Cosmetic microbiology

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Cosmetics and toiletries are in daily use to cleanse, perfume, beautify or decorate the human body. They are mainly applied to the skin or hair, but some, such as toothpastes and mouthwashes, are also used internally. Cosmetics are not intended to permanently alter the physiology of the target organ, although some 'healthcare' products may contain an active substance or make medicinal claims. These include cosmetics that help with conditions such as dandruff, spots and poor gum health. The microbiology of cosmetics is therefore complex due to the wide range of formulations, manufacturing procedures and conditions of consumer use.

Good Manufacturing Practice (GMP) should ensure that products, whilst not necessarily sterile, contain no harmful organisms and that the benign population is of a low and stable order and/or declines over the product lifetime. However, it is still necessary to add chemical preservatives to cosmetics to suppress the proliferation of the micro-organisms which almost inevitably get into them after manufacture. Since micro-organisms are ever-present in the home, especially in warm, moist areas such as bathrooms and kitchens, cosmetics and toiletries are exposed to contamination with both spoilage and potentially hazardous micro-organisms during their use. Although we live in equilibrium with a wide range of microbes, confirmed reports do exist of contaminated cosmetic products causing infections.

Contamination in use

From the moment the product is opened until the consumer discards it, it is subject to constant and variable microbial contamination from the domestic environment and the consumers' hands and body fluids. For example, micro-organisms are readily introduced when fingers are dipped into products. Spillage of water into shampoos or shower preparations and consumers using saliva to remoisten old mascara or 'swigging' from bottles of mouthwashes are unfortunately common sources of potential contamination.

A family-size shampoo can be over 80% water and may be used by several different people over a prolonged period. In a warm, moist environment such as a shower where it is easily contaminated, micro-organisms are very likely to enter the product.

A sun-tan lotion shared by the same family over a two-week holiday is contaminated daily through multiple use and most probably is left for several hours at optimal growth temperatures in the sun, sand and sea. Unfinished at the end of the holiday, it is re-used the following year and the exercise repeated.

Mascara usage represents the ultimate challenge to a cosmetic. Consumers are not likely to store their shampoo in a car glove box, subjected to extreme temperature changes, but this does happen with mascara. Consumers have also been known to apply mascara whilst driving, poking themselves in the eye with the brush in the process and allowing the introduction of microbes. Even more likely is a mascara being stored in a humid bathroom environment where brushes are dropped on the floor and containers are left open to contamination by harmful micro-organisms.

Spoilage

Micro-organisms in the home are adapted to a wide range of environments and can degrade a host of product ingredients. Whilst mouldiness, colour change, frothing, and packaging that bulges, leaks or explodes as a result of gas production are obvious effects of gross contamination, more subtle changes can occur. Shampoos, which necessarily contain surfactants, are particularly susceptible to contamination by water-borne Gram-negative bacteria which may cause, at the very minimum, a visible loss of lathering activity. Active ingredients may also be rendered ineffective.

Other contamination effects may be unpleasant aromas or tastes (yeasts, actinomycetes) and change of tactile effects. Aesthetically unpleasant viscosity changes can occur in cream formulations which may also diminish the performance of the product.

Manufacture

There is widespread exposure to potential contaminants during manufacture, particularly from the raw materials. Water is the most common ingredient and poses obvious problems, but a seemingly innocuous material such as talc can be contaminated with dangerous pathogens. The principles of GMP must always be followed and raw materials, particularly those of natural origin, must be tested for contamination before use and limits of acceptability established. Areas where contamination may be introduced must be identified and controlled. The manufacturing facility offers a unique challenge as no two units are likely to be the same. Adequate Quality Assurance (QA) procedures must be in place to ensure unacceptable levels of contamination are never reached. Effective cleaning and sanitization programmes need to be validated and in place. Finally, people offer an unpredictable challenge. Adequate training must be undertaken and updated as appropriate.

Due to GMP, contamination during actual production is of such a low order that modern cosmetics manufacturing plants can achieve 'absence of micro-organisms'

Activities like having a shower, washing our hair or applying deodorant involve the regular use of cosmetics and toiletries. Brian Perry reveals the incessant battle against microbes that has to be waged by manufacturers to make these products safe.

ABOVE:
A young woman applies her make-up in a bathroom mirror.
PHOTO MARTIN RIEDL/ SCIENCE PHOTO LIBRARY

RIGHT:
A technician at the Christian Dior plant in St Jean de Braye, France, checks the quality of a sample of red lipstick during its manufacture.
PHOTO PASCAL NIETO, JERRICAN/ SCIENCE PHOTO, LIBRARY

BELOW:
The 'made-up' eye of a young woman.
PHOTO ADAM HART-DAVIS/ SCIENCE PHOTO LIBRARY

in almost 100 % of units produced. Manufacturers also aim wherever possible to develop formulations which are incapable of microbial growth.

Once the product is made and packaged the preservative system must be able to withstand the normal microbial challenge. This includes storage and use. Packaging should be designed to minimize the chances of contamination.

Specific organisms in cosmetic products

Organisms commonly isolated from poorly preserved water-based products include *Klebsiella*, *Enterobacter*, *Staphylococcus* and *Bacillus* species, *Pseudomonas*, including *P. aeruginosa*, *Burkholderia cepacia*, *Penicillium* and *Candida albicans*. Gram-negatives are most common and, as they have very diverse metabolic capabilities, can survive in a wide range of environments. They are often introduced through water supplies.

A Japanese study of professional shampoo products in hairdressers found that over 60 % of samples were contaminated with Gram-negatives, including *P. aeruginosa*. This may reflect multiple use, poorly preserved products or the consequences of dilution after purchase. In Denmark 22 % of samples of suncare products in use on a beach contained *Candida* species.

Clinical consequences of contamination

Potential pathogens have been found in cosmetics and toiletries. The more vulnerable members of society – neonates, the elderly, people with debilitating diseases or those undergoing drug therapy – are especially at risk. Contamination of talc with *Clostridium tetani*, infection of neonates with *P. aeruginosa* from contaminated cleansing solution and scalp infection leading to fatality in a granulocytopenic patient from diluted stored shampoo in a hospital beauty salon with *P. aeruginosa* are but three examples. A contaminated hand cream was shown to be the source of septicaemia in an Intensive Therapy Unit.

The eye is particularly vulnerable to infection, especially if it is already damaged or has been injured by the consumer with the cosmetic applicator. Cases of *Pseudomonas*-induced corneal ulceration associated with mascara wand trauma and mascara contamination after multiple use of product have been reported. New mascara is rarely contaminated.

The incidence of such reports has declined in recent years as manufacturing processes have improved and there is better understanding of preservation. Nevertheless, there is still a need for vigilance and good practice.

Principles of product preservation

Product preservation has two functions: one is to inhibit spoilage organisms and the other is to prevent the growth of potential pathogens. None of us would appreciate a cosmetic product with a foul odour, traces of mould or ingredients which had separated/degraded due to microbiological contamination. More importantly, any product which posed a potential health risk would rightly be unacceptable to the public.

Whilst preservatives are selected because they are toxic to micro-organisms, they are also required to be safe for human exposure to the products into which they are incorporated. Whatever the method or ingredient employed, the manufacturer seeks preservation at the lowest level consistent with the inhibition of microbial contamination. This has to maintain product integrity whilst ensuring safety in use for the consumer, repeatedly and for the life of the product.

The preservative efficacy of a formulation cannot be predicted and has to be established by empirical microbial challenge, since the activity of the preservative is dependent on the effect of individual ingredients and the packaging in which it is stored.

Considerable scientific/technical effort and money is invested in reducing the risk of microbial contamination of cosmetics. The manufacturer has the ultimate responsibility for assessing the risk of using an ingredient compared with the potential benefits to be obtained. It is now generally recognized that the incorporation of a preservative system within a product is necessary and should be a primary consideration rather than an afterthought. Ingredients are increasingly selected in conjunction with perceived consumer desires as well as those of the manufacturer and the legislator.

The advent of 'green' and 'natural' products has led to apparent consumer pressure for preservative-free products. Such cosmetics contain multi-functional additives which are not included primarily for their anti-microbial activity and which may only impart partial microbial stability. 'Preservative-free' may result in a reduced ability to prevent contamination with micro-organisms over the anticipated lifetime of a product.

There are currently no internationally agreed standards for microbial preservation of cosmetics owing to the range of organisms, multiplicity of products and diversity of storage conditions.

Microbial limits

Industry has made good progress in producing cosmetics according to guidelines which assure a high safety standard. In attempting to set suitable microbial limits

Further reading

Cosmetics Toiletry & Perfumery Association Ltd (1996). *Microbial Quality Management: CTPA Limits and Guidelines.*

Gray, J.E. & McNamee, P.M. (2000). Preservatives – their role in cosmetic products. *Scientific Review Series*, Munksgaard, Copenhagen.

or standards we are faced with the problem that because of the multiple factors involved it is difficult to define precisely which levels and types of contamination represent a health hazard and which are safe. The Cosmetics, Toiletry & Perfumery Association UK recommends a total viable count of aerobic bacteria, yeast and moulds of less than 100 c.f.u. per gram for eye and baby products, and 1,000 c.f.u. per gram for other products at completion of manufacture. Harmful micro-organisms should not be detectable using standard plate count (SPC) techniques and *P. aeruginosa*, *Staphylococcus aureus* and *C. albicans* are used as indicator organisms.

In setting stricter standards, low levels of micro-organisms below the limit of detection of the SPC can be determined by enrichment testing. If this approach is pursued then the recovery diluent, selective media and the incubation conditions should be selected to promote the growth of the chosen indicator micro-organisms.

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