

# Challenging times for preservation

From a personal care perspective, preservation is the protection of products and raw materials from the effects of bacterial and fungal growth. While this sounds simple enough in practice, selecting the right preservative system can be one of the toughest challenges facing a formulator. It is not sufficient to merely ensure the finished product is sterile or contains an acceptable level of organisms. Further steps must be taken to minimise contamination and spoilage of the product during storage and use.<sup>1</sup>

Spoilage due to inadequate preservation can include loss of viscosity, breakdown of emulsions, colour change, malodor, the production of harmful toxins and potentially skin irritation and disorders. The importance of preservation after the product is placed into the market place is emphasised by the recommendation of setting a date of durability, or period after opening (POA). According to the article 6(1) (c) of the Cosmetic Directive (76/768/EEC) the period of time after opening shall be indicated for all the products which are not single-use products or that cannot lead in case of deterioration to damages to the human health according to article 2 of the same directive. The expiry date of a product is obviously influenced by the preservatives used in the formulation.<sup>2</sup>

To give an idea of the potential scale of contamination, a study by Baird<sup>3</sup> investigated 232 products intended for use on babies and found that 53 of these were contaminated (23%). The study included products which had not been used, products used in the domestic environment, and products used at a maternity ward in a hospital; contamination was found in all three groups. *Staphylococcus* spp. and *Pseudomonas* spp. were among the isolated bacteria.

A preservative is defined as a substance used to protect food, wood etc. against decay, discoloration or spoilage.<sup>4</sup> Although there are many hundreds of chemicals which meet this definition, the cosmetic scientist is restricted by legislation to a limited number of chemistries, and further

still by the level at which these chemistries are allowed to be included in product. In a perfect world we would incorporate a single preservative which possessed broad spectrum activity, efficacy at low concentrations, excellent water solubility, compatibility with all other cosmetic ingredients, no significant odour or colour, pH tolerance, global approval and heat stability. Of course, being perfectly safe, easy to handle and cheap would also be welcome attributes. Unfortunately, at the present time, this material simply does not exist.

Skin itself provides a virulent medium upon which microorganisms can grow so has adapted various defence mechanisms to prevent or inhibit microbial invasion and growth.<sup>5</sup> As always, certain microorganisms have developed ways of circumventing these mechanisms, and while generally innocuous, these can prove dangerous if a person's skin is damaged or the immune system compromised. For example, *Propionibacterium acnes* is a common, usually innocuous, resident of the skin but can, in some cases, contribute to the development of acne.<sup>6</sup> It is also important that any product applied to the skin poses

no threat to the natural system but supports the natural defence mechanisms already in place.

## New approaches

Modern personal care products are becoming increasingly complex and this complexity brings with it further challenges. While some ingredients, such as chelating agents, can boost preservative efficacy, many modern ingredients have a negative effect. Actives and vitamins provide nutrients for growth, nonionic ingredients can inactivate preservatives and powders, such as talc, can absorb them. It is advisable to keep preservative levels as low as possible, so bearing this in mind, many formulations utilise the principals of "Hurdle Technology".<sup>7</sup> Hurdle technology is a term used to describe the intelligent combination of different preservation factors, or hurdles, to deteriorate the growth of microorganisms, a system originally developed in the food industry. This includes good manufacturing practice (eg. water filtration), appropriate packaging (single application if possible), emulsion form (W/O is preferred), low water activity, pH control and using antimicrobial



Testing bacterial and fungal growth.

Courtesy of Lonza



Inadequate preservation can lead to microbial growth and spoilage as can clearly be seen in the two products above.

ingredients (eg. certain essential oils).<sup>8</sup> It can not be stressed too much that the preservative is in the formulation to protect the product during its lifetime and not to remove heavy microbial contamination arising from poor manufacturing, storage and packing procedures. High levels of preservative are to be avoided as the incidence of contact allergy to preservatives is concentration-dependent, so over-preservation may lead to more cases of cosmetic related contact allergy.<sup>9</sup>

### Consumer perception

A growing sector of consumers, fuelled by often ill-informed media reports, have begun to question the safety of certain preservatives leading to products claiming eg. "paraben free" or even completely preservative free. Preservative free products in general use a combination of the hurdle technology mentioned above alongside the inclusion of other multifunctional ingredients, plant essential oils etc., which have an antimicrobial effect but are not listed in Annex VI of the Cosmetic Directive. Many papers have been published showing the efficacy of these materials in cosmetic formulations.<sup>8,10</sup> It should be noted however that the use of the materials in place of more traditional preservative systems does not guarantee the absence of adverse events, irritation or sensitisation.<sup>8</sup>

The oils may have to be used at high concentrations and may contain many different chemical components some of which are highly allergenic.<sup>9</sup> It has also been reported that the risk of adverse effects associated with a preserved product is low as opposed to the risk associated with an unpreserved product which is high, leading to the conclusion that unpreserved topical products should never be used.<sup>11</sup>

More recently there has been a growth

in the interest in natural and organic personal care products, a trend which many have predicted will grow over the next few years.<sup>12</sup> This presents further challenges for formulators as the various standards and certification bodies involved have their own rules detailing which preservatives are permitted and which are not. The Cosmetics Organic Standard (COSMOS) introduced by several different certifying associations, assembled in the Standards Working Group, is addressing the need for a reliable, harmonised standard not only for preservation but also for the labelling of these products. One of the more innovative preservatives which has been used in organic products is Geogard Ultra from Lonza. This preservative, a patented synergistic blend of sodium benzoate and gluconolactone, can be used in all product types as the sole preservative. Cornelius and Lonza have been working with Soil Association Certification Ltd. to explore and develop the idea of an approved list of suppliers and materials which will be accessible to formulators and developers making the selection of materials for products to be certified to the Soil Association standards quicker and simpler.

### Conclusion

In the 21<sup>st</sup> Century, formulators must use all their knowledge of both preservatives and other formulation ingredients to ensure their products are both preserved when they leave the factory and also throughout the products lifetime. Selecting the right preservative system which will not have any incompatibility in their formulation, present broad and long term efficacy and avoid consumer irritation and complaints is a difficult task. Preservative suppliers have a wealth of experience with preservative materials and today's formulators would be

well advised to form partnerships with their suppliers to ensure the optimal system is used and to keep abreast of any new developments and legislation. PC

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