

NICNAS COSMETICS GUIDELINES 2007

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Terms and acronyms used in these Guidelines

AICS	Australian Inventory of Chemical Substances
Cosmetics Guidelines	This document is the 'Cosmetics Guidelines'. This is intended to be a plain-English guide for stakeholders about the requirements in relation to cosmetics. It is an administrative document only and is not a legally binding document.
Cosmetics Standard	This is the Standard for Cosmetics made by the Minister under section 81 of the ICNA Act. The Cosmetics Standard sets out the "rules" or "conditions" that apply to certain cosmetics. The Cosmetics Standard is a legislative instrument made under the ICNA Act and must be complied with. Failure to comply with the Cosmetics Standard is an offence under the ICNA Act.
ICNA Act	<i>Industrial Chemicals (Notification and Assessment) Act 1989</i>
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
Regulations	The definition of 'cosmetic' enables certain types of products to be included, and excluded, from the definition of cosmetic. This is done by the making of 'Regulations' under the ICNA Act. There are currently no Regulations made under the ICNA Act in relation to the definition of a cosmetic.
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration

A. About these Guidelines

These Guidelines are issued by the Director of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to explain the recent changes to the *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA Act) in relation to cosmetics and to provide general guidance on the new legislative requirements. To this end, the Guidelines describe:

- the requirements applying to cosmetics regulated by NICNAS (refer Part B);
- further information about the definition of cosmetic (refer Part C);
- products that are regulated as cosmetics (including specific conditions applying to certain cosmetics) (Part D);
- examples of products that are not regulated as cosmetics and continue to be regulated as therapeutic goods (Part E);
- the chemicals that are prohibited from use in cosmetics, or restricted in their use in cosmetics (refer Part F);
- the consequences of non-compliance with the requirements in relation to cosmetics (refer Part G); and
- opportunities to seek further information (refer Part H).

These Guidelines replace the NICNAS Cosmetics Guidelines dated February 2007. The requirements relating to cosmetics remain largely the same, however the structure of these new Guidelines differs from the old Guidelines (which relied, for example, on concepts of cosmetic criteria and cosmetic product categories). This is because these new Guidelines have been drafted in accordance with the amendments to the ICNA Act which distinguish between:

- products that are regulated as cosmetics and products regulated as therapeutic goods; and
- cosmetics that are subject to Cosmetics Standards and cosmetics that are not.

This is explained in more detail in these Guidelines.

It is important to note that the guidelines do not constitute legal advice and users are encouraged to seek professional advice about the application of the legislation to their particular circumstances. In these guidelines, some aspects of the legislation and policy have been simplified. In cases of discrepancy between the guidelines and the legislation, the legislation should be relied on.

Any updates to these Guidelines will be published on the NICNAS website and stakeholders will have the opportunity to seek amendments to these guidelines from time to time, by formal application to NICNAS. Amendment to the Guidelines will be at the discretion of the Director.

B. Summary of Requirements for Cosmetics

In general, cosmetics must meet the following criteria or requirements:

- The product must meet the definition of cosmetic in Australia under the *Industrial Chemicals (Notification and Assessment) Act 1989*, namely:

cosmetic means:

- (a) a substance or preparation intended for placement in contact with any external part of the human body, including:
 - (i) the mucous membranes of the oral cavity; and
 - (ii) the teeth;with a view to:
 - (iii) altering the odours of the body; or
 - (iv) changing its appearance; or
 - (v) cleansing it; or
 - (vi) maintaining it in good condition (also see Part C of these Guidelines) ; or
 - (vii) perfuming it; or
 - (viii) protecting it; or
 - (b) a substance or preparation prescribed by regulations made for the purposes of this paragraph;
- but does not include:
- (c) a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*; or
 - (d) a substance or preparation prescribed by regulations made for the purposes of this paragraph.

Note: Part C of these guidelines provides more explanatory information about this definition.

AND

- The product must NOT be for preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons. However, this does not preclude use of the words prevent/preventing/prevention for general cosmetic purposes.

AND

- The product must not be scheduled by S2, S3 or S4 or S8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

AND

- The product must be marketed as a cosmetic taking into account the labelling, packaging, advertising and/or the label statements:
 - the product must have full ingredient disclosure in accordance with the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*;
 - the product may be presented as being explicitly for cosmetic purposes only; and
 - the product name would NOT of itself make the product a therapeutic good, unless that name makes a reference to a disease, ailment, defect or injury in persons.

AND

- The product must meet any applicable conditions detailed in the new Cosmetics Standard (made under section 81 of the ICNA Act). The Cosmetics Standard sets out the standards (or conditions) that apply to certain product categories. These requirements are described in Table B of Part D of these Guidelines.

AND

- The product must NOT contain chemicals prohibited for use in cosmetics or meets restrictions specified for chemicals used in cosmetics (see the List of Prohibited or Restricted Cosmetic Chemicals in Part F).

C. Further information about the definition of Cosmetic

The purpose of this section of the Guidelines is to describe the new definition of 'cosmetic' in the ICNA Act and also to provide some guidance regarding the rationale for the definition and the interpretations of some of the terms used in the definition.

The definition draws on the wording currently contained in the definition of chemical product within the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*. Previously the definition of cosmetic in the ICNA Act simply cross-referenced this definition. For the purpose of clarity, the definition has now been included, in full, in the ICNA Act. The inclusion of the definition does not represent any change in policy.

For the purposes of clarification:

- in general, "maintaining in good condition" includes controlling through, for example, cleansing, moisturising, exfoliating and/or drying;
- the definition of a cosmetic does not preclude the use of the words prevent, preventing or prevention for general cosmetic purposes specifically qualified by the purposes detailed in (a)(iii) - (viii) of the definition of cosmetic;
- the definition states that a cosmetic does not include a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*¹. This has been included for clarity, and to address interface issues between NICNAS and the Therapeutic Goods Administration Order². A change will also be made to the therapeutic excluded goods order, to provide that any product meeting the definition of a cosmetic, as defined in the ICNA Act, and the requirements in the Cosmetics Standard will not be a therapeutic good. Further information

¹ The definition of 'therapeutic goods' can be found in section 3 of the *Therapeutic Goods Act 1989*.

therapeutic good means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or

(f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

² The Therapeutic Excluded Goods Order can be found at <http://www.tga.gov.au/legis/tgeg0801.htm>

about those products that are cosmetics and those that are therapeutic goods is included in the following parts of these Guidelines; and

- the definition includes, and excludes, any substance or preparation set out in Regulations made under the ICNA Act. The power to make Regulations has been included to ensure flexibility, enabling the legislation to respond, where appropriate, to: any significant changes in the nature of the cosmetics industry (which is recognised as an evolving and innovative industry); and any changes in national or international definitions that may occur over time.

Rather than needing to amend the Act (which can take a considerable period of time) Regulations can be made more quickly to ensure that products do not “fall through the gaps”. As at August 2007, there are no Regulations in relation to the definition of cosmetics.

D. Products that are regulated as cosmetics

Table A

The specific types of products contained in the right-hand column of Table A must comply with the general requirements relating to cosmetics (detailed in Part B of this document). However, the NICNAS Cosmetics Standard (made under section 81 of the ICNA Act) does not apply to the following products. In other words, there are no product-specific conditions (standards) for these products.

It is important to note that Table A is **not exhaustive**. Omission from the Table does not necessarily stop a product from being classified as a cosmetic.

Product category	Product type
Face and Nail	Products for nail care (including preparations that are applied topically to the nails to harden or to deter biting of the nails)
	Products for make up
	Products for colouring nails/varnish
	Tinted bases/foundation (liquids, pastes, powders) without SPF
	Products for making-up and removing make-up from the face and eyes.
	Products intended for application to the lips without SPF
	Face masks and scrubs
Hair care and hairdressing products	Hair tints and dyes and bleaches
	Products for waving, straightening, and fixing
	Setting products
	Cleansing products such as lotions, powders, shampoos
	Conditioning products (e.g. lotions, creams, oils)
	Hairdressing products (e.g. lotions, lacquers, brilliantines)
Oral Hygiene	Products for care of the teeth and the mouth (other than desensitising toothpastes/gels) including dental bleaches/whiteners and denture cleansers and adhesives
Perfumes	Perfumes
	Toilet waters
	Eau de colognes
Personal hygiene	Feminine hygiene products
	Deodorants
	Antiperspirants
	Cleansers such as toilet soap, deodorant soap, astringent and skin washes
	Shaving products (e.g. creams, foams, lotions)
	Bath and shower preparations (e.g. salts, foams, oils, gels, etc.)
	Depilatories
	After-bath powders
	Hygienic powders
Skin care	Moisturising products for dermal application eg creams, lotions, gels, foams (without SPF)
	Sunbathing products (without SPF or SPF <4).

	Emollients eg creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc)
	Products for tanning without sun (without SPF)
	Skin-whitening products (without SPF)
	Anti-wrinkle products (without SPF)
	Anti-ageing products (without SPF)

Table B

The specific product types contained in the centre column of Table B must comply with the general requirements that apply to all cosmetics as well as the products-specific requirements detailed in the NICNAS Cosmetics Standard (and summarised in the right hand column).

Product category	Product type	Additional requirements as described in the Cosmetics Standard
Face and Nail	Tinted bases or foundations (liquids, pastes, powders) with sunscreen	The Cosmetics Standard requires that these products must: <ul style="list-style-type: none"> • contain a sunscreen for a secondary purpose only • meet the definition of <i>secondary sunscreen product</i> as defined in AS/NZS 2604:1998 • if the product states an SPF or equivalent category description on the label, the SPF or equivalent category description on the label must meet the requirements of clauses 6.2 and 6.3 of AS/NZS 2604:1998
	Products intended for application to the lips with sunscreen	

<p>Skin care</p>	<p>Moisturising products with sunscreen for dermal application, including but not limited to anti-wrinkle, anti-ageing and skin whitening products</p> <p>Sunbathing products (e.g. oils, creams or gels, including products for tanning without sun and after sun care products) with SPF ≥ 4 and ≤ 15</p>	<p>The Cosmetics Standard requires that these products must:</p> <ul style="list-style-type: none"> • contain a sunscreen for a secondary purpose only • meet the definition of “secondary sunscreen product” as defined in AS/NZS 2604:1998 • not be presented as having SPF >15 • not be presented as being water-resistant • include an expiry date or use-by date on the label if the product is not stable for at least 36 months • have a pack size that does not exceed 300mL or 300g • not have therapeutic claims made in relation to the product, including any representation about skin cancer • only make representations about premature skin ageing linked to sun exposure if the product meets the performance requirements for a <i>broad-spectrum product</i> in clause 7.2 of AS/NZS 2604:1998 • if the products states an SPF or equivalent category description on the label, the SPF or equivalent category description on the label must meet the requirements of clauses 6.2 and 6.3 of AS/NZS 2604:1998
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<p>Skin care (continued)</p>	<p>Antibacterial skin products</p>	<p>The Cosmetics Standard requires that these products:</p> <ul style="list-style-type: none"> • must only be presented as being active against bacteria; • must not be presented as being: <ul style="list-style-type: none"> - active against viruses, fungi or other microbial organisms (other than bacteria), or - for use in connection with disease, disorders or medical conditions, or - active against a named bacterium that is known to be associated with a disease, disorder or medical condition, or - for use in connection with piercing of the skin or mucous membrane, whether for cosmetic or any other purpose, or - for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids, or - for use before any physical contact with any person who is accessing medical or health services, or who is undergoing any medical or health care procedure, or - for use in connection with any procedure involving venipuncture or delivery of an injection
	<p>Anti acne products (including spot treatments, face scrubs, cleansers and masks)</p>	<p>The Cosmetics Standard requires that these products:</p> <ul style="list-style-type: none"> • must be presented as controlling or preventing acne only through cleansing, moisturising, exfoliating or drying the skin

Oral hygiene	Products for care of the teeth and the mouth (such as dentifrices ² , mouth washes and breath fresheners)	<p>The Cosmetics Standard requires that:</p> <ul style="list-style-type: none"> • where benefits are claimed to result from the use of the goods, such benefits must be restricted to those consequential on improvements to oral hygiene, including for the prevention of tooth decay, and/or the use of fluoride for the prevention of tooth decay • the product must not claim benefits in relation to other diseases or ailments such as gum, oral disease or periodontal condition
Hair care	Anti-dandruff products	<p>The Cosmetics Standard requires that these products:</p> <ul style="list-style-type: none"> • must be presented as controlling or preventing dandruff only through cleansing, moisturising, exfoliating or drying the scalp

² The term “prevention of tooth decay” may be used for dentifrices that are marketed as cosmetics. This exclusion from the therapeutic goods legislation is strictly limited to tooth decay and is not to be extended to other diseases or ailments such as gum or other oral disease or condition.

E. Examples of products that continue to be regulated as therapeutic goods

The following products will continue to be regulated as therapeutic goods and will not be regulated as cosmetics:

- Products that meet the definition of a therapeutic good in the *Therapeutic Goods Act 1989* including products that are for preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons.
- Primary sunscreens with SPF ≥ 4 as defined in AS/NZS 2604:1998.
- Antibacterial skin products where information is presented on the label, or by other promotional means (e.g. advertising, internet site, point of sale material) to indicate the products:
 - are active against viruses, fungi or other microbial organisms other than bacteria; or
 - are to be used in connection with a specific disease, disorder or medical condition; or
 - are active against a named bacterium that is known to be associated with a specific disease, disorder or medical condition.
 - are to be used in connection with piercing of the skin or mucous membrane whether for cosmetic or any other purpose; or
 - are to be used in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or
 - are to be used before any physical contact with any person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or
 - are to be used in connection with any procedure involving venipuncture or delivery of an injection³.
- Personal lubricants.

³ This guidance is consistent with the Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting, Australian Government, Department of Health and Ageing. "Medical or health services" include hospitals, general practice, day surgery centres, domiciliary nursing services, residential aged care, community services or office practices such as dentistry or podiatry.

F. List of Prohibited or Restricted Cosmetic Chemicals in Australia

The following chemicals must not be used in cosmetics or must only be used in the limited way specified. The list below is currently being updated and is not exhaustive.

Chemical Name	Prohibition or Restriction
Phenylenediamines	Prohibited in preparation for skin colouration (eg tattoos)
Diethylphthalate	Restriction: in sunscreens except at 0.5% or less
Dimethylphthalate	Restriction: in sunscreens except at 0.5% or less
Coal tar	Prohibition

It is proposed that each of the prohibitions or restrictions will be included as an annotation on the Australian Inventory of Chemical Substances (AICS) or through other relevant Commonwealth, State or Territory legislation. As AICS is being regularly updated, it is possible that new prohibitions or restrictions will be added and that the list above will not always be complete. It is recommended that all importers and manufacturers of cosmetics check AICS to ensure they have a complete list of prohibitions or restrictions.

G. The consequences of non-compliance with the requirements in relation to cosmetics

As noted previously, it is the responsibility of each manufacturer or importer of cosmetics to ensure that they comply with the legislation including the new Cosmetics Standard (where applicable). Non-compliance may have significant consequences. For example, under the ICNA Act it is an offence to:

- import into, or manufacture in, Australia a cosmetic that is subject to a standard set under section 81 (i.e. the Cosmetics Standard) and that does not meet the standard; and
- import into, or manufacture in, Australia an industrial chemical that is subject to a condition under section 13 (i.e. a condition of use listed on the Australian Inventory of Chemical Substances) and that breaches the condition.

The maximum penalty for failure to comply with each of these offences is 120 penalty units which is equivalent to \$13,200 for an individual or \$66,000 for a corporation.

H. Opportunities to seek further information

For further information relating to the regulation of cosmetics, please contact NICNAS.

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