54.

Please note

For the purpose of this consultation version of the guidance, the future Therapeutic Goods Order (TGO) is referred to as **TGO X**. When the new TGO is finalised and assigned a number, this will be updated.

Hospital grade and commercial/household grade disinfectants, including disinfectant wipes and surface sprays must meet the requirements of TGO X.

Sanitisers and sanitary preparations must meet the labelling requirements of TGO X.

Please see TGO X for definitions of these products.

Note

If you have a problem with an exempt disinfectant, please tell us about it here.

It is an offence to import and/or supply therapeutic goods in Australia that do not conform with a standard applicable to the goods (refer sections 14 and 14A of the *Therapeutic Goods Act 1989*).

Related guidance and legislation

The Therapeutic Goods Administration (TGA) is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods. Hard surface disinfectants are regulated by the TGA and form part of the category of therapeutic goods known as 'other therapeutic goods'. The regulatory requirements for the supply of hard surface disinfectants to the public are currently set out in the:

- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods Regulations 1990* (the Regulations)
- Therapeutic Goods Advertising Code*
- Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991
- Therapeutic Goods Order 54: Standards for Disinfectants (TGO 54), and
- Therapeutic Goods Order 37: General Requirements for Labels for Therapeutic Devices (TGO 37).

*The Therapeutic Goods Advertising Code 2015 will be replaced by the Therapeutic Goods Advertising Code (No. 2) 2018 from 1 January 2019.

Regulatory requirements

This guidance does not cover sponsor transfers and/or change of sponsor's name. The requirements related to sponsor transfers are set out to Regulation 10F of the Therapeutic Goods Regulations 1990, and our guidance on Sponsor transfer and change of sponsor name amendments.

You should also ensure that your product(s) (where applicable) meet the requirements under:

- The Poisons Standard (the SUSMP)
- The Australian Dangerous Goods Code

Poisons which are packed and sold solely for industrial, manufacturing, laboratory or dispensary use are exempt from all labelling requirements included in the SUSMP as they are covered by Safe Work Australia's National Code of Practice for the Labelling of Workplace Substances.

Basic requirements

All exempt disinfectants must still meet the regulatory requirements as outlined above. Before you supply your disinfectant, you should ensure that you have the following information available as it may be requested by the TGA at any point in time:

- The intended use of the disinfectant
- A common name and trade name for the product
- Presentation as stated on the label (example, 1 litre, etc.)
- Name and address for all manufacturers involved in the process of producing the disinfectant and the ability to identify which steps in the production each manufacturer is responsible for
- Information relating to the formulation of ingredients including fragrance and colourants
- Microbial efficacy data
- Stability data to the extent that it is available. If you are asked to provide stability data and this information is not complete, you will need to supply preliminary stability data and indicate the protocol to be used for monitoring product performance until a final shelf life determination is made. Your approach will need to be consistent with Schedule 2 of the proposed TGO X.
- Toxicity data, where appropriate.

Note

If your exempt disinfectant(s) makes specific claims, you will need to submit a new application for a listed disinfectant to the TGA, and you may be required to supply the documents (as outlined above) as part of your application.

The term ***specific claims*** applies to virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity, and activity against bacteria other than those consistent with the characteristics of organisms covered by the TGA Disinfectant Test.

Formulation

Ingredients included in the formulation of therapeutic goods supplied in Australia must be identified using the relevant Australian approved names.

Australian approved names (AAN)

The TGA develops and maintains approved terminology to ensure accuracy and consistency of the information about goods both on the Australian Register of Therapeutic Goods (ARTG) and exempt from inclusion on the Register.

Note

You can apply for an Australian Approved Name for a chemical substance at Proposed Australian Approved Name (AAN) application form.

Microbial efficacy

You will need to adhere to the test requirements as set out in TGO X in order to demonstrate microbial efficacy. If requested, you will need to provide all test methodologies and results – a summary will be insufficient. Full test methodologies and results will need to be in English with clear indexing and organisation. A summary of tests and results in English is not acceptable.

Toxicity

Manufacturers must take reasonable steps to ensure their product is safe when used as intended or when accidental contact with the product is made. Toxicity tests on disinfectants used on surfaces should clearly identify any potential hazards to the user through accidental body contact. These hazards must be clearly identified in the labelling and the product information. It is expected that toxicity data will relate to the individual components of a formulation rather than the formulation itself.

Manufacturers should consider the following when determining toxicity of their product:

- Cytotoxicity
- Acute oral toxicity
- Inhalation toxicity
- Skin irritation
- Sensitisation
- Eye irritation
- Haemocompatibility
- Sub-chronic toxicity
- Mutagenicity
- Carcinogenicity
- Environmental toxicity

- Any other known toxicity of an active ingredient or where the basic poisons related safety information suggests other forms of toxicity not mentioned above may be a hazard (e.g. neurotoxicity).

Basic poisons related safety information is required for all disinfectants. Additional information should also be supplied for the following, where applicable:

- **Acute Oral toxicity**: Additional information on acute oral toxicity should be collected unless it can be shown that the disinfectant is unlikely to be used in a way that will cause it to contact the digestive tract. The information should relate to tests conducted at concentrations equivalent to those likely to be encountered in use.
- **Inhalation toxicity, skin irritation, sensitisation and eye irritation**: Additional information on residue tests should be collected unless it can be shown that the disinfectants or their residues are unlikely to come into contact with skin, mucous membrane or eyes. The basic poisons related safety information is that which would satisfy the Poisons Standard or Material Safety Data Sheet (MSDS) requirements of the Worksafe Australia National Code for the labelling of workplace substances.
- **Haemocompatibility, sub-chronic toxicity, mutagenicity and carcinogenicity**: Information is required only if the disinfectant or its residues are likely to come into contact with intact tissue.
- **Environmental toxicity**: Ecotoxicological information should be held for all listable disinfectants, according to the requirements outlined by any relevant state or federal environmental protection legislation. The information provided should be reflected in appropriate handling, storage, transport, use, disposal, waste management and neutralisation instructions. The potential for reuse or recycling should be considered whenever appropriate.

Packaging

The container for a disinfectant must:

- be impervious to and incapable of reacting with its contents
- be sufficiently strong to prevent leakage arising from ordinary risks of handling, storage or transport, and
- have sufficient excess capacity to prevent breakage of the container or leakage of the contents if the contents are likely to expand during handling, storage or transport.

Note

Depending on the ingredients of your product, you may also need to comply with the requirements of the Poisons Standard (the SUSMP) and the Australian Dangerous Goods Code.

Labelling

All listed disinfectants must have labelling in place that includes the following:

- approved name(s) of ingredient(s)
- acceptable common name of the disinfectant (Schedule 3 TGO X)
- quantity/proportions of ingredients(s), and proportion of available chlorine/bromine/iodine if applicable
- quantity of disinfectant
- batch number
- expiry date or use by date
- the AUST L number1
- name and address of the sponsor
- the chemical and physical specifications of the formulation of the product
- clear and adequate instructions for use, including:
  - details on how to prepare the disinfectant and use it to ensure specifications are met, including details on: type of diluent, the required strength, and any limitations on quality, contact time, allowable temperature range, minimum effective concentration and pH range if significant
  - installation instructions (if applicable)
  - limitations of use, including reuse period (if applicable) and managing dilution factor if disinfectant is reused
  - where reuse is provided for, complete information on how to properly monitor the effectiveness of the reused solution (use of test strips), and
  - limitations on storage conditions for stock solutions and activated solution.
- The words:
  - 'Hard surface disinfectant only', and
  - 'Not to be used on skin'.

  For hospital grade, the words:
  - 'Not intended to be used on medical devices or other therapeutic goods'.

[1] Disinfectant products transitioning from Registered to Listed will change from an AUST R number to an AUST L number. A transition period of 12 months to 31 January 2020 is proposed, to enable sponsors to consume current packaging stocks.

Supporting information

You will need to retain the following information in case it is requested by the Secretary or their delegate:

- Labels
- Packaging (a simple characterisation or pictorial images of the container used should be provided for products subject to evaluation. Mention should be made of any unusual features and of those provided to comply with the SUSMP or elsewhere)
- Test Certificates to support new ingredients or specific claims, for each batch of disinfectants prior to supply in Australia. Specific claims are claims the manufacturer wishes to make for organisms that are not consistent with the characteristics of organisms covered by the TGA Disinfectant Test as outlined in TGO X.
- Formulation of stock disinfectant and for any dilutions or activated compounds specified on the labelling, and
- The chemical and physical specifications for the formulation.

Note

Evidence to demonstrate compliance with (*the proposed*) TGO X must be held by the manufacturer or sponsor for examination on request in the event of a problem arising with the product or as part of a routine compliance evaluation. This guidance is relevant only in so far as there is a requirement to be met in the proposed TGO X.

Post market – ongoing responsibilities

Your disinfectant must continue to meet all the regulatory requirements as set out in TGO X for as long as you continue to supply within Australia.

When requested by the TGA, sponsors of exempt disinfectants should provide:

- information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect
- information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective.

Note

It is also recommended that sponsors report adverse events Report a medical device adverse event (sponsor/manufacturer).

Version history

Version	Description of change	Author	Effective date
V1.0	Consultation version	Therapeutic Goods Administration, Medical Devices Branch	18/12/2018

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication # D18-11338791