International Cooperation on Cosmetics Regulation

# ICCR Working Group on Cosmetic Product Preservation

## General and Technical Frequently Asked Questions (FAQs) on Preservatives in Cosmetics

### Scope and Background

The International Cooperation on Cosmetic Regulation (ICCR) held its eighth annual meeting (ICCR-8) July 8-10, 2014 in Ottawa, Canada[1].

At this meeting, participants raised the observation that there was a general lack of awareness regarding the important role preservatives have in cosmetic products and the potential impact on public health should they be absent. It was concluded that this topic was of high interest and importance to both regulators and industry and should be addressed by the ICCR. Therefore, it was agreed to add a new work item on this issue and to prepare an ICCR report on the role and importance of preservatives for the global cosmetics sector.

The Working Group agreed that the most effective way to raise awareness and inform the various stakeholders about the use of preservatives in cosmetics would be through the development of Frequently Asked Questions (FAQs) available on the ICCR website.

This document provides an accessible and understandable approach to the main topics concerning product preservation, the need for preservatives in cosmetics, and their mode of action.

This document is organized as a FAQ approach targeting two different audiences. The first set of questions is aimed at consumers, whereas the second set is geared toward a more technical audience, or a consumer who is looking for additional information.

The FAQ format facilitates the dissemination of useful information for the general public. The regulatory authorities and industry associations involved in the development of this document may translate it, if needed, and share the information on their respective websites or publications.

[1] A more comprehensive discussion of the outcomes from this and previous meetings may be found on the ICCR website at: http://www.iccrnet.org/chairmanships/.

## Responsibilities

The FAQs were prepared by the following members of the ICCR Cosmetic Product Preservation Joint Working Group:

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# General FAQs

## 1. What are preservatives?

Preservatives are ingredients/substances that have the ability to prevent or decrease microbial growth in a cosmetic. Preservatives protect products from contamination of microorganisms, like bacteria and fungi[2], during storage and use by the consumer. They can prolong the shelf-life of cosmetic products.

## 2. Why are preservatives needed in cosmetics?

Preservatives are present in cosmetics to reduce the risk of microbial contamination of the product and to ensure the product remains suitable and safe during shelf-life and the period of their use by consumers. Without the use of preservatives, cosmetic products - just like food and other products handled directly by consumers - can become contaminated with microorganisms, leading to product spoilage, loss of product performance, and possibly irritation, infections or other adverse health reactions to the consumer.

## 3. Are all preservatives the same?

Preservative ingredients differ widely and so do their ability to preserve a cosmetic product. Preservative ingredients differ as per the range of microorganisms that they are able to control. Some may be effective against bacteria and not fungi; whereas, others may only be effective against fungi.

Some preservative ingredients may work effectively in certain types of cosmetic products because of the chemical properties of the formulation. For example, certain preservatives may only be effective in a formulation where the pH is low, whereas other preservative ingredients work in a broad pH range. Therefore, a wide palette of preservative ingredients is required in order to meet all product formulation needs.

## 4. How is it determined that the preservatives used in cosmetics are safe?

Preservatives must undergo rigorous evaluation, including safety assessments and quality testing, before they are used. Government authorities regulate preservatives to ensure the safety of these ingredients.[3]

In every situation, cosmetic products placed on the market must be safe for use. Thus, all ingredients, including preservatives, must also be safe for the consumer.

## 5. How do manufacturers identify and select the preservatives used in cosmetics?

Many factors are considered when choosing which preservatives to use. These choices are dictated by the products' other ingredients, desired performance, product packaging, part of the body where the product is to be applied, as well as consumer behaviour during use. Preservatives need to be safe, compatible with all ingredients, soluble, and well-dispersed to optimise preservation.

The goal is to use a minimum concentration to obtain optimal efficacy while avoiding any safety issues associated with a particular preservative.

[2] Yeast and mould are examples of fungi.
[3] Please refer to Annex 1 for more information.

Different product types, as well as varying consumer needs, may require the use of different preservatives at varied levels to prevent product contamination and ensure consumer safety. Experience and knowledge of the interaction between preservatives and the other ingredients in a formula is necessary for selecting a successful preservative system. The product formulation and its intended use dictate the types and concentration of preservatives to be used for efficacy purposes.

## 6. What is the cosmetic preservative 'palette' and why is it important to have a wide array of preservative ingredients?

The cosmetic preservative palette describes the spectrum of available ingredients which are able to control the growth of micro-organisms in cosmetic products. A diverse palette of available preservatives is needed to ensure that all product types can be adequately protected from contamination and ensure consumer safety. Different preservatives work in different ways, and consequently, product formulators need access to an array of preservative options to ensure an adequate preservative system for any type of product.

## 7. How are cosmetic products exposed to microorganisms?

Microorganisms thrive in moist, humid, warm, and dark conditions. Many cosmetic products are water-based and are typically stored and used at room temperature in moist and humid household environments (e.g. bathroom), which increases the possibility of contamination. Furthermore, microorganisms can also be introduced into products that are used repeatedly by consumers during application. An example would be skin cream sold in a wide jar and applied with the finger tips.

## 8. How do manufacturers ensure that a product is adequately preserved?

Preservatives have been safely used in cosmetic products for decades. It is the responsibility of product manufacturers to ensure that the preservatives are safe and effective for this use.

In order to determine the effectiveness of the selected preservation system, it is necessary to perform tests at each step of development of the cosmetic formulation, and then again on finished products once filled into the final packages. These tests assure that the product meets regulatory requirements to ensure consumer safety.

## 9. What types of cosmetic products need to contain preservatives?

Cosmetic products with high water content, such as creams and lotions, mascara or liquid eye liner need to contain preservatives to keep them in good condition and safe to use. Products that are self-preserving (i.e. bacteria cannot grow in them due to their composition) do not need preservatives unless there is a likelihood that consumer-use could result in microbial growth. As an example, lipsticks or make-up products that are used repeatedly may support mould growth on the surface if they are formulated without an anti-fungal preservative.

## 10. How products labelled as “natural” or "organic" are preserved?

Regardless of specific marketing claims or designations, or how a product is labelled, all cosmetic products need to be adequately preserved and tested. This is particularly important for products containing water (or 'aqua') included on the product label, as microorganisms thrive under moist conditions.

"Natural" or "organic" cosmetic products are no different and must undergo the same level of testing to ensure that they are adequately preserved and safe for the consumer as any other cosmetic product.

## 11. What would it mean if cosmetic products did not contain preservative ingredients?

Without preservative ingredients, a cosmetic product would pose a risk to the consumer, have a very limited shelf life and would easily spoil. Products with high water content may need to be replaced in a week, or less. Similar to perishable foods, refrigeration might extend the shelf life of unpreserved cosmetics. Even then, product quality could not be guaranteed in many products.

# Technical FAQs

## 12. What are preservatives?

Preservatives are ingredients/substances that are specifically chosen for their properties to prevent microorganisms, like bacteria or mould, from contaminating a cosmetic product, during storage and use by the consumer. Preservatives are added to cosmetic products and many other consumer commodities, such as foods, beverages, or pharmaceuticals to prevent spoilage by microbial growth or by undesirable chemical changes.[4]

## 13. Why are preservatives needed in cosmetics?

Bacteria and fungi are naturally present on our skin, in the air around us, and even in the food and water we eat and drink. Cosmetics contain a certain amount of water, and once opened the exposure of a product to oxygen and variation in temperatures can lead to an environment prone to the growth of bacteria or fungi, which may increase the likelihood of an individual to develop an infection. Such microbial contamination can spoil products by breaking down ingredients, degrading or destroying the intended properties of the product, and may result in health risks to consumers. Therefore, products that are not well preserved could have shortened shelf life and furthermore could put consumers at risk.

## 14. How are the preservatives used in cosmetics determined to be safe?

The determination of safety of the preservative begins with the supplier of the preservative and this extends throughout the development and life cycle of the product. The aim is to use preservatives at low levels whereby the actual level is limited to that which is necessary for effective product preservation and safe use for the consumer. Regulatory authorities closely follow international scientific and regulatory reports to regularly review the safety of cosmetic ingredients.

## 15. What is a preservative system?

A preservative system describes the combination of the unique physical properties of a cosmetic product, its packaging, and the preservative ingredients used in cosmetic formulations to ensure the quality of the product and safety for the consumer. Water activity[5] and pH are two of the most important physical attributes of a cosmetic that form the basis of selecting compatible preservative ingredients. Very high or very low pH tends to inhibit microbial growth but is not often suitable for cosmetic products and the desired consumer benefits. Cosmetic products that are in the neutral range provide an environment which is more susceptible to the survival and to the growth of

[4] Donald S. Orth, *Insights Into Cosmetic Microbiology*. 2010, Allured Business Media.

[5] Water activity or $a_w$ is the partial vapour pressure of water in a substance divided by the standard state partial vapour pressure of water. $a_w$ controls microbial growth and hence as $a_w$ increases, the product becomes more prone to bacterial growth.

microorganisms. Water activity will affect the potential for microbial growth. Finally, how a cosmetic is packaged or intended to be used affects the likelihood of a cosmetic being contaminated during use by the consumer. For example, an open jar of face cream has a higher potential to become contaminated when compared with a lotion that is dispensed through a pump. This is a simplified example of how scientists approach the task of designing preservative systems.

## 16. How do preservatives used in cosmetics work?

Preservative ingredients protect cosmetic products by preventing and controlling the growth or proliferation of microorganisms, like bacteria and fungi, which can be introduced throughout the lifespan of a product during consumer use. These important ingredients are designed to specifically and selectively target various microorganisms.

Preservatives work in two ways. The first is to kill vegetative cells that are present in the cosmetic product at the time of manufacture. This usually occurs by chemical forces that disrupt cell walls or interfere with biochemical pathways. The second is by stopping or reducing growth of microorganisms by creating an environment that does not allow the microorganisms to reproduce or to germinate (in the case of spores).

In minimizing the growth and proliferation of microorganisms, these ingredients play an important role in preventing product spoilage and protect consumers from potential adverse health effects such as skin or eye infections that could result from the contamination of products by such microorganisms.

## 17. How are cosmetic products exposed to microorganisms?

Cosmetic products are exposed to microorganisms in three main ways. First, undesirable microorganisms may be present in some raw materials. Secondly, undesirable microorganisms may be introduced during the manufacturing process. Thirdly, the consumer can introduce microorganisms into cosmetic products during use. For those reasons, control of raw materials, good manufacturing practices and packaging design all play major roles in the design of cosmetic preservative systems.

Microorganisms are ubiquitous in the environment and on the human body and can be introduced into a product at any time throughout the product lifecycle. Microorganisms will feed on an inadequately preserved cosmetic product, ultimately leading to it becoming spoiled, undesirable and unusable. Many cosmetic products are water-based and are typically stored at room temperature and used in environments that are humid and moist (e.g. bathroom), dark, warm, or under conditions where water can be easily introduced into the product. Furthermore, many cosmetic products are designed for multiple/repeated use and as such, microorganisms can be directly introduced into a product during consumer handling or use.

The opportunities for microbial contamination vary greatly depending on the type of cosmetic product, intended use, and specific package design. Therefore, a number of factors are taken into account when assessing and selecting the type of preservative ingredients that will be required to adequately ensure the safety of any given product.

*For example:*

Mascara: Although the chance for microbial contamination may be relatively small, these products are used around sensitive areas such as the eye.

Hair shampoo and conditioner: Higher risk for contamination given that water can be introduced into the product during use while opening the bottle in the shower. Pump bottles and other package designs that keep water from getting into the bottle reduce the risk of contamination.

Face cream in an open jar: Consumers will dip their fingers into a product every time it is used. This habit results in the potential introduction of microorganisms into the product during every application of use.

## 18. What happens if a product is inadequately preserved?

If a product is inadequately preserved, it could undergo changes in appearance and smell or it may separate out into different layers. However, microorganisms present in products may remain unnoticed. The consumer may not be able to determine if a product is adequately preserved or not. Manufacturers validate the effectiveness of preservative systems prior to marketing a product; if a product fails this test, it is not placed on the market.

## 19. How are products labelled as “natural” or "organic" preserved?

Irrespective of any marketing claims or designations or the labelling of a product as "natural" or "organic", product manufacturers must undertake testing to ensure that a product is adequately protected from microbial contamination.

For naturally sourced or "organic" raw materials, the same considerations apply as for synthetic materials to ensure the product is safe when used as directed.

All cosmetic products, regardless of their claim or brand positioning, are required to undergo the same degree of scrutiny and assessment by product manufacturers to ensure that a product is adequately preserved.

## 20. What would it mean if cosmetic products did not contain preservatives?

Without preservatives, cosmetics would have a very limited shelf life, would spoil quickly, or at a minimum, would need to be stored in refrigerators or be packaged in single-use applications. Installing refrigerators in bathrooms and showers, of course, would not be practical, and, from an environmental sustainability perspective, the amount of waste that would be generated from single-use packaging would be astronomical. Additionally, the potential microbial contamination of the cosmetic could lead to skin or eye infections or irritations.

# ANNEX – Documents on Cosmetic Products

## European Union:

http://ec.europa.eu/growth/sectors/cosmetics/legislation/index_en.htm

**EU Cosmetics Regulation (including Annex V: List of preservatives allowed in cosmetic products)**
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

## Brazil:

http://portal.anvisa.gov.br/wps/wcm/connect/2222a4804fe2aa099430fcece77a031c/Resolu%C3%A7%C3%A3o+RDC+n%C2%BA+19+de+11+de+abril+de+2013.pdf?MOD=AJPERES

http://portal.anvisa.gov.br/wps/wcm/connect/2569e7004c58f11fb8e7f8dc39d59d3e/Resolu%C3%A7%C3%A3o+RDC+N%C2%BA+29%2C+de+1%C2%BA+de+junho+de++2012.pdf?MOD=AJPERES

http://portal.anvisa.gov.br/wps/wcm/connect/82f733004aee4c53b7cebfa337abae9d/Resolu%C3%A7%C3%A3o+RDC+n%C2%BA+481+de+27+de+setembro+de+1999.pdf?MOD=AJPERES

http://portal.anvisa.gov.br/wps/wcm/connect/523f6980486e9bb7bed8bf734e60b39c/RDC+N%C2%BA+15%2C+DE+24+DE+ABRIL+DE+2015.pdf?MOD=AJPERES

**Norms**
http://www.abntcatalogo.com.br/norma.aspx?ID=1198

http://www.abntcatalogo.com.br/norma.aspx?ID=1213

http://www.abntcatalogo.com.br/norma.aspx?ID=1164

http://www.abntcatalogo.com.br/norma.aspx?ID=1151

http://www.abntcatalogo.com.br/norma.aspx?ID=1156

http://portal.anvisa.gov.br/wps/wcm/connect/92f15c004e219a73a96dbbc09d49251b/Guia_cosmeticos_grafica_final.pdf?MOD=AJPERES

https://www.abihpec.org.br/en/2015/07/guia-de-microbiologia/

https://www.abihpec.org.br/en/2015/07/manual-higiene-e-limpeza/

## USA:

http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073598.htm

http://www.fda.gov/Cosmetics/GuidanceRegulation/default.htm

http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVICosmetics/default.htm

http://www.fda.gov/RegulatoryInformation/Legislation/ucm148722.htm

http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm126613.htm

## Canada:

**Consumer Product Safety Program - Cosmetics**
http://www.hc-sc.gc.ca/cps-spc/cosmet-person/index-eng.php

**Food and Drugs Act**
http://laws-lois.justice.gc.ca/eng/acts/F-27/page-5.html#h-7

**Cosmetic Regulations**
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._869/index.html

## Japan:

**Pharmaceuticals and Medical Devices Agency**
http://www.pmda.go.jp/english/

**Standards for Cosmetics**
http://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/0000032704.pdf