Australian Government
Department of Health
Therapeutic Goods Administration

Regulation of borderline disinfectant and related products with antiviral claims including COVID-19

Information for sponsors and manufacturers

Version 1.0, August 2021

TGA Health Safety Regulation

The purpose of this guidance is to help sponsors and manufacturers comply with the requirements of the therapeutic goods legislation.

This is a guide only, and sponsors and manufacturers 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 and/or manufacturer 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.

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About this guidance

The following guidance aims to assist sponsors and manufacturers in understanding the regulation of borderline disinfectant and related products with antiviral claims (including COVID-19) to determine their regulatory obligations.

The guidance covers a range of borderline products and contains some specific examples to provide clarity on regulation by the TGA.

Background

Due to the COVID-19 pandemic, there has been significant interest from potential sponsors and manufacturers on whether claims made to remove, kill or reduce viruses (such as the virus that causes COVID-19) are permitted under therapeutic goods legislation. Also, whether such claims would render a product a therapeutic good requiring inclusion in the Australian Register of Therapeutic Goods (the ARTG) prior to its importation and/or supply in Australia.

In general, the intended purpose and claims made for a product will determine the type of good and the relevant regulatory requirements the product must comply with. As a general rule, a product that has a therapeutic claim is a therapeutic good.

Advertising requirements

There are laws governing the types of claims that can be made in advertisements for therapeutic goods, including claims that relate to viruses such as COVID-19. For example, claims relating to the advertised good having a virucidal effect are either ‘restricted’ or ‘prohibited’ representations under the *Therapeutic Goods Act 1989*, which must not be used in advertisements to consumers unless approved or permitted by the TGA.

Further information about restricted representations is on the TGA website at: https://www.tga.gov.au/restricted-representations

Enquires about advertising can be made through the portal on the TGA website at: https://compliance.tga.gov.au/advertising-enquiry/

Disinfectants

A disinfectant is defined in the *Therapeutic Goods Regulations 1990* as a substance:

(a) that is recommended by its manufacturer for application to an inanimate object to kill microorganisms; and

(b) that is not represented by the manufacturer to be suitable for internal use.

Disinfectants have multiple mechanisms of action or ways of killing microorganisms, which include cross-linking, coagulating and clumping of proteins, structure and function disruption (cell wall and internal structures) and oxidation. Disinfectants can be chemically complex and modes of action for some of these compounds are not always fully elucidated.

Please note

Products that are intended for use on human skin for antisepsis do not meet the definition of a disinfectant and may instead be regulated as antiseptic skin products. For guidance about the process and data requirements for the registration of skin antiseptics, the Complementary and Over the Counter Medicines Branch can be contacted by email at: OTC.Medicines@health.gov.au

Examples - Disinfectants

Example 1

Emily is manufacturing sponges for cleaning kitchen benches. The sponges absorb liquid and do not make claims in relation to killing any microorganisms. **The sponges are general consumer goods and are not regulated by the TGA.**

Example 2

Bert wishes to manufacture wipes for cleaning to disinfect surface areas. Bert will claim that his wipes disinfect an area and can kill the virus that causes COVID-19 on that surface. **The wipes are disinfectants and will need to be included in the ARTG as a listed disinfectant prior to their importation or supply in Australia.**

Disinfectant regulation

Disinfectants are regulated as either an Other Therapeutic Good (OTG) or a Class IIb medical device, depending on the intended purpose of the product as discerned from the claims made in the instructions for use, labelling and promotional material.

An overview of how products commonly known as disinfectants and sterilants are defined and regulated, including relevant legislation, can be found at https://www.tga.gov.au/disinfectants-sterilants-and-sanitary-products.

Disinfectant products will also need to meet requirements under:

- The Poisons Standard (the SUSMP) and
- The Australian Dangerous Goods Code (link is external).
- The Therapeutic Goods Advertising Code (link is external).

Poisons that are packaged and supplied solely for industrial, manufacturing, laboratory or dispensary use and labelled in accordance with requirements under applicable work health and safety laws in the states and territories are exempt from all labelling requirements included in the SUSMP. Please see Safe Work Australia's Model Code of Practice: Labelling of workplace hazardous chemicals.

Please note

The TGA does not regulate disinfectants or sanitisers registered under the Agricultural and Veterinary Chemicals Code Act 1994 for which no claim or representation for disinfectant use is made, other than an agricultural or veterinary chemical use for which the disinfectant is registered under that Act.

There are special rules relating to the advertising of disinfectants that are registered, listed or included on the ARTG. In certain circumstances, claims in relation to viruses may be made for disinfectants. For further information, see *Therapeutic Goods (Prohibited Representations – Disinfectants) (COVID-19) Permission 2020*.

Different types of disinfectants

Medical device – disinfectants

Disinfecting and cleaning liquids, sprays, wipes and aerosols that are intended to be **used on medical devices** are regulated as medical devices in Australia. These products must be included in the ARTG as a medical device prior to importation or supply. Medical devices are classified according to the level of risk. The classification rules for medical devices are prescribed in Schedule 2 and Schedule 2A to the *Therapeutic Goods (Medical Devices) Regulations 2002.* Some examples are outlined below:

Cleaners intended to be used on medical devices that do not claim to be a medical device disinfectant or sterilant are regulated as **Class I medical devices**.

Liquids, sprays, wipes and aerosols intended to be used on medical devices that make disinfectant or sterilant claims are regulated as **Class IIb medical devices**.

Medical device cleaners and disinfectants must be included in the ARTG prior to importation or supply in Australia.

For comprehensive guidance to assist with making an application to include the medical device in the ARTG, please see www.tga.gov.au/publication/medical-device-inclusion-process.

Please note

Any product that claims to disinfect or clean a medical device, is regulated as a medical device and is not considered to be an OTG.

Other therapeutic good (OTG) – listed disinfectants

Listed disinfectants are disinfectant liquids, sprays, wipes, sponges and aerosols that make **specific claims** that a product kills, or is active against, viruses, spores, tuberculosis, mycobacteria or fungi and that:

- are intended for use on inanimate objects such as hard and soft surfaces (for example floors, walls, door handles, bench tops, curtains, lounge furniture and carpets)
- are not intended for use internally or on skin
- are not intended for use on medical devices.

Specific claims include claims to kill or reduce the COVID-19 virus, or to provide residual protection from the COVID-19 virus.

For further information on specific claims, please refer to https://www.tga.gov.au/publication/disinfectant-claim-guide-specific-claims-and-non-specific-claims

Listed disinfectants are required to be included in the ARTG prior to importation or supply in Australia, and must meet all regulatory requirements for listed disinfectants, including compliance with the *Therapeutic Goods* (*Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019*, available at https://www.legislation.gov.au/Details/F2021C00008

For further guidance on the regulation of listed disinfectants in Australia, please refer to https://www.tga.gov.au/publication/guidance-regulation-listed-disinfectants-australia.

Examples – Listed Disinfectants

Example 1

Ivan wishes to manufacture cleaning sprays. The sprays are for cleaning around a house and removing dust from surfaces. The sprays do not claim to kill any viruses, spores, tuberculosis, mycobacteria fungi, or other microorganisms. **The sprays are general consumer goods not regulated by the TGA and are not eligible for inclusion in the ARTG.**

Example 2

Sarah wishes to manufacture a liquid to be used in a hospital setting to clean benches. The liquid claims to kill the virus that causes COVID-19 that it comes into contact with. **This liquid is a disinfectant and must be included in the ARTG as a listed disinfectant before it can be imported or supplied in Australia.**

Other therapeutic good (OTG) – exempt disinfectants

Exempt disinfectants are liquids, sprays, wipes, sponges and aerosols that are intended to kill microorganisms but **do not make claims** that the product kills, or is active against, viruses, spores, tuberculosis, mycobacteria or fungi and that:

- are intended for use on inanimate objects such as hard and soft surfaces (for example floors, walls, door handles, bench tops, curtains, lounge furniture and carpets)
- are not intended for use internally or on skin
- are not intended for use on medical devices.

Disinfectants that do not make specific claims relating to viruses, spores, tuberculosis, mycobacteria or fungi are exempt from the requirement to be included in the ARTG prior to importation and supply in Australia. However, exempt disinfectants must still comply with other relevant regulatory requirements such as the *Therapeutic Goods* (*Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019*, and the Therapeutic Goods Advertising Code.

For further guidance on the regulation of exempt disinfectants in Australia, please refer to https://www.tga.gov.au/publication/guidance-regulation-exempt-disinfectants-australia.

Examples – Exempt Disinfectants

Example 1

Jay wishes to manufacture wipes for general purpose cleaning of surface areas. The wipes only claim to kill 99.9% of germs, with no other claims of being effective against other specific microorganisms. **The wipes are exempt disinfectants and are not required to be included in the ARTG prior to importation or supply. However, they must still comply with the regulatory requirements such as the *Therapeutic Goods* (*Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019*, and the Therapeutic Goods Advertising Code.**

Example 2

Josh is manufacturing aerosol sprays. The sprays will be used to clean and disinfect surface areas. Josh will be claiming that his sprays can kill certain organisms such as the influenza type A viruses on that surface. **The spray is a listed disinfectant and must be included in the ARTG prior to importation or supply.**

Excluded goods (including sanitation and environmental control equipment)

A range of products are excluded from regulation under the therapeutic goods framework. While these products may be required to meet relevant legislative requirements under consumer or other legislation, they are not required to meet any of the legislative requirements regulated by the TGA.

The *Therapeutic Goods (Excluded Goods) Determination 2018* (the Determination) specifies goods that are not regulated by the TGA. According to Schedule 1 of the Determination, the following relevant goods are excluded goods:

- disinfectant and sterilant gases
- disinfectants or sanitisers that are represented to be for the treatment of water only
- sanitation, environmental control and environmental detoxification equipment (including films and coatings), other than articles specified in item 3 of Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*.

Products that fall within Schedule 1 to the Determination are excluded from the operation of the *Therapeutic Goods Act 1989* irrespective of the manner in which those goods are advertised or presented for supply.

A number of products that are used to sanitise the environment, which do not meet the definition of a disinfectant, are considered to be excluded goods under Schedule 1 of the Determination. Such products generally have claims relating to air or environmental sanitation, and **do not make claims in connection with treating a person or having a direct influence in or on the human body**. Examples of sanitation, environmental control and environmental detoxification equipment include:

- air sanitisers and deodorisers (e.g. ozone)
- machinery including robotic equipment and drones for dispensing disinfectant
- UV lights/systems for the sanitation or disinfection of a built environment, such as a room
- antimicrobial articles such as copper tape, sanitizing film, paints and other coatings applied to inanimate surfaces such as door handles
- laundry detergents that clean by mechanical action
- clothing, towels, bedsheets and other items for sanitation purposes that are claimed to have general antiviral properties and do not make claims relating to COVID-19

Examples – Excluded goods

Example 1

Mia is manufacturing air sanitisers that filter and cleanse the air. Mia claims the sanitisers will remove pollen and common allergens. **The sanitisers are sanitation/environmental control equipment and are not required to be included in the ARTG prior to importation or supply.**

Example 2

Marvin is manufacturing sanitation film that has been impregnated with antimicrobial copper. The films can be applied to door handles, public railings in shopping malls and elevator buttons. **These are sanitation/environmental control equipment and are not required to be included in the ARTG prior to importation or supply.**

Example 3

Sophie is manufacturing air sanitisers that filter and cleanse the air. Sophie claims that her air sanitisers can produce special air particles that will alleviate asthma and other lung conditions when ingested. **These are not considered sanitation/environmental control equipment because they are designed to have an effect in the human body. The sanitisers are medical devices and are required to be included in the ARTG prior to importation or supply.**

Please note

Liquid disinfectants with specific claims that the disinfectant is dispensed through automated airborne systems or fogging applications are not excluded goods and must therefore be included in the ARTG (as a listed disinfectant or medical device disinfectant)

Regulatory approach to borderline disinfectants and related products

The following product categories are representative examples of products for which the TGA has received numerous enquiries in recent months about the regulatory requirements.

General cleaners

General cleaners that do not make therapeutic claims (including disinfectant claims) are considered to be general consumer goods and are not regulated by the TGA. For cleaners that meet the definition of a disinfectant, please refer to the section on disinfectants.

Regulatory approach: Not regulated by the TGA

Products that are not regulated by the TGA do not require inclusion in the ARTG. However, these products remain subject to the *Competition and Consumer Act 2010*, which is administered by the Australian Competition and Consumer Commission. Among other things, manufacturers and suppliers must ensure that any advertising does not mislead or deceive the public.

Examples – General cleaners

Example 1

Sarah is manufacturing general-purpose surface cleaning solutions such as carpet cleaners, hardwood floor cleaners, and window cleaning solutions. The products do not make any disinfectant claims (or other therapeutic claims) and are only intended for general cleaning. **The products are not regulated by the TGA and are not required to be included in the ARTG prior to importation or supply.**

Detergents

Detergents used for applications such as laundry, dishwashing, or washing fruits and vegetables, typically cleanse by mechanical action to remove dirt and microorganisms.

The active cleaning agents in these detergents are generally surfactants and their mechanism of action is to disrupt the bonding of water molecules, enabling the wetting of the surface and the loosening and removal of soil.

These products are considered distinct from disinfectants as the main function is cleaning, which can occur by mechanical action but also via other mechanisms, such as emulsification, saponification and enzymatic action. As such, these products are not characterised as disinfectants as the active agent is not producing a microbiocidal effect.

For detergents that meet the definition of a disinfectant, please refer to the section on disinfectants.

Regulatory approach: Excluded good (sanitation/environmental control equipment)

Examples – Detergents

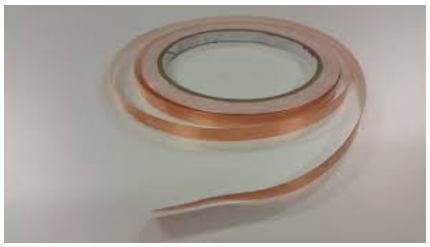
Example 1

Karen is manufacturing laundry detergents for cleaning clothes. As the cleansing action is via mechanical action, Karen is careful not to market her detergent as a disinfectant. **Her detergents are not required to be included in the ARTG prior to importation or supply.**

Example 2

Matthew is manufacturing laundry disinfectants that can be added to laundry detergents for cleaning clothes. The laundry disinfectant claims to kill viruses, including the virus that causes COVID-19. **This liquid is a disinfectant and must be included in the ARTG as a listed disinfectant before it can be imported or supplied in Australia.**

Surface modifying coatings



Surface modifying coatings are typically applied to goods to provide a protective barrier. These coatings are generally slow acting because the antimicrobial action often requires a considerable time to become effective. The primary aim of the coating is to kill or provide protection against microorganisms that come into contact with the coating. The antimicrobial effect is often long lasting.

Examples of surface modifying coating products include

- sanitizing film (for application to non-medical products such as door knobs, railings etc.)
- antimicrobial copper tape
- liquid / spray applications to textiles, paints etc.
- anti-viral alloy metal coatings.

Some of these products are used in the production of finished goods rather than being finished goods themselves.

The mechanism of action for such products varies greatly. Some are described as anti-adhesive while others are stated to be contact active (releasing biocide as the surface). This is a fast developing area and products relying on other mechanisms of action may become available in the future.

With the exception of biocide release, the mechanisms of action are different from those usually found for liquid disinfectant products and the exposure times can be significantly prolonged. It is therefore not appropriate for such products to be regulated as disinfectants.

Such products are generally characterised as

- ‘surface modifying coatings’
- ‘protective barriers, films or coatings’
- ‘surface treatments’.

Regulatory approach: Excluded goods (sanitation / environmental control equipment)

Examples – Surface modifying coatings

Example 1

Linda is manufacturing an antimicrobial solution for application to textiles and paints to create end products that kill microorganisms that come into contact with the textile or paint. **The solution is considered to be a component of a finished product and is therefore not required to be separately included in the ARTG prior to its importation or supply.**

Example 2

Raphael is manufacturing sanitation film that has been impregnated with antimicrobial copper. The film can be applied to public railings in shopping malls and elevator buttons. **The film is considered to be sanitation/environmental control equipment and is not required to be included in the ARTG prior to importation or supply.**

Products that are excluded from our regulations will remain subject to the *Competition and Consumer Act 2010*, which is administered by the Australian Competition and Consumer Commission. Among other things, manufacturers and suppliers must ensure that any advertising will not mislead or deceive the public

End products with surface modifying coatings

The regulatory approach to products with surface modifying coating applied to it will depend on the intended purpose of the product and claims made.

The following table provides non-exhaustive examples:

Item to which surface modifying coating is applied	Regulatory approach
Public infrastructure (e.g. railings, elevator buttons)	Excluded good (sanitation/environmental control equipment)
Furniture (e.g. sofas, tables)	Excluded good (sanitation/environmental control equipment)
Room furnishings (e.g. curtains, carpet)	Excluded good (sanitation/environmental control equipment)
Bedding, clothing towels and other articles made principally of fabric that are intended to be used primarily on or in close contact with the human body; and are represented expressly to be effective against the virus that causes COVID-19	Medical device (item 3 of Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*). These articles for personal use are specified to be medical devices in order to clarify that when claimed to be effective against COVID-19, which is a severe and immediate threat to human health, they are not considered to be sanitation/environmental control equipment. Similar fabric articles in respect of which general antiviral claims are made (as opposed to express references to the SARS-Cov-2 virus or COVID-19) will continue to not be regulated as therapeutic goods, unless the articles are clothing/apparel.
Clothing represented to be used for the prevention of the transmission of disease between persons (e.g. jackets with antiviral fabric treatment, with claims of antiviral protection)	Medical device (item 1 of Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*). Articles that are non-sterile personal protective equipment or safety apparel intended, by the person under whose name the articles are or are to be supplied, to be used for the prevention of the transmission of disease between persons, including where that intention may be ascertained from the articles being represented as suitable for use in surgery, or clinical, medical or other health services, are specified to be medical devices.

There are restrictions on the advertising of articles that are represented expressly to be effective against the virus which causes COVID-19 (e.g. clothing, towels, bedsheets). Representations which refer to COVID-19 are 'restricted representations' under the *Therapeutic Goods Act 1989*, and must not be used in advertisements to consumers unless approved or permitted by the TGA. There are stringent legislative requirements that must be satisfied prior to the TGA granting approval or permission to use restricted representations. For example, express or implied claims about COVID-19 would need to be substantiated by appropriate evidence.

Examples – End products with surface modifying coatings

Example 1

Jessica is manufacturing shirts and jackets using textiles that have antimicrobial properties. Jessica wants to market her shirts and jackets to be used for preventing the transmission of disease between people. **The goods are specified to be medical devices under the *Therapeutic Goods Act 1989*. These goods will need to be included in the ARTG prior to importation or supply.**

Example 2

Tobias is a furniture manufacturer and manufactures sofas, dining tables, and chairs. His products have been surface treated to be effective against the SARS-CoV-2 virus. **These products are sanitation/environmental control equipment and are not required to be included in the ARTG prior to importation or supply.**

Please note

Non-sterile PPE or safety apparel (including but not limited to aprons, face masks, gloves, goggles, gowns and visors) that is not presented to be, or claimed to be, for use for the prevention of transmission of disease between persons is not a therapeutic good and does not require inclusion in the ARTG. For further guidance, please refer to https://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19

Skin antiseptic products (e.g. hand sanitisers)

Unless excluded, antiseptic products for use on the skin are regulated as therapeutic goods and must be included in the ARTG prior to importation or supply in Australia. Antiseptic products for use on the skin that claim to kill specific organisms or that are for use in health care settings such as clinics or hospitals are regulated as registered over-the-counter (OTC) medicines. Guidance and legislation governing over-the-counter medicines can be accessed at OTC medicines regulation basics

Examples of skin antiseptic products regulated as OTC medicines include antiseptic hand washes/rubs used in GP clinics and hospital wards; surgical hand antiseptics used by health professionals; and pre-surgical antiseptics that are used on patients' skin prior to surgery.

Hand sanitisers are excluded from TGA regulation and regulated as consumer goods ('cosmetics') if:

- They contain only low-risk ingredients (i.e. does not contain a substance included in Schedule 2,3,4 or 8 of the Poisons Standard, the claims are limited to low level activity against bacteria (e.g. kills 99.9% of bacteria) and they are not for use in health care settings; or
- They meet the formulation, manufacturing, labelling, presentation and advertising requirements specified in the *Therapeutic Goods (Excluded Goods – Hand Sanitisers) Determination 2020*.

Please refer to Hand sanitisers: Information for manufacturers, suppliers and advertisers for more information about antibacterial skin care products (hand sanitisers) that are excluded goods and therefore regulated as general consumer products (cosmetics).

Regulatory approach: OTC medicines

Examples – Skin antiseptic products

Example 1

Xavier is manufacturing antiseptic hand rubs for use in doctor's surgeries. The products are marketed to health professionals as being effective against a specific organism, *Escherichia coli*. **These products are regulated as OTC medicines and will need to be included in the ARTG prior to importation or supply.**

Example 2

Ella is also manufacturing antiseptic hand rubs for use in doctor's surgeries. However, the products are not marketed as being effective against specific organisms and the products comply with all requirements of the *Therapeutic Goods (Excluded Goods – Hand Sanitisers) Determination 2020*. **These products are not regulated as therapeutic goods and are not required to be included in the ARTG prior to importation or supply. These products are subject to the *Competition and Consumer Act 2010*, which is administered by the Australian Competition and Consumer Commission.**

Version	Description of change	Author	Effective date

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Authorisation Branch	August 2021

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Reference/Publication # D21-2071473