Cosmetic preservation: what it should be and what it is

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I am quite new in the Cosmetics field, few years of experience only, all focused on preservation. Ever since the beginning of this interesting and fascinating experience, I felt the responsibility of my small drop in the ocean: the value of cosmetics proper preservation. Like some years ago, the cosmetic preservation is still facing what experts define a "crisis period". I do believe it is time to bring back the attention to the importance of a safe, effective and economically sustainable preservations. The topic will be deepened in a four articles path, proposed by H&PC Journal during 2018: first, a picture of worldwide preservation state of the art, then possible consequences of inaccurate preservation; together with this, new challenging marketing messages, in light of end users' perceptions and knowledge of cosmetic market. Finally, support to formulators: some suggestion for a safe and successful 3.0 product.

PRINCIPLES OF COSMETIC PRESERVATION

The majority of cosmetic formulas copes with microbial contamination nightmare. Goods spoilage can be caused by several factors: skin microflora, usage of the product, certain formula raw materials, hygienic condition of the production plan, etc. In cases where the application of *Hurdle Technology (*eg high process and/or low storage temperature, acidity increase, water activity and/or redox potential reduction, selection of specific packaging type, etc.) (1) cannot secure microbial safety, here come preservatives! Preservatives are natural or synthetic ingredients designed to ensure the safety and quality of products by protecting them against the growth of microorganisms during storage and consumers use (2).

Preservatives efficacy lies in their activity against cells, this is the base of preservatives' antimicrobial action. As a consequence, great concern arises about their potential adverse activity against eukaryotic cells as well. This is one of the reasons putting constantly preservatives under the microscope. Hence, cosmetic formulators daily face a challenging issue: protecting the formula from microbial infection, likewise guaranteeing its safety. The key to success is an effective, safe and economically sustainable preservative system. How to find it?
The "perfect preservative system" has to be selected according to scientific and ethic criteria. First: ingredient quality can make the difference! Purest molecules allow good efficacy, lowering the dosage; at the same time purer often means safer. Second: union makes strength! It is well known that synergistic effects can occur between preservatives and other cosmetic ingredients; thanks to these effects it is easier to reach a broad spectrum of microbial protection, while decreasing the amount of needed preservative. Finally, quantity counts! In preservation, the tendency "as much as I can" is quite common, but totally no sense: the right dosage, as it happens for other cosmetic ingredients (eg perfumes, UV filters, surfactants) has to be decided following experimental evidence of efficacy.

PRESERVATION TODAY: A POSTCARD FROM EUROPE

In Europe, safety of cosmetics is guaranteed by Cosmetic Regulation 1223/2009. It includes a positive list of authorized preservatives (Annex V), which is composed of 57 actives and gives instructions and limits for a safe and effective use. In this context, the SCCS (Scientific Committee on Consumer Safety) supports the European Commission by providing risk assessments and scientific advices on cosmetic ingredients, including preservatives (3).

If we move from this regulatory framework to European cosmetic market, we face what experts have defined "preservation crisis": several factors have caused the decrease of accessible and usable molecules to preserve cosmetic formulas. Great pressure comes from the use of *Free From* marketing claims, often unfair and denigrating preservatives.

Additionally, regulatory restrictions/bans together with the classification of certain preservatives as carcinogenic, mutagenic, or toxic for reproduction (CMR). Another example is the non-scientific based marketing demonization of certain preservatives: parabens are a glaring example! According to EFfCI data, among the 57 active entries of Annex V, only 9 remain available for the preservation of the whole Cosmetic formulas (4).

Safety of cosmetics seems to be in danger. Is it still a key parameter for the formulation and marketing of cosmetics?

The question is particularly interesting if referred to the entire cosmetic world. In 2016, Europe registered a cosmetic consumption of 77 bn €; If compared to US (64 bn €) and China (41 bn €) (5), the old continent reaffirms its solidity and leadership. In addition, analysing finished products launched globally in the past three years, we count five European countries in the top 10 of Cosmetics producers (6). In brief, Europe is the global flagship producer of Cosmetics. Therefore, it is reasonable to assume that cosmetic trends raising in the old continent influence the rest of the world.

	Europe	US	APAC region (Main Cosmetic Markets)			
			Australia	China	Japan	Korea
Reference Cosmetic Legislation	Regulation (EC) No 1223/2009	FD&C Act, United States Code, Title 21	Cosmetics Standard 2007 NICNAS Cosmetic Guidelines 2007 Poison Standard	Safety and Technical Standard for Cosmetics	Standards for Cosmetics (Ministry of Health and Welfare Notification No.331 of 2000)	KFDA Notification No. 2013-2 as of 16 January, 2013 "Regulation on Safety Standards of Cosmetics"
Preservative Positive List	Annex V	/	/ cosmetic ingredients have to be listed in Australian Inventory of Chemical Substances (AICS)	List 4 Allowed preservatives in cosmetic products	Appendix 3 and 4	Annex 2 Restrictive ingredients used in cosmetics, disinfectants and preservatives
Legislator Technical Support	Scientific Commitee on Consumer Safety (SCCS)	-U.S. Food and Drug Administration (FDA); -Personal Care Products Council (PCPC) -Cosmetic Ingredient Review (CIR)	National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	China Food and Drug Administration (CFDA)	Ministry of Labour Health and Welfare (MLHW)	-Korean Food and Drug Administration (KFDA) -Cosmetic Review Division and Cosmetic Policy Division

Table1. Personal Care Preservative Regulatory Framework EU, US and APAC region (ROELMI data).

PRESERVATION MARKETS IN COMPARISON: EU, US AND APAC REGION

In order to understand if, globally, cosmetic products safety, achieved through a proper preservation, is still a key parameter, an analysis on preservation trends in Europe, US and APAC region has been carried out (7). Whilst preservative regulation differs from one region to the other (Table 1), preservation trends interestingly look similar.

The percentage of preserved products, on the total launched in the three regions, has remained constant over the past ten years: around 35 to 40% in EU and US, over 40% in the APAC region. All three markets are definitely driven by *colour cosmetics* (lower need of preservation).

	2009 - 2011	2012 - 2014	2015 - 2017
Europe	47.3% Phenoxyethanol	50.3% Phenoxyethanol	50.4% Phenoxyethanol
	34.2% Methylparaben	28.9% Sodium Benzoate	34.3% Sodium Benzoate
	26.2% Propylparaben	21.8% Benzyl alcohol	24.7% Benzyl alcohol
	22.7% Sodium Benzoate	21.2% Potassium Sorbate	24.4% Potassium Sorbate
	19.8% Benzyl alcohol	17.3% Methylparaben	10.6% Methylparaben
US	46.9% Phenoxyethanol	50.8% Phenoxyethanol	58.7% Phenoxyethanol
	29.6% Methylparaben	18.0% Potassium Sorbate	20.2% Sodium Benzoate
	23.8% Propylparaben	17.1% Methylparaben	19.4% Potassium Sorbate
	13.6% Potassium Sorbate	16.5% Benzyl alcohol	18.1% Benzyl alcohol
	13.5% Benzyl alcohol	16.3% Sodium Benzoate	12.6% CIT-MIT
APAC region	42.9% Methylparaben	45.5% Phenoxyethanol	51.7% Phenoxyethanol
	39.5% Phenoxyethanol	33.8% Methylparaben	27.1% Methylparaben
	27.3% Propylparaben	20.1% Propylparaben	18.2% Sodium Benzoate
	12.7% CIT-MIT	14.9% CIT-MIT	15.5% Propylparaben
	11.1% Ethylparaben	14.2% Sodium Benzoate	12.3% CIT-MIT

Table2. Percentage of finished products containing Preservative on the total preserved products (HBBS SA Data).

Focusing on the TOP 5 preservatives, we see equivalent trends in Europe and US: ten years ago (2009/2011) Phenoxyethanol was used in nearly 50% of preserved formulas, immediately followed by Parabens (Methyl- and Proplyl- respectively). Starting from 2012, parabens collapse in favour of Organic Salts (Sodium Benzoate and Potassium Sorbate) and Benzyl Alcohol (Table 2).

Regarding APAC region, Parabens were on top, followed by Phenoxyethanol and Isothiazolinones (2009-2011); Nowadays trends see Phenoxyethanol on top, Parabens decreased, and emerging use of Sodium Benzoate (Table 2).

The analysis of marketing claims used in finished products reflects trends in preservation just described: ten years ago 10.9% of all finished products launched in Europe were claimed "*Paraben Free*"; in recent years (2012-2017) this number has increased up to 15%, bringing the "*Paraben Free*" in the TOP 10 of the most used cosmetic claims.

Data are even more representative in US, where "*Paraben free*" is in the top 10 of the most used claims ever since 10 years, increasing from 14.6% (2009-2011) up to nearly 23% (2015 – 2017).

As for APAC region, "*Paraben Free*" claim is not that trendy, even though its use in finished products has more than doubled in the past 10 years: 4.0% (2009-2011) up to 8.3% (2015-2017).

The increasing use of *multifunctionals* is another trend in preservation we have analysed. Multifunctionals are cosmetic ingredients with interesting antimicrobial performances. They do not belong to Annex V of EU Cosmetic Regulation, therefore, they are not subjected to restriction.

To demonstrate the remarkable increased use of this class of ingredients, we have focused on Caprylyl Glycol and Ethylhexylglycerin. In EU and US, their use has nearly doubled in the past ten year; in the APAC region we face a notable increase as well (Table 3).

		2009-2011	2012-2014	2015-2017
Europe	*Caprylyl Glycol*	4.5%	6.4%	8.0%
	Ethylhexylglycerin	3.4%	5.5%	7.4%
US	*Caprylyl Glycol*	6.6%	8.5%	10.0%
	Ethylhexylglycerin	4.0%	6.4%	8.4%
APAC region	*Caprylyl Glycol*	2.9%	3.6%	3.6%
	Ethylhexylglycerin	2.2%	2.8%	3.1%

Table 3. Percentage of finished products containing Multifuntionals on the total (HBBS SA Data).

Reported data show that, over the past ten years, the type of molecules used to preserve cosmetics has changed; all emerging molecules seem characterized by limitations: the pH dependence activity of organic salts is well established, Benzyl Alcohol is commonly known to behave as allergen (8) and *multifunctionals* are not preservatives, they can be good enhancers, but they should not substitute preservatives.

It is clear that the cosmetic field is facing a decrease of available preservative choice and, globally, a restricted number of molecules is used to preserve a much bigger variety of cosmetics. We work in a field where safety should be the first parameter for placing products on the market; nevertheless, ingredients as fundamental as preservatives are constantly under attack. On this basis, what is the future for cosmetics safety?

REFERENCES AND NOTES

1. New Methods of Food Preservation By Grahame W. Gould
2. http://www.cosmeticsinfo.org/ingredient/preservative-ingredients
3. EU regulatory framework for preservatives in cosmetic products EFfCI Annual Conference 19-20 October 2016, Potsdam - Petra Leroy □adová, DG GROWTH, European Commission
4. Preservatives Update, and Free-From Claims - Ian Watt, Dow Microbial Control, Chair Preservatives Working Group EFfCI. Annual Conference, October 11th 2017
5. Beauty Trend Watch, Cosmetica Italia – December 2017
6. HBBS SA Data – January 2018
7. HBBS SA Data – January 2018
8. Listed in Annex III – entry 45 of European Cosmetic Regulation 1223/2009 as substance potentially cause of allergic reactions ■