Australian Government
Department of Health
Therapeutic Goods Administration

Guidance on the regulation of exempt disinfectants in Australia

Version 1.3, May 2021

TGA Health Safety Regulation

The purpose of this guidance is to help sponsors understand how the TGA interprets regulations, and thus indicate how a sponsor can comply.

This is a guide only, and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

Contents

Introduction

An overview of how products commonly known as disinfectants and sterilants are defined and regulated can be found on the TGA website. The following guidance relates to products that meet the definition of an exempt disinfectant. Exempt disinfectants are not required to be included in the Australian Register of Therapeutic Goods (ARTG) before they are supplied, but must **still meet all regulatory requirements** as set out in the following legislation:

- *Therapeutic Goods Act 1989* (the Act);
- Therapeutic Goods Regulations 1990 (the Regulations);
- Therapeutic Goods Advertising Code (No.2) 2018;
- Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991; and
- Therapeutic Goods (Standard for Disinfectants and Sanitary Products (TGO 104) Order 2019 and TGA Instructions for Disinfectants.

Depending on the ingredients of your product, you should also ensure that your disinfectant product meets the requirements under:

- The Poisons Standard (the SUSMP) and
- 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 Labelling of workplace hazardous chemicals — Code of Practice.

Note

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

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*).

The following guidance contains information about:

- basic requirements
- formulation
- packaging requirements
- labelling requirements
- post-market – ongoing responsibilities.

Basic requirements

All exempt disinfectants must meet all 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 (see below).
- Microbial efficacy data.
- Stability data to the extent that it is available.
- Toxicity data, where appropriate.

Formulation

Ingredients included in the formulation of therapeutic goods supplied in Australia must be identified using the relevant Australian Approved Names (AANs).

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.

These approved terms must be used to identify ingredients in your listed disinfectant:

- On labels and packaging for therapeutic goods; and
- Product Information documents provided with the goods.

Note

You can apply for an AAN for a chemical substance by completing and submitting a Proposed Australian Approved Name (AAN) application form, available on the TGA website.

Proprietary ingredients

Proprietary ingredients are entered into the TGA Business System (TBS) by the TGA, using details submitted by the supplier of the ingredient or by a medicine sponsor (on behalf of the supplier) using the Notification of a new proprietary ingredient form. This allows for the capture of complex formulation details and other relevant information, and the provision of a unique name and number. Sponsors may select proprietary ingredients using the assigned ingredient ID number for use in their application for a listed disinfectant.

Proprietary ingredient formulations for disinfectants are usually fragrances or colouring ingredients and are considered to be “commercial-in-confidence”.

Microbial efficacy

You will need to adhere to the test requirements as set out in the TGA Instructions for Disinfectant Testing 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.

Note

Testing as described above may not be applicable to automated airborne disinfectant technologies. These include hydrogen peroxide vapour, hydrogen peroxide + peracetic acid fogging.

Toxicity

Manufacturers must take reasonable steps to ensure the disinfectant product is safe when used as intended, or if there is accidental contact with the product.

There is no expectation that studies will need to be initiated to assemble the necessary data. While a new study might be needed for a new chemical entity, it is expected that this section can be satisfied with information available through a competent search of the available literature and/or databases.

The TGA will accept information generated for other regulatory agencies. It is understood that most available toxicity data will be in relation to the individual components of a formulation rather than the formulation itself.

Toxicity tests on disinfectants used on surfaces should clearly identify any potential hazards of the formulation and risks to the user, through either intended use or accidental body contact. These hazards and risks must be clearly identified on labels and in product information.

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

- Acute oral toxicity
- Inhalation toxicity
- Skin irritation
- Sensitisation
- Eye irritation
- 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. The basic poisons-related safety information is that which would satisfy the Poisons Standard or Safety Data Sheet requirements of
  - Safe Work Australia's *Model Code of Practice: Labelling of workplace hazardous chemicals*.

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 Safe Work Australia's *Model Code of Practice: Labelling of workplace hazardous chemicals*.

- **Environmental toxicity:** Ecotoxicological information should be held for all 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.

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.

Packaging requirements

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.

Labelling requirements

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

- approved name(s) of all ingredient(s) that are active against pathogenic or food spoilage micro-organisms;
- acceptable common name of the Disinfectant (Schedule 1 TGO 104);
- quantity/proportions of ingredients(s) which result or contribute to the disinfectant action, and proportion of available chlorine/bromine/iodine if applicable (expressed as either % w/w, %w/v, % m/m, % m/v or % v/v);
- quantity of disinfectant;
- batch number;
- expiry date or use by date;
- name and address of the manufacturer or sponsor;
- 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.
- For a disinfectant that contains chlorhexidine, the words:
  - "Not to be used on skin".

Note

Household grade disinfectants and commercial grade disinfectants *must not* be labelled "hospital grade" or use words implying that they are hospital grade.

Labelling must comply with the requirements of the Poisons Standard (SUSMP).

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 *Model Code of Practice: Labelling of workplace hazardous chemicals*.

Post-market – ongoing responsibilities

Your disinfectant must continue to meet all regulatory requirements for as long as you continue to supply within Australia.

Note

Sponsors of disinfectants should report adverse events relating to your disinfectant product at Report a medical device adverse event (sponsor/manufacturer).

You will need to retain the following information in case it is requested by the TGA:

- 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 efficacy claims in accordance with the TGA Instructions for Disinfectant Testing.
- Formulation of stock disinfectant and for any dilutions or activated compounds specified on the labelling.
- The chemical and physical specifications for the formulation.

Note

Evidence to demonstrate compliance with regulatory requirements 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.

Advertising

Advertising for disinfectants (including the label) must comply with all applicable therapeutic goods advertising requirements. These include:

- If the disinfectant is not included in the ARTG and it is not exempt from the requirement to be included in the ARTG, it cannot be advertised to the public (subsection 42DL (12) of the Act). Claims to be able to supply such a disinfectant to any party are also prohibited (subsection 22(6) of the Act).
- Disinfectants included in the ARTG can only be promoted for those purposes included in the ARTG and (where relevant) the label. The promotion of 'off-label' use to any audience is prohibited (subsections 22(2) to (5) of the Act).
- Advertising to the public for disinfectants must comply with the Therapeutic Goods Advertising Code (the Code).
  - Note there are particular requirements for 'other therapeutic goods' (which includes disinfectants) in sections 12 and 13 of the Code, which prescribe the mandatory information that must appear in advertising.
  - Disinfectant advertising to the public must comply with all other relevant provisions of the Code.
- Before advertising disinfectants to consumers, you should check to see if your advertising material (for example, posters, media and social media advertising) contains restricted and/or prohibited representations, as defined in the Code.
  - If it does, you will need prior approval or permission from the TGA. Refer to the Australian Regulatory Guidelines on Advertising Therapeutic Goods.
  - There is no application process for prohibited representations on labelling, as labelling is reviewed by the TGA as part of your application to list a product on the ARTG.
  - If you believe there is a need for a prohibited representation to be used in the advertising (other than the label) of your disinfectant, please contact TGA.Advertising@tga.gov.au for further advice.
  - Note the TGA has already permitted the use of certain restricted and prohibited representations in relation to labelling for disinfectants – see restricted and prohibited representations for disinfectants.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	July 2019
V1.1	Replaced references to Safe Work Australia's *National Code of Practice for the Labelling of Workplace Substances [NOHSC: 2012(1994)]* with Safe Work Australia's *Model Code of Practice: Labelling of workplace hazardous chemicals*	Therapeutic Goods Administration	April 2020
V1.2	Changes to reflect the requirement for advertising pre-approval in specified media ending on 30 June 2020	Therapeutic Goods Administration	July 2020
V1.3	Minor updates	Therapeutic Goods Administration	May 2021

Therapeutic Goods Administration

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Reference/Publication #