ACCC analytical survey of microbiological contamination of cosmetics for use around the eyes

Final report

July 2015

Contents

This report describes the findings of an ACCC survey of microbiological contamination of cosmetics for use around the eyes.

The report reflects the findings for the specific samples at the time of the survey only. The results should not be taken to be indicative for all products of the same kind either before, during or after the survey period.

When a survey result suggests a product may be unsafe or non-compliant the ACCC will contact the supplier and work with them to investigate the issue and remove the product from the marketplace where adverse results are confirmed.

Importantly, while adverse survey results may result in products being corrected quickly, there is also no assurance that favourable survey results will mean a product continues to be safe or compliant in the future.

1. Background

The Australian Competition and Consumer Commission (ACCC) plays an important role in consumer product safety. The ACCC administers national product safety regulations under the *Competition and Consumer Act 2010* and monitors the safety of general consumer products. This includes educating suppliers and consumers about regulations, emerging issues, and the safe use of products to minimise the risk of injuries.

In 2013 the ACCC conducted a survey involving microbiological testing of cosmetics for use on the face. The 2013 survey identified a small number of products with unacceptable microbiological contamination. The ACCC brought these results to the attention of suppliers and negotiated recalls of the contaminated products. A positive outcome of this activity was that suppliers improved their manufacturing processes to reduce the risk of microbiological contamination in their products.

This survey targeted cosmetics for use around the eyes because of reports of injuries to eyes associated with the use of cosmetics and because the consequences of eye injuries can be serious.

2. Potential Hazards

Consumers are highly exposed to cosmetics as they are directly applied to the human body, often on a daily or nightly basis over long periods of time. Cosmetics are also widely used across the population, with products designed for consumers of all ages (i.e. from baby products to anti-ageing products, for example). Many cosmetic products are susceptible to microbial growth, especially those that contain water, ineffective preservatives, or nutrients such as vitamins, minerals and proteins[1]. Microbial contamination can occur in raw materials; during production, filling and storage; and during use of the cosmetic by consumers[2]. Cosmetic products are not expected to be sterile and low levels of microbial activity are unlikely to be harmful to consumers[3]. However, high levels of microbial contamination or the presence of certain pathogens can cause infections, particularly among vulnerable consumers. An infection in the eye can lead to impaired vision or blindness.

While consumers seem to be aware of risks posed by exposure to chemicals in cosmetics, there seems to be less public understanding of the risks that may come from exposure to the microbiological contamination of cosmetics. A report published in 2007 noted that many consumers are unaware of the potential risks of contamination from unintended uses (misuse) of cosmetics, such as diluting products with water, which may compromise preservative efficacy[4]. A consumer research survey found that 72 per cent of women never wash makeup sponges or brushes and 68 per cent of women say they replace cosmetics only when they run out, regardless of use-by dates[5].

2.1 Microbial contamination

Microorganisms are small organisms that require microscopic tools for visualisation, and include bacteria, fungi (e.g. yeast and mould), viruses and some parasites[6]. Many microorganisms are harmless to humans and serve useful functions, but others can cause serious harm. These disease-causing microorganisms are called pathogens and if allowed to multiply in cosmetic products, they can infect the human body and cause serious harm to consumers. Some microorganisms, called opportunistic pathogens, do not normally cause disease in healthy people but may cause disease in those with weakened immune systems[7]. The skin and mucous membranes are protected from microbial attack by a natural mechanical barrier and various other defence mechanisms. However, these may be damaged by the action of some cosmetics and this may enhance the likelihood of microbial infection. According to the Scientific Committee on Consumer Safety (SCCS), microbial infection is of particular concern when cosmetics are used around the eyes[8].

[1] Roden K, 2010, *'Preservatives in Personal Care Products'*, Microbiology Australia, Cambridge Publishing, viewed 17 August 2015, http://journals.cambridgepublishing.com.au/UserDir/CambridgeJournal/Articles/roden1197.pdf.
[2] Siegert, W. 2010, '*Microbiological Quality Management for the Production of Cosmetics and Detergents'*, SOFW-Journal | 138 | 11-2012, 6, viewed 2 August 2013, http://www.researchgate.net/publication/233414828_Microbiological_Quality_Management_for_the_Production_of_Cosmetics_and_Detergents.
[3] ibid.
[4] Procter and Gamble, viewed 25 August 2015, Procter and Gamble, http://216.35.217.118/assets/files/defining-issues1.php
[5] PRWeb 2010, '*Debenhams reveals the make-up time bomb in British women's cosmetic bags'*, London, England, viewed 12 July 2013, http://www.prweb.com/releases/2010/02/prweb3653044.htm.
[6] The University of Chicago 2013, Department of Microbiology, Chicago, Illinois, viewed 12 July 2013, http://microbiology.uchicago.edu/.
[7] National Institute of Health, NIH Office of Science Education, Bethesda, MD, viewed 12 July 2013, https://science.education.nih.gov/supplements/nih1/diseases/guide/understanding1.html.
[8] European Commission 2012, *The SCCC'S notes of guidance for the testing of cosmetic substances and their safety evaluation',* European Commission, Brussels, viewed 2 July 2014, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf.

3. Regulations and Standards

Australia

Cosmetics are subject to a range of regulations in Australia including the *Industrial Chemicals Notification and Assessment Act 1989* (ICNA Act) and the Cosmetics Standard 2007. Cosmetics must also comply with the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (the Standard), which requires that ingredients used in cosmetics be declared on the label. This list helps consumers identify the presence of ingredients to which they may be allergic, sensitive or otherwise concerned about, and allows comparison of different cosmetic products. While ingredient labelling is an information standard, it is widely accepted that one of the key justifications for mandating cosmetic ingredient labelling is to support consumer safety.

The ACCC does not undertake pre-market approval of cosmetic products. The Australian Consumer Law (ACL) provides a range of statutory guarantees to consumers when they purchase goods and services. Suppliers must ensure that goods are safe and of acceptable quality, and fit for any disclosed purpose in order to comply with those guarantees. Goods must also match descriptions made by the salesperson, on packaging and labels, and in promotions or advertising. The ACL provides for the ACCC and other consumer protection agencies in Australia to require a person to substantiate any claim made about goods or services they provide. There are heavy penalties for failure to substantiate claims and for misleading consumers. Companies and individuals who market cosmetic products have a legal responsibility to ensure the safety of their products, and face penalties if their products do not comply with the law.

Cosmetic ingredients, even those described as naturally-occurring, are classed as industrial chemicals in Australia and are regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Cosmetic ingredients must be legally permitted for use and meet requirements under the ICNA Act. Cosmetics must also comply with the Cosmetics Standard 2007, which sets specific standards for six cosmetic product categories[9]. Cosmetic products that fall within these six product categories must comply with the general requirements that apply to all cosmetics, as well as the product-specific requirements detailed in the Cosmetics Standard 2007. These product categories include:

Face and nail	Tinted bases/foundation with sun protection factor (SPF) Lip products with SPF
Skin care	Moisturising products with SPF for dermal application Sunbathing products with sun protection for a secondary purpose (SPF ≥4 and ≤15)
Skin care	Antibacterial skin products
Skin care	Anti-acne skin products[10]
Oral hygiene	Products for the care of teeth and mouth
Hair care	Anti-dandruff products

Under the Cosmetics Standard, a ‘cosmetic’ is defined as:

> “A substance or preparation intended for placement in contact with any external part of the human body, including: the mucous membranes of the oral cavity and the teeth; with a view to:
>
> - altering the odours of the body; or
> - changing its appearance; or
> - maintaining it in good condition; or
> - perfuming it; or

[9] The Cosmetics Standard 2007 falls under the Industrial Chemicals Notification and Assessment Act 1989.
[10] Anti-acne and anti-dandruff products are regulated as cosmetics provided they control acne or dandruff through cleansing, moisturising or exfoliating.

- protecting it."

The Cosmetics Standard provides some conditions to ensure safety and microbiological quality for certain goods, including specific expiry date label requirements for skincare products with secondary sunscreen properties that are not stable for at least 36 months (see Schedule 1, Item 2(b) (iii)).

Other weight and measurement requirements may also apply under relevant national measurement regulations.

For therapeutic goods, microbial quality acceptance criteria apply for various non-sterile over-the-counter medicines under Therapeutic Goods Order 77 (TGO 77). The TGO 77 adopts harmonised British Pharmacopoeia, European Pharmacopoeia, and US Pharmacopeia-National Formulary microbial acceptance criteria at 10 colony forming units per gram (CFU/g)[11]. While it should not be regarded as comprehensive microbial quality acceptance criteria, these limits are considered the minimal requirements to be met throughout the shelf life of a non-sterile medicine.

For cosmetic products more generally, there are no specific Australian regulations that regulate the microbiological quality of cosmetics; mandate quantitative limits on microbial growth in cosmetics; or legally require expiry dates or period after opening (PAO) labels on all cosmetic products.

Cosmetics are also a regulated good under the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (the Standard) which requires that ingredients used in cosmetics be declared on the label. The ACCC is responsible for the administration and enforcement of the Standard.

International Regulations

European Union

In the EU cosmetics are regulated by the Cosmetic Products Regulation, EU Regulation 1223/2009. This regulation replaced the Cosmetics Directive (76/768/EEC) and aims to streamline and modernise the legislation currently in place for cosmetics and personal care products across Europe. Cosmetics are not subject to pre-market approval in the EU. Manufacturers are responsible for ensuring that cosmetic products comply with the law before they are marketed. The manufacturer or importer of cosmetics is responsible for demonstrating that the product is safe for its intended use. Regulations are enforced at the national level, and each country in the EU has an authoritative body that is responsible for upholding compliance.

The EU Cosmetic Products Regulation requires that cosmetic products should be safe under normal or reasonably foreseeable conditions of use. It also requires the manufacture of cosmetic products to comply with good manufacturing practice (GMP) as set out in a number of published guidelines. To ensure the above conditions, cosmetic products must undergo a safety assessment before they are placed on the market. The resulting safety report must include, as a minimum, the microbiological specifications of the cosmetic product and the results of a preservation challenge test. This report must be contained in a Product Information File (PIF), which must also include a description of the method of manufacturing and a statement of compliance with GMP.

The EU Cosmetic Products Regulation also contains cosmetic labelling requirements under Article 19, which require cosmetics to be clearly labelled with:

- the name or registered name and the address of the responsible person
- the country of origin for imported products

[11]Therapeutic Goods Administration 2014, Therapeutic Goods Administration, Canberra, 2014, viewed 2 June 2014, http://www.tga.gov.au/industry/otc-argom-app2-10-microbiological.htm#s102 .

- the weight or volume of the content at the time of packaging
- precautions for use, including cosmetics for professional use
- the batch number of manufacture or a reference for identifying the cosmetic
- the list of ingredients
- the date of minimum durability or a period after opening symbol (for cosmetics with a minimum durability of more than 30 months)[12].

In its 'Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation'[13] the SCCS specify quantitative microbiological limits for Category 1 and 2 cosmetic products:

Category 1	Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	TVC should not exceed 100 CFU/g or CFU/mL of the product
Category 2	Other products	TVC should not exceed 1000 CFU/g or CFU/ml of the product

The limits are expressed as a total viable count (TVC) of aerobic mesophilic microorganisms that can contaminate a gram or millilitre of a cosmetic product. The unit of measurement is by CFU/g or CFU/mL. According to the Guide, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* must not be detectable in 1 gram or mL of a Category 1 cosmetic and in 0.1 g or 0.1 mL of a Category 2 cosmetic, as they are considered the main potential pathogens in cosmetic products.

United States

Cosmetics are regulated by the US Food and Drug Administration (US FDA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labelling Act (FPLA)[14]. The FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in the US. Under this Act, a cosmetic is adulterated if:

- it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labelling thereof, or under conditions of use as are customary and usual (with an exception made for hair dyes)
- it consists in whole or in part of any filthy, putrid, or decomposed substance
- it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health
- its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health, or
- it is, or it bears or contains, a colour additive which is unsafe (except for hair dyes).

Cosmetic products sold in the US are not expected to be aseptic. However, they must be completely free of high-virulence microbial pathogens, and the total number of aerobic microorganisms per gram or millilitre of the product must be low. There are no widely acceptable standards for microbiological limits in cosmetics in the US. Therefore, temporary guidelines are used instead (see below):

[12] The date of minimum durability is the date until which the cosmetic will continue to fulfil its initial function, assuming it is stored under appropriate conditions. For cosmetics with a minimum durability of more than 30 months, a period after opening (POA) symbol can be used instead to specify the period of use after opening for which the product is safe.
[13] European Commission 2012, *The SCCC'S notes of guidance for the testing of cosmetic substances and their safety evaluation',* European Commission, Brussels, 2012, viewed 2 July 2014, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf.
[14] US Food and Drug Administration 2013, US Food and Drug Administration, Silver Spring, MD, viewed 13 September 2013, http://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074162.htm.

Eye-area products	TVC of aerobic microorganisms should not be greater than 500 CFU/g or CFU/mL
Non-eye-area products	TVC of aerobic microorganisms should not be greater than 1000 CFU/g or CFU/mL

Pathogens of particular concern, especially if found in eye-area cosmetic products, include *S. aureus*, *Streptococcus pyogenes*, *P. aeruginosa* (and other *Pseudomonas* species) and *Klebsiella pneumoniae*. Some microorganisms normally regarded as non-pathogenic may be opportunistically pathogenic e.g. in wounds[15].

The FDA does not undertake pre-market approval of cosmetic products and ingredients before they enter the market. Companies and individuals who market cosmetics have the legal responsibility to ensure the safety of their products. However, the FDA may pursue enforcement action against firms or individuals that violate the law.

[15]US Food and Drug Administration 2001, US Food and Drug Administration, Silver Spring, MD, viewed 13 September 2013, http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073598.htm.

4. Survey aim and rationale

The primary aim of this survey was to purchase commonly available cosmetics that are used around the eyes and test them for the presence of potentially hazardous microorganisms. A further aim was to assess whether the products displayed a list of ingredients as required by the Standard.

This survey targeted cosmetics for use around the eyes because of reports of injuries to eyes associated with the use of cosmetics and because the consequences of eye injuries can be serious. In 2014 the ACCC received 14 reports of injuries associated with eye cosmetics. The ACCC last undertook a survey involving microbiological testing of certain cosmetics in 2013.

4.1 Survey

Survey methodology

Between 23 February and 21 March 2015 ACCC staff purchased 31 cosmetics designed to be applied to the eyes from a representative range of mainstream suppliers in the ACT. No online suppliers were included in this survey.

Analytical method for microbiological testing

Approximately 10 grams of each eye cosmetic sample was tested for total viable aerobic count (TVAC) in accordance with the ANSI/AAMI/ISO 11737-1 Standard. Each cosmetic sample was subjected to two 30˚C incubation periods (3 days and 5 days) to test for a TVAC of microorganisms. Cosmetics with a microbial count of above 100 CFU/g would be considered to reflect excessive microbial activity and would be subjected to further identification testing for specific microbial contaminants. If pathogens were identified, preservative efficacy testing of the product would then be considered.

The methods we used are standard published methodologies, used in many jurisdictions, including the EU and US. The reference limit for a high microbial count was set at 100 CFU/g, as this is the quantitative limit specified in EU guidelines for cosmetics used around sensitive areas such as the eyes and lips.

Assessment of ingredient labelling

The ingredient listing was assessed by visual inspection to determine whether the list was present and if it was prominent and clearly legible, as required by the Standard.

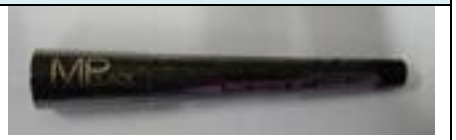
Where an ingredient list was not present on the product, the store was examined to see whether a list was accessible close to the display or at the point of sale.

If the label satisfied the requirements of the Standard, a result of ‘adequate’ was recorded. If the label didn’t satisfy the requirements of the Standard an ‘inadequate’ result was recorded.

5. Conclusions

- Of the 31 cosmetics purchased, 28 were tested. The lab was unable to extract a sufficient sample size from three of the cosmetics and these were not tested.
- All 28 of the eye cosmetics tested for microbiological contamination returned TVAC results below the Limit of Reporting of 10 CFU/g.
- No pathogenic organisms were identified in any of the samples tested.
- These results demonstrate that cosmetics for application around the eyes that are commonly supplied in Australia meet benchmark safety thresholds for microbiological activity and appear to be free from microbiological contamination, at the time of initial opening. Production hygiene and conditions of storage and handling up to the point of retail sale appears to be sound for all samples at the time of this survey.
- As preservative efficacy challenge testing was not conducted, this survey did not provide any information about whether the products were likely to maintain acceptable microbiological status throughout the expected life of the product after initial opening and during typical use.
- The apparent incidence of eye injury associated with the use of cosmetics around the eye may not relate to microbiological agents or product contamination at the time of opening.
- Given the potentially severe consequences of eye injuries, cosmetic suppliers should continue to ensure products for use around the eyes are free from microbiological contamination and consumers should always follow the instructions for the safe storage and use of the product and the recommended life of the product.
- Six (21%) of the 28 products were assessed as ‘inadequate’ in terms of compliance with the Standard for ingredient labelling. Two of these samples had no ingredient list on the product/packaging and the ingredient lists displayed on the remaining four did not appear to be prominent and clearly legible as required by the Standard.
- A further six samples had no ingredient list on the product/package however, there was an accessible ingredient list displayed at the point of sale in the store and these products were assessed as not being able to display the ingredient list on the product itself.
- The ACCC will continue to monitor the safety of cosmetics for use around the eye.

Attachment 1 – Results table

Product	Purchase details	Total Viable Aerobic Count (LOR 10 CFU/g)	Ingredient list assessment	Photograph
Models Prefer - Precision Wet Look Liner - Shiny Black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate – ingredient list available in store	
Models Prefer - Bold and Beautiful - High Impact Mascara - extra black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate – ingredient list available in store	
Rimmel - Waterproof Wonderfull - mascara with Argan Oil - Black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate – ingredient list available in store	
Rimmel - Kate - Eye Rock - Jet Black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate – ingredient list available in store	
Rimmel - Volume Flash -Scandal Eyes - mascara - black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate – ingredient list available in store	

Product	Purchase details	Total Viable Aerobic Count (LOR 10 CFU/g)	Ingredient list assessment	Photograph
Natio - lash definition mascara - black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate – ingredient list available in store	
Bourjois Paris - Beauty Full volume - mascara - beauty full black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Inadequate	
Nude by Nature - Mineral Mascara - Onyx	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
Revlon - lashfinder mascara - waterproof - black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Inadequate	
Revlon - Lash Potion by grow luscious - blackest black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Inadequate	

Product	Purchase details	Total Viable Aerobic Count (LOR 10 CFU/g)	Ingredient list assessment	Photograph
Covergirl - lashblast volume - mascara - very black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
Covergirl - Bombshell volume by lashblast mascara - very black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
Covergirl - Clump Crusher by lash blast mascara - very black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	

Product	Purchase details	Total Viable Aerobic Count (LOR 10 CFU/g)	Ingredient list assessment	Photograph
Maybelline - Great Lash Mascara - blackest black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
Maybelline - Volum' Express - the falsies - black drama	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
L'Oreal Paris - Volume Million Lashes - New Generation Volume Mascara - Black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
L'Oreal Paris - Miss Manga - The Secret of Big Manga Eyes - All Black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	

Product	Purchase details	Total Viable Aerobic Count (LOR 10 CFU/g)	Ingredient list assessment	Photograph
Max Factor - False Lash Effect - Clump Defy - Black	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
Max Factor - 2000 Calorie - Black - up to 300% more volume	Priceline Pharmacy, Canberra Centre 23 February 2015	Not detected	Adequate	
Chi Chi - Super Long Lash - Extra Long Length and Natural Volume	Target, Canberra City 10 March 2015	Not detected	Adequate	
Napoleon Perdis - Set - Pasarella Mascara	Target, Canberra City 10 March 2015	Not detected	Inadequate	
BOE Professional Volumising Mascara - extra large brush - Black	Big W, Canberra Centre 10 March 2015	Not detected	Adequate	

Product	Purchase details	Total Viable Aerobic Count (LOR 10 CFU/g)	Ingredient list assessment	Photograph
Face of Australia - impact - full - volumising mascara - blackest black	Big W, Canberra Centre 10 March 2015	Not detected	Inadequate	
Australis - Mega Lash mascara - Black	Big W, Canberra Centre 10 March 2015	Not detected	Inadequate	
Designer Brands - Lash Extensions - Extreme volume and length - Blackest Black - Water Resistant	Price Attack, Canberra Centre 10 March 2015	Not detected	Adequate	
Designer Brands - Showoff - Mascara - brown black	Price Attack, Canberra Centre 10 March 2015	Not detected	Adequate	
Eye of Horus - Goddess Mascara	Muse Beauty Boutique, Canberra Centre 10 March 2015	Not detected	Adequate	

Product	Purchase details	Total Viable Aerobic Count (LOR 10 CFU/g)	Ingredient list assessment	Photograph
Klara - Magic Mascara	Coles Supermarket, Gungahlin 21 March 2015	Not detected	Adequate