



Factsheet: Cosmetics and therapeutics

Introduction

The Australian Government has banned the use of animals for cosmetic testing. The ban does not apply to the use of animals for testing of therapeutics.

This document is intended to provide information about the types of products that are considered to be cosmetic products and therapeutic products.

Information in this document has been sourced from the websites of the Australian Industrial Chemical Introduction Scheme and the Therapeutic Goods Administration (as at 22 April 2021). The information may be updated from time to time, and readers are referred to these websites for current information (see Table 1).

Table 1: Relevant websites

Organisation	Website URL
Australian Industrial Chemical Introduction Scheme, Commonwealth Department of Health	https://www.industrialchemicals.gov.au/cosmetics-and-soap/cosmetics-and-therapeutics
Therapeutic Goods Administration, Commonwealth Department of Health: Cosmetics	https://www.tga.gov.au/cosmetics
Therapeutic Goods Administration, Commonwealth Department of Health: Therapeutics	https://www.tga.gov.au/sme-assist/my-product-therapeutic-good
Therapeutic Goods Administration, Commonwealth Department of Health: Australian regulatory guidelines for sunscreens (ARGS) (Version 1.2)	https://www.tga.gov.au/publication/australian-regulatory-guidelines-sunscreens-args

Products are determined to be either 'cosmetics' or 'therapeutic goods' based on three factors:

- the primary use of the product
- the ingredients in the product
- the claims made about the product.

The Australian Industrial Chemical Introduction Scheme (AICIS) regulates chemicals that are imported or manufactured for an 'industrial' use – including the ingredients in cosmetics.

The Therapeutic Goods Administration (TGA) regulates medicines and products that are marketed as having a 'therapeutic' effect – including most skin-whitening lotions, primary sunscreens, disinfectants, complementary medicines and blood products.

Cosmetics

A cosmetic product is a substance designed to be used on any external part of the body – or inside the mouth – to change its odour or appearance, cleanse it, keep it in good condition or protect it.

Examples of cosmetic products are provided in Table 2.

Table 2: Examples of cosmetic products

Group	Examples
Face and nail	<ul style="list-style-type: none"> Lipstick and lip balms with SPF sunscreen that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018 Nail care products including nail hardeners and products to deter nail biting Make-up such as mascara, eyeshadow, primer and bronzer Nail polish and varnish Tinted bases and foundation without SPF sunscreen, including liquids, pastes and powders Make-up removers Lipstick and lip balms without SPF sunscreen Face masks and scrubs
Hair care and hairdressing products	<ul style="list-style-type: none"> Anti-dandruff hair care products that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018 Hair tints, hair dyes and bleaches Products for waving, straightening and fixing hair Hair-setting products such as gels, sprays and lotions Shampoo and hair-cleansing products, including lotions and powders Hair conditioner Hairdressing products such as lotions, lacquers and brilliantines
Oral and dental hygiene	<ul style="list-style-type: none"> Toothpaste and gel Denture cleansers and adhesives Some dental bleaches and whiteners Desensitising toothpastes and gels are not cosmetics. They are therapeutics and are regulated by the TGA.
Perfumes	<ul style="list-style-type: none"> Perfumes and colognes Eau de toilette Eau de colognes Eau de parfum
Personal hygiene	<ul style="list-style-type: none"> Feminine hygiene products such as intimate cleaners, deodorants, wash, powder, moisturisers and gels. Deodorants Cleansers, including soap, deodorant, astringent and skin washes Shaving products, such as creams, foams and lotions Bath and shower preparations, such as salts, foams, oils and gels Depilatories After-bath powders Hygienic powders

Group	Examples
Skin care	<ul style="list-style-type: none"> • Secondary sunscreen products that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018 • Anti-acne skin care products that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018 • Skin moisturisers without SPF sunscreen such as creams, lotions, gels and foams • Sunbathing products without SPF sunscreen or with SPF sunscreen • Emollients such as creams, emulsions, lotions, gels and oils for the skin • Products for tanning without sun (without SPF sunscreen) • Some skin-whitening products (without SPF sunscreen) • Anti-wrinkle products (without SPF sunscreen) • Anti-ageing products (without SPF sunscreen)

Therapeutics

A therapeutic good is a product for therapeutic use; that is, they are intended to be used for human health. Therapeutic use means use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- influencing, inhibiting or modifying a physiological process in persons; or
- testing the susceptibility of persons to a disease or ailment; or
- influencing, controlling or preventing conception in persons; or
- testing for pregnancy in persons; or
- the replacement or modification of parts of the anatomy in persons.

Therapeutic goods fall under three different categories:

- medicines (including prescription, over-the-counter and complementary medicines, such as paracetamol and echinacea)
- biologicals (something made from or containing human cells or tissues, such as human stem cells or skin)
- medical devices (including instruments, apparatuses and appliances, such as pacemakers and sterile bandages).

Examples of therapeutics that may be confused with cosmetics are provided in Table 3.

Table 3: Examples of therapeutics

Group	Examples
Sunscreens	<p>Primary sunscreens (products that are primarily used for protection from UV radiation) are regulated as therapeutics. Included in this category are:</p> <ul style="list-style-type: none"> • primary sunscreens with SPF 4 or more • secondary sunscreens - except those regulated as cosmetics • primary or secondary sunscreens with SPF 4 or more that contain an insect repellent • sunscreens that are exempt from being listed under the Therapeutic Goods Act 1989 because they come within the exemption in Item 8(g) of Schedule 5 of the Therapeutic Goods Regulations 1990.
Other	<ul style="list-style-type: none"> • Moisturisers that contain a sun-screening agent as a secondary component and have a stated therapeutic purpose ('helps protect skin from the damaging effects of UV radiation') are regulated as medicines • Skin-whitening lotions that inhibit the physiological process of melanin production are regulated as medicines. For example, products that contain the chemical hydroquinone • Tablets can have side effects or interact in unwanted ways with other prescriptions, and are regulated as medicines.