



## NICNAS Existing Chemicals Information Sheet

### Chemicals commonly used in cosmetics

February 2011

#### What is a cosmetic?

A cosmetic is a substance or preparation that is designed to be used on any external part of the human body – including in the mouth – to change the odours of the body, to change its appearance, cleanse it, keep it in good condition, perfume it or protect it.

Cosmetics include soap, shampoo, moisturiser, hair dye, perfume, lipstick, mascara and many other products, but do not include products regulated as therapeutic goods (medicines).

Cosmetics are made from a range of ingredients which are deemed to be industrial chemicals. Industrial chemicals may be either synthetic chemicals or naturally occurring chemicals and these range from ammonium lauryl sulfate (a detergent used in shampoo, cleanser and bubble bath), to lanolin (oil from sheep skin, which used to moisturise skin, hair and nails) and Blue 1, a dye used to give colour to products.

#### Who regulates cosmetics in Australia?

The Australian Government – through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) – regulates the ingredients used in the manufacture and importation of cosmetics in Australia, to ensure that all *ingredients in them which are classed as industrial chemicals* are safe for workers handling them, the environment, and consumers.

This means that Australia's regulatory system for cosmetics is one of the most stringent in the world.

Against a background in which there is mounting public concern that some of the increasing numbers of chemicals used in cosmetics may potentially cause adverse reactions in consumers who use products containing them:

- o cosmetic chemicals already in use in Australia are reviewed by NICNAS on a priority basis, based on concerns raised (anyone can nominate a chemical or chemicals for review)
- o all new cosmetic ingredients must be notified and assessed to NICNAS prior to their use in consumer products
- o NICNAS scientifically assesses the risks to human health and the environment, and
- o when risks are identified, NICNAS recommends if and how they can be controlled to enable safe use.

Amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) for cosmetics came into force in September 2007.

#### Note

NICNAS has produced a general Cosmetics information sheet, available at: [www.nicnas.gov.au/xxxx](http://www.nicnas.gov.au/xxxx)

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## Well-known chemicals used in cosmetics

NICNAS is active in regulating chemicals, including those used in cosmetics. Other chemicals already in use in Australia are subject to review based on health and/or environmental concerns and potential exposure.

NICNAS holds a public nomination period during which the public, NGOs, Government agencies or industry can nominate chemicals for review.

### ✿ Alcohol — isopropyl alcohol (SD-40)

Isopropyl alcohol has a low order of acute toxicity. It is irritating to the eyes, but not to the skin. Repeated or prolonged exposure to pure isopropyl alcohol may produce central nervous system depression and narcosis. Isopropyl alcohol is not a genetic toxicant in *in vivo* and *in vitro* studies. Isopropyl alcohol is not considered to be carcinogenic (OECD report 2000).

### ✿ Ammonium lauryl sulfate

Ammonium lauryl sulfate (ALS) is an anionic surfactant used in cosmetics such as cleansing agents, hair shampoos, bubble baths and hair bleaches. NICNAS has published an information sheet on ALS and this can be accessed at: [www.nicnas.gov.au/Publications/Information\\_Sheets/Existing\\_Chemical\\_Information\\_Sheets/ECIS\\_ALS\\_PDF.pdf](http://www.nicnas.gov.au/Publications/Information_Sheets/Existing_Chemical_Information_Sheets/ECIS_ALS_PDF.pdf)

Information on formulations containing ALS ranging from 0.11 to 15% is available from studies for acute oral toxicity, skin and eye irritation and repeat dermal toxicity in animals, along with skin and eye irritation, and skin sensitisation clinical studies in humans. Together, these data support the findings on ALS that the chemical is of low acute oral toxicity, and an irritant to the skin and eye in both animals and humans. Data in humans indicate

ALS is not a skin sensitiser.

According to the CIR, sodium and ammonium lauryl sulphate “appear to be safe in formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with skin, concentrations of ammonium lauryl sulfate should not exceed 1 percent” (see: [www.cir-safety.org](http://www.cir-safety.org)).

The risk to humans from ALS will depend on the amount of exposure to the chemical. The amounts of ALS used in cosmetics, and hence the potential human exposure, is significantly lower than the doses used in animal studies. Consequently, the risk from this chemical is minimal.

### ✿ DEA (diethanolamine) — MEA (Monoethanolamine) — TEA (triethanolamine)

#### ⊗ Triethanolamine

Triethanolamine can cause mild to moderate skin and eye irritation. Occupational exposure to triethanolamine has been reported to cause allergic contact dermatitis and eczema in workers upon repeated exposure. These acute adverse effects of triethanolamine were likely to be due to its alkalinity rather than its inherent toxicity ([www.chem.unep.ch/irptc/sids/oecd/sids/102716.htm](http://www.chem.unep.ch/irptc/sids/oecd/sids/102716.htm)).

Triethanolamine is not genotoxic, carcinogenic, or toxic to development or the reproductive system. It is listed in the SUSMP under Schedule 5, as follows:

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## Schedule 5

TRIETHANOLAMINE (excluding its salts and derivatives) except in preparations containing 5 per cent or less of triethanolamine.

### ⦿ Diethanolamine

Diethanolamine is a skin and severe eye irritant in rabbits. It is not a skin sensitiser in animals. In rodents, systemic signs of toxicity consisted predominantly of anemia and liver and kidney damage at high doses. In Australia diethanolamine is regulated by inclusion in Schedules 5 and 6 of the SUSMP as follows:

#### Schedule 5

DIETHANOLAMINE (excluding its salts and derivatives) in preparations containing 5 to 20 per cent of diethanolamine.

#### Schedule 6

DIETHANOLAMINE (excluding its salts and derivatives) in preparations containing more than 20 per cent of diethanolamine.

### ⦿ Monoethanolamine

Monoethanolamine is irritating to skin, eyes and respiratory system. In Australia it is regulated by inclusion in Schedules 5 and 6 of the SUSMP as follows:

#### Schedule 5

ETHANOLAMINE (excluding its salts and derivatives) in preparations containing 5 to 20 per cent of ethanolamine.

#### Schedule 6

ETHANOLAMINE (excluding its salts and derivatives) in preparations containing more than 20 per cent of diethanolamine.

### ✿ Ethoxylated surfactants —

*PEG, polyethylene, polyethylene glycol, polyoxyethylene, -eth, or -oxynol*

1,4-dioxane is produced in trace amounts as an unwanted by-product in the manufacture of ethoxylated substances (for example, as impurity in PEG). Exposure to trace amounts of 1,4-dioxane can potentially occur when using products that contain ethoxylated substances such as detergents, cosmetics, toiletries, etc.

The public health risk assessment, conducted by NICNAS, concluded that the main potential source of exposure of the general public to 1,4-dioxane is from consumer products containing 1,4-dioxane as an impurity. No analytical data were available on levels of 1,4-dioxane in consumer products in Australia. However estimation of daily intake of 1,4-dioxane, using a worst case scenario, indicated that the exposure did not pose significant health risks to the general public.

In the interest of public health the report recommended levels of 100 ppm or less in consumer products. Industry have reported that 1,4-dioxane levels in ethoxylated substances used in pharmaceutical, personal care and household products are generally less than 10 ppm. 1,4-dioxane is listed in Schedule 6 of the SUSMP.

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## ✿ FD&C colour pigments

Use of coal tar in cosmetics is banned in Australia by inclusion in *Appendix C* of the SUSMP, which includes substances of such danger to health as to warrant prohibition of sale, supply and use.

A specific coal-tar ingredient called phenylenediamine is listed in NICNAS's *Cosmetics Guidelines* (2007) as prohibited for use in skin colouration (see: [www.nicnas.gov.au/Current\\_Issues/Cosmetics/Cosmetic\\_Guidelines\\_PDF.pdf](http://www.nicnas.gov.au/Current_Issues/Cosmetics/Cosmetic_Guidelines_PDF.pdf)).

When used in eyelash/eyebrow tinting products, the immediate container and primary pack need to be labelled with the following statement:

*WARNING - This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.*

## ✿ Formaldehyde

Formaldehyde is toxic by inhalation, skin contact, and swallowing. Skin contact with formalin solution can cause skin rashes and allergic skin reactions.

Breathing formaldehyde vapour can result in irritation of nerves in the eyes and nose, which may cause burning, stinging or itching sensations, a sore throat, teary eyes, blocked sinuses, runny nose, and sneezing. This health effect is commonly referred to as sensory irritation. Formaldehyde has been shown to cause nasal cancers in animals at levels not found in any consumer products or even at majority of workplaces.

Formaldehyde in cosmetics is regulated by inclusion in the SUSMP. Preparations containing 0.05 per cent or less of free formaldehyde are listed in Schedule 6 of the SUSMP with the signal word 'POISON' on the containers, except for human therapeutic use, in oral hygiene preparations, in nail hardener cosmetic preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement (PROTECT CUTICLES WITH GREASE OR OIL) or in all other preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement (CONTAINS FORMALDEHYDE).

The following preparations containing formaldehyde are banned in Australia by inclusion in Appendix C of the SUSMP.

- oral hygiene preparations containing more than 0.1 per cent of free formaldehyde
- aerosol sprays for cosmetic use containing 0.005 per cent or more of free formaldehyde
- nail hardener cosmetic preparations containing 5 per cent or more of free formaldehyde
- all other cosmetic preparations containing 0.05 per cent or more of free formaldehyde **except** in preparations containing 0.2 per cent or less of free formaldehyde when labelled with the warning statement: CONTAINS FORMALDEHYDE.

## ✿ Imidazolidinyl urea (Germall 115), Diazolidinyl urea and DMDM Hydantoin

Imidazolidinyl urea present in cosmetic products may release formaldehyde into cosmetics at temperatures above 10 °C. An assessment undertaken by NICNAS classified imidazolidinyl urea as a skin sensitiser. As imidazolidinyl urea is a formaldehyde-releaser its use is restricted to low concentrations in cosmetic products by State/Territory poisons legislations via adoption of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) (*please see formaldehyde, above*).

The Australian cosmetic associations has advised that the Australian cosmetics industry follows international practice based on the Cosmetic Ingredient Review (CIR) reports for formaldehyde and formaldehyde donor

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products, such as DMDM Hydantoin (CIR Expert Panel, 1988). These reports concluded that the concentration of free formaldehyde should not exceed 0.2% and aerosolised cosmetic products containing formaldehyde should not be used. These reports have been reviewed recently and no changes have been made.

### ✿ Lanolin

Lanolin originates as a secretion from a sebaceous gland in sheep skin. It is removed from the wool by scouring processes and then recovered by high speed centrifugal separators to give a product known as wool grease that, after distillation and a series of other processes, yields the finished lanolin.

Lanolin and its related ingredients moisturize the skin, hair and nails. These ingredients act as a lubricant on the skin surface, which gives the skin a soft, smooth appearance. Lanolin helps to form emulsions and blends well with nearly all other substances used in cosmetics and personal care products.

According to an evaluation by the US EPA, the pesticide levels found in lanolin should not pose a hazard to public health. The EPA report based on the US Food and Drugs Authority's (USFDA) estimates of "worst case" pesticide exposure supported the USFDA conclusion that health risk from the pesticide residue level found in lanolin is negligible.

The safety of Lanolin and lanolin-derived ingredients has also been assessed by the CIR Expert Panel, which concluded that lanolin, lanolin oil, lanolin wax, lanolin alcohol, acetylated lanolin, acetylated lanolin alcohol, hydrogenated lanolin and hydroxylated lanolin were safe for use in cosmetics and personal care products.

A study of various skin sensitisers conducted by NICNAS in 2005 concluded that from the data available for the assessment, lanolin did not meet the criteria for classification as a hazardous substance with respect to sensitisation by skin contact according to the Australia's *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

### ✿ Lead

Lead compounds have diverse effects on multiple body systems such as the nervous, gastrointestinal, reproductive and circulatory systems. The toxicity of lead compounds is mostly related to the lead portion in the compound.

Lead compounds at or above 100 mg/kg are listed in Schedule 6 of the SUSMP. Cosmetics products containing lead compounds at a concentration greater than 100 mg/kg (ie. 0.01% w/w) are required to carry the signal word "POISON" on their containers along with appropriate warning statements and safety directions. Lead compounds present in hair cosmetics are included in Schedule 5 of the SUSMP and these cosmetics should carry the signal word "Caution" on their containers along with appropriate warning statements and safety directions. This is designed to ensure that users are provided with sufficient information to be able to use products safely.

Under the *Customs (Prohibited Imports) Regulations 1956*, the importation of cosmetics products containing more than 250 mg/kg (0.025% w/w1) of lead or lead compounds (calculated as lead), except products containing more than 250 mg/kg of lead acetate designed for use in hair treatments, is prohibited unless written permission is granted by the Minister.

Based on the information provided by Australian industry neither lead nor lead compounds are used intentionally as cosmetic ingredients in Australia apart from known uses as hair colorants. However, it is recognised that there is a potential for certain raw materials that are used in cosmetics to be contaminated with small amounts of lead, and industry indicates this is managed as part of the specification process. As

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per best practice industry should continue to manage this potential contamination via the quality control process.

NICNAS has produced an information sheet on lead in cosmetics which can be accessed at: [www.nicnas.gov.au/Publications/Information\\_Sheets/Existing\\_Chemical\\_Information\\_Sheets/Lead\\_in\\_Cosmetics\\_%20March\\_2008.pdf](http://www.nicnas.gov.au/Publications/Information_Sheets/Existing_Chemical_Information_Sheets/Lead_in_Cosmetics_%20March_2008.pdf)

## ☀ Mercury

Exposure to high levels of any type of mercury can permanently damage the brain, kidneys, and developing foetus. Under the SUSMP, Mercury is listed in many schedules: as a pharmacy medicine (schedule 2) it is allowed for external use in preparations containing 0.5 % or less of mercury; as a prescribed medicine (schedule 4) for cosmetic or therapeutic use; as a dangerous poison (schedule 7) in preparations containing 0.01 % or more of mercury in organic form as a preservative, as mercury (metallic) in scientific instruments, in dental amalgams or in a sealed device for therapeutic use which prevents access to the mercury. Appendix G of the SUSMP lists maximum allowable concentration of mercury as 1mg/kg.

## ☀ Mineral oil — including *liquidum paraffinum*, paraffin oil, paraffin wax, petrolatum

White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature. It is obtained from petroleum, and is intensively refined following several steps including atmospheric and vacuum distillation, removal of aromatic and unsaturated compounds, dewaxing and further processing. Some petroleum oil derivatives may contain polycyclic aromatic hydrocarbons, some of which are known to be carcinogens.

Only the highest purity medicinal-grade white mineral oil, with extremely low levels of harmful hydrocarbons, is used in cosmetics. It complies with the requirements of the various national pharmacopoeias and regulations on food-grade material and is used as a lubricant for food-handling machines and as an ingredient in pharmaceutical preparations and cosmetics.

The SUSMP schedules light mineral and paraffin oils (but excluding their derivatives) in Schedule 5 under "hydrocarbons, liquid". However food grade and pharmaceutical grade white mineral oils are exempted.

## ☀ Nanoparticles in mineral make up

There is currently no agreed national or international definition of nanomaterials. An interim definition of nanomaterials as published in the [Chemical Gazette of December 2010](#) can be used:

*Industrial nanomaterials are industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"*

This size range refers to individual particle size, and does not take into account agglomeration of particles.

The toxicity of nanomaterials is related to multiple factors, the most significant among them seem to be chemical composition, specific surface area and the number and size of particles. According to available information, not just size but also particle shape, surface chemistry, solubility etc. are important parameters that can influence potential risk of the particle.

The European Commission's Scientific Committee on Consumer Products' (SCCP) *Opinion on the Safety of Nanomaterials in Cosmetics* (December 2007) noted that:

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"Nanoparticles can be divided into two groups: i) soluble and/or biodegradable nanoparticles which disintegrate upon application to skin into their molecular components (eg. liposomes, microemulsions, nanoemulsions), and ii) insoluble and/or biopersistent particles (eg. TiO<sub>2</sub>, fullerenes, quantum dots). For the first group, conventional risk assessment methodologies based on mass metrics *may* be adequate, whereas for the insoluble particles other metrics, such as the number of particles, and their surface area as well as their distribution are also required. It is crucial when assessing possible risks associated with nanoparticles to consider their uptake. ....It is primarily for the insoluble particles that health concerns related to possible uptake arise. Should they become systemically available, translocation/ transportation and eventual accumulation in secondary target organs may occur. This could become important with repeated application of cosmetic products. Inevitably, insoluble nanoparticles do represent a burden for the environment and a complete life cycle analysis is required."

Nanomaterials, used for industrial purposes, fall within the scope of NICNAS and this includes nanomaterials used in cosmetic products. Each ingredient of a cosmetic product introduced into Australia through import or manufacture must either be listed on the Australian Inventory of Chemical Substances (AICS), or be notified as a new chemical prior to its introduction, subject to certain exemptions.

The NICNAS regulatory framework is currently being reviewed to address nanomaterials. See [www.nicnas.gov.au/Current\\_Issues/Nanotechnology.asp](http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp) for more information.

### ✿ Nitrosamines — other chemicals with nitrosamines

The safety of acyl sarcosines and sarcosinates has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in the US. The Panel evaluated the scientific data and concluded that Cocoyl Sarcosine, Lauroyl Sarcosine, Myristoyl Sarcosine, Oleoyl Sarcosine, Stearoyl Sarcosine, Sodium Cocoyl Sarcosinate, Sodium Lauroyl Sarcosinate, Sodium Myristoyl Sarcosinate, Ammonium Cocoyl Sarcosinate and Ammonium Lauroyl Sarcosinate were safe as used in rinse-off products, and safe for use in leave-on products at concentrations of 5% or less. The data were insufficient to determine the safety for use in products where the sarcosines and sarcosinates were likely to be inhaled.

The USFDA has also reviewed the safety of lauroyl sarcosine, stearoyl sarcosine, and sodium lauroyl sarcosinate and approved their use as [indirect food additives](#) for use in cellophane having incidental contact with food. N-Acyl sarcosines such as lauroyl or oleoyl sarcosines with the combined fatty acids of coconut oil have been approved as anti-static and/or anti-fogging agents for food packaging material.

### ✿ Oxybenzone

Oxybenzone is used in sunscreens. It is not scheduled in the SUSMP due to low concerns about its toxicity. It is approved by the Therapeutic Goods Administration (TGA) as a sunscreen agent. Oxybenzone is also approved by the USFDA, the European Commission and Canada as a safe and effective sunscreen ingredient.

In its latest opinions (Dec 2008), the SCCP concluded, that: "the use of benzophenone-3 as a UV-filter up to 6% in cosmetic sunscreen products and up to 0.5% in all types of cosmetic products to protect the formulation does not pose a risk to the health of the consumer, apart from its contact allergenic and photoallergenic potential"

### ✿ Paraben preservatives: *methyl, propyl, butyl, and ethyl*

Parabens are [esters](#) of [para-hydroxybenzoic acid](#) widely used as preservatives in food, cosmetic and therapeutic products and some parabens are found at low levels in nature.

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The 'Opinion on the Safety Evaluation of Parabens' released by the SCCP in 2005 states that, based on acute and chronic toxicity studies in rats, dogs and mice, parabens have been proven to be practically non-toxic, not carcinogenic, not genotoxic nor co-carcinogenic, and not teratogenic. Parabens rarely sensitize but may provoke a response when applied to eczematous skin. Sensitized patients can often tolerate parabens in cosmetics applied to normal skin, but, understandably, not broken skin (Food Chem. Toxicol. 2005;43:985-1015). Recent claims that parabens present in deodorants and antiperspirants may cause breast cancer has not been substantiated.

### ✿ Phthalates: dibutylphthalate (DBP), diethylphthalate (DEP) and dimethylphthalate (DMP)

Phthalates are a group of chemicals that are used predominantly as solvents and plasticisers (plastic softeners) in both industrial and consumer products. There are many phthalate chemicals in use worldwide.

Certain phthalate chemicals are known to possess endocrine disrupting effects at high doses in experimental animals. This endocrine disruption, associated mainly with disruption of male sexual development, varies significantly between phthalates. Studies show that DBP and DEP induce subtle hormonal or structural changes mainly in male reproductive organs in rodents at high doses. Endocrine disrupting effects are not as evident for DMP. The endocrine disruption observed in rodent studies with certain phthalates is not seen when these phthalates are tested in non-human primate studies (monkeys), raising the question as to whether this effect is of concern for human health.

Because of the differences in toxicity profiles for different phthalates, only particular phthalates are restricted for certain applications in the European Union. On the basis of the potential for effects on human health, DBP is not allowed for use in cosmetics and is restricted for use in children's toys to 0.1% by weight of plastic. These restrictions do not apply for DEP or DMP.

Listed in Appendix C of the SUSMP, DEP and DMP are allowed in sunscreens or personal insect repellents for human use in preparations containing 0.5 per cent or less of the phthalate. Appendix C of the SUSMP lists substances other than those included in Schedule 9, that are of such danger to health as to warrant prohibition of sale, supply and use.

NICNAS has published detailed hazard assessments for a total of 24 phthalate chemicals. These include DMP, DEP and DBP. These individual reports, in addition to a Phthalate Hazard Compendium containing comparative physicochemical, toxicity and use information on phthalates, are available from the NICNAS website at [www.nicnas.gov.au/Media/Latest\\_News.asp](http://www.nicnas.gov.au/Media/Latest_News.asp). NICNAS is currently conducting public health risk assessments for 9 individual phthalates for use in children's toys, childcare articles and cosmetics. These risk assessments will contain recommendations for further regulatory actions as appropriate.

### ✿ Propylene/Butylene Glycol

Propylene glycol and butylene glycol can penetrate the skin, however they are low toxicity compounds. Propylene glycol is widely used as a food additive and in pharmaceutical preparations.

Repeated exposure of rats to propylene glycol in feed (up to 2.5 g/kg body weight) for up to 2 years, did not result in any adverse effects. Butylene glycol is very low in toxicity when given in repeated oral doses. Twenty percent butylene glycol administered in the drinking water of rats for 44 days was without any effects on growth, blood parameters, liver, kidney, and bladder.

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## ✿ Silicone derived emollients — Dimethicone, Dimethicone Copolyol, and Cyclomethicone)

Dimethicone is listed in SUSMP in Appendix B - substances considered not to require control by scheduling due to low toxicity.

Health Canada have recently assessed the human health effects of decamethyl cyclopentasiloxane (D5) and octamethyl cyclotetrasiloxane (D4) and concluded that none of the chemicals is harmful to human health.

## ✿ Sodium Lauryl Sulfate

Sodium lauryl sulfate (SLS) is a detergent used in very low amounts in some consumer products. NICNAS has published an information sheet on SLS and this can be accessed via: [www.nicnas.gov.au/Publications/Information\\_Sheets/Existing\\_Chemical\\_Information\\_Sheets/ECIS\\_sls\\_PDF.pdf](http://www.nicnas.gov.au/Publications/Information_Sheets/Existing_Chemical_Information_Sheets/ECIS_sls_PDF.pdf). There are no data on SLS and their formulations to indicate SLS to be a skin sensitiser, genotoxic, carcinogenic, or a reproductive toxicant. The toxicity of SLS appears to be restricted to acute toxicity at high doses and skin and eye irritation. The amounts of SLS used in cosmetics, and hence the potential human exposure, is significantly lower than that used in animal studies. Consequently, the risk from this chemical is minimal.

## ✿ Triethanolamine (TEA) compounds

TEA is used as an emulsifier and surfactant and serves as a pH balancer in many different cosmetic products. Cleansing milk/cream emulsions based on TEA are particularly good at removing makeup. It converts to nitrosamines - organic substances formed by a specific reaction of two nitrogen containing substances one of which is an amine (such as a protein). The second nitrogen containing material is called a nitrosating agent such as nitrites used as food preservatives (particularly in lunch meats). Nitrosamines may be formed in cosmetic and personal care products only if they contain an ingredient which acts as a Nitrosating agent and an amine. Nitrosation occurs during manufacture or during product storage.

Some nitrosamines have been found to be carcinogens when tested at high levels in animals. The ones that cause cancer are well known and steps are taken to minimize their occurrence in cosmetics and personal care products. Cosmetic and personal care products are formulated to eliminate or reduce the formation of nitrosamines. Most cosmetic products do not contain any nitrosamines and when they do occur, the levels are typically very low and do not present any health risk to consumers.

## ✿ Toluene/ Butylated hydroxytoluene

The US Agency for Toxic Substances and Diseases Registry (ASTDR) reports that low to moderate levels of toluene can cause tiredness, confusion, weakness, drunken-type actions, memory loss, nausea, loss of appetite, and hearing and color vision loss. But these symptoms usually disappear when exposure is stopped. Preparations containing toluene at 50% or more are listed in Schedule 6 of the SUSMP and those containing less than 50% toluene are listed in Schedule 5.

Butylated hydroxytoluene (BHT) is used as an antioxidant in food, animal feed and cosmetics. For the use of BHT as an antioxidant in food, an acceptable daily limit of 0 – 0.125 mg/kg bw/day has been established by the World Health Organization/Food and Agriculture Organization (WHO/FAO). BHT is of low acute toxicity. In rats, thyroid hyperactivity and liver enlargement were noted only after long term exposure and only at concentrations above 25 mg/kg bw/day.

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## More information

- ➔ National Industrial Chemicals Notification and Assessment Scheme – NICNAS – contact NICNAS staff for assistance on Free Call 1800 638 528.
- ➔ Therapeutic Goods Administration – TGA – visit the TGA web site (part of the Australian Government Department of Health and Ageing) at [www.tga.gov.au](http://www.tga.gov.au) or contact the TGA on Free Call 1800 020 653.
- ➔ Australian Consumer and Competition Commission (ACCC) – visit the ACCC web site at [www.accc.gov.au](http://www.accc.gov.au) or phone the nearest ACCC office in your State or Territory.
- ➔ All legislation mentioned in this information sheet can be found on the Australasian Legal Information Institute web site at [www.austlii.edu.au](http://www.austlii.edu.au)