Preservatives in personal care products

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Studies conducted on personal care products (cosmetics) in the 1960s and 1970s found up to 24% of unopened products were contaminated, mainly with Pseudomonads, while up to 49% of used samples were also contaminated. These studies highlighted the need for the incorporation of preservatives into water-based formulations along with improvements to manufacturing practices.

Microbial growth may lead to development of unpleasant odour, perfume and colour changes or variation in viscosity due to degradation of thickening polymers or slime formation. The presence of pathogenic or opportunistic pathogenic organisms may also have public health implications such as causing wound or eye infections from the use of contaminated products. In August 2005, an outbreak of severe nosocomial infections in the intensive care unit at the Universitari del Mar Hospital in Barcelona was caused by the use of moisturising body milk contaminated with *Burkholderia cepacia.*[1]

In the European Union (EU) from 2005 to May 2008 of 173 cosmetics recalled, 24 were due to microbial contamination, with *Pseudomonas aeruginosa* being the most commonly isolated organism. The number of contaminations appears to be increasing each year[2].

Figure 1. Contaminated cream.

Cosmetics are defined as products that are intended to be applied to various surfaces of the human body to cleanse, perfume, protect, change appearance or correct body odour. This covers all products generally considered as cosmetics plus hair shampoo and conditioner, body wash and liquid hand soaps, including antibacterial hand washes, which only claim action against unspecified bacteria. Cosmetics may contain surfactants, proteins, oils, emulsifiers, vitamins, minerals and botanical extracts mixed together with water and presented within a pH range that a vast variety of microorganisms find attractive. For this reason there are many species that are capable of growth in them, and in general it is the water activity of the product that determines if it is susceptible to the growth of microorganisms.

Contamination of cosmetics high in surfactants, such as shampoo and hand and body wash, is generally by Gram-negative bacteria with *Pseudomonas aeruginosa* and *Burkholderia cepacia* being amongst the most commonly isolated. Enterobacteriaceae, such as *Klebsiella pneumoniae* have also been isolated and bacteria tolerant to surface active substances may favour growth in such products.

Creams consist of emulsions of water and oil and are stabilised with emulsifiers. They are prone to contamination with the same bacteria mentioned above, but also with Gram-positive cocci, such as Micrococci and Staphylococci, including *Staphylococcus aureus*. Aerobic spore formers may also be found in these products. As well as the effects listed above, bacteria that produce alcohols or degrade the emulsifiers may lead to instability and splitting of the emulsion.

Visible surface growth is usually caused by moulds which may appear on the product surface but commonly grow on the semi-dried material on the undersides of lids or sides of partly used containers due to their ability to grow in reduced water activity.

Contamination may originate from the raw materials, especially water, factory equipment, packaging materials and also from the end user during use of the cosmetic.

Preservatives

Preservatives, the usual term for biocides used in cosmetics, are

Figure 2. Fungal-contaminated wet wipe.

chemical compounds added to cosmetics to prevent the growth of microorganisms. They are intended to be added to clean products to prevent contamination by consumers while in use. They are not intended to make up for poor production hygiene or the use of contaminated raw materials and should not be used to treat contaminated products.

All preservatives incorporated into personal care products have limitations on the organisms they are active against. They are affected by the physical characteristics of the products they will be incorporated into, and also by the manufacturing processes utilised during production of the finished goods. It is critical to ensure that the preservative selected for a particular product is matched to the physical and chemical requirements of the product and will provide protection against the full spectrum of microorganisms likely to be encountered.

The ideal preservative would have broad-spectrum activity against all microorganisms, be effective at low concentrations, not have any effect on odour or colour, not interact with any other ingredients, have high water solubility and low oil solubility to keep it in the water phase, be stable across the entire pH and temperature spectrum with an unlimited shelf life, be safe to use when concentrated and diluted and have a low cost.

Unfortunately, as no single substance meets all of these requirements, it is common practice to use two or more actives with different modes of action or overlapping activity spectrum, either complementing each other or showing synergistic activity.

Regulations

Ingredients in cosmetics are classed as industrial chemicals in Australia and are regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to enure they are safe for the workers handling them, the environment and for use by consumers. Regulations came into force on 17 September 2007 and introduced a Cosmetics Standard which sets the standards for six cosmetic product categories. NICNAS also released their Cosmetics Guidelines to provide a plain English guide about the legislative requirements that apply to all cosmetics. The amended version was released in December 2008 and both documents are available at the NICNAS website[3].

Neither document contains any specific controls on preservatives that may be used in cosmetics. The Standard for the Uniform Scheduling of Medicines and Poisons (previously the Standard for the Uniform Scheduling of Drugs and Poisons) regulates the retail sale of products containing specified substances and this has been used to effectively ban the use of one preservative, **Methyldibromo Glutaronitrile**, from use in cosmetics following a review of the substance by NICNAS[4,5].

The labelling requirements for cosmetics are regulated by the Australian Competition and Consumer Commission (ASCC) under the *Trade Practices (Consumer Product Information Standard) (Cosmetics) Amendment Regulations 1998*.

The EU developed the Cosmetics Directive, which was adopted in 1976. This directive established regulation for the manufacture and marketing of cosmetics in the EU. A new European Regulation for cosmetics entered into force on 11 January 2010, although the majority of the Regulations provisions will not be enacted until 11 July 2013. The regulation lists preservatives that have been assessed for safety and approved for use in cosmetics in Annex V's (originally Annex VI in the Directive), List of Preservatives Allowed in Cosmetic Products and defines preservatives as "substances which are exclusively or mainly intended to inhibit the development of microorganisms in the cosmetic product". Toxicity data required to be assessed before a preservative can be listed in Annex V are shown in Table 1.

The EU Cosmetic Directive and associated Annexes have been used as the basis for regulations in China (The Hygienic Standard for Cosmetics), ASEAN countries (ASEAN Cosmetics Directive), Korea, (Cosmetics Law 6025) and New Zealand (Cosmetic Group Standard). Australia does not have specific regulations covering the use of preservatives in cosmetics and while some multinational producers may follow American or Japanese regulations, most manufacturers voluntarily follow the EU regulations both in terms of which preservatives they will use, and also on limits imposed on the use of them. Annex V of the EU Cosmetic Regulation lists 55 different preservatives, plus their salts and esters, but only a limited number of these are routinely used. The actives most commonly used are shown in Table 2.

MIC values for cosmetic preservative actives

Table 3 gives an indication of the relative activities of the various actives by listing the minimum inhibitory concentration (MIC) of the actives in parts per million (ppm) against a range of organisms.

Trends in preservatives

As with all consumer products there is currently a trend towards 'natural', 'organic' and even 'chemical-free' cosmetics on the perceived notion that natural substances are safer and more pure than synthetic chemicals. Natural cosmetics require natural preservatives and although there are some natural compounds listed in Annex V, such as the acids and formaldehyde, none are available as purified naturally occurring products, so a number of certifying bodies allow the use of nature identical preservatives to be used until a truly natural alternative can be found. A number of botanical extracts and essential oils have been found to possess antimicrobial activity but none have had the full toxicity assessment required to be listed in Annex V. In most cases they have strong odour or colour and are far more expensive than synthetic actives. In reality, all preservative actives must be toxic to cells to be effective, regardless of whether they

Table 1. Toxicity data required for listed preservatives[6].

Reproductive toxicity	Irritation and corrosivity	Skin sensitisation	Dermal/percutaneous absorption
Acute toxicity	mutagenicity/genotoxicity	carcinogenicity	
Toxicokinetics	photo-induced toxicity	human data	repeated dose toxicity

Table 2. Preservative actives in common use in cosmetics.

Class	Active	Efficacy		
		Bacteria		Fungi
		Gram-positive	Gram-negative	
Phenolic	Parabens (ethyl, methyl, propyl, butyl, isobutyl)	+	-	+
	Phenoxyethanol	+/-	+	+/-
	Benzyl alcohol	+	-	-
Formaldehyde	Formaldehyde	+	+	+/-
Formaldehyde releasing	Imidazolidinyl Urea	+	+	-
	Diazolidinyl Urea	+	+	+/-
	Sodium Hydroxymethylglycinate	+	+	+/-
	Dimethylol Dimethyl Hydantoin (DMDMH)	+	+	+/-
Halogenated	Methylchloroisothiazolinone and methylisothiazolinone(MCI/MI)	+	+	+
	2-Bromo-2-Nitropropane-1, 3-Diol (Bronopol)	+	+	+
	Chlorphenesin	-	-	+
	Iodopropynyl Butylcarbamate (IPBC)	-	-	+
	Triclosan	+	-	-
Non halogen isothiazolinones	Methylisothiazolinone (MI)	+	+	-
	Benzisothiazolinone (BI)	+	+/-	+/-
Organic Acids	Sorbic acid, Benzoic acid, Formic acid	+/-	+/-	+

Table 3. Minimum inhibitory concentration – MIC value (ppm).

Active	*Pseudomonas aeruginosa*	*Staphylococcus aureus*	*Aspergillus niger*	*Candida albicans*
MCI/MI	4	3	4	5
MI	40	30	750	100
BIT	250	40	100	200
MI/BIT	20	30	50	35
IPBC	625	156	10	39
Bronopol	50	50	3200	400
Methyl paraben	2000	1500	1000	1000
Phenoxyethanol	3200	6400	3200	3200
Benzoic acid	160	20	1000	1200
Dihydroacetic acid	>20,000	10,000	200	100
Diazolidinyl Urea	1000	800	3000	>6000

are natural or synthetic. In the meantime, some manufacturers promote their products as being 'preservative-free' on the basis they do not contain a listed preservative, assuming anything not listed in Annex V is not a preservative, just an undisclosed toxic compound usually described as perfume on labels.

Conclusion

Water containing cosmetics are prone to microbial contamination that may render the product unusable or a potential source of infections. The use of preservatives is controlled by regulations in most countries that specify what substances may be used and any limitations on their use. Their correct use coupled with good manufacturing practices provides protection to cosmetics from microbial contamination while ensuring safety for the consumer.

References

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Biography

Kevin Roden is the Regional Technical Manager Asia Pacific, responsible for technical support to the Thor Specialties operating companies in the Asia-Pacific region. Kevin was employed in 1991 by Thor Specialties Limited in the position of Technical Services Manager and established a NATA-accredited Microbiological Testing Laboratory for evaluating the performance of biocides in industrial and personal care products.