

The foundation of Cosmetics innovation are formula safety and stability

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"Would you ever buy a car without seat belts, airbag or ABS system?" this is what I recently answered to my dear cousin, who was pushing me to buy her new discovery: a super innovative, double phases face cream, "It is also paraben free!" she told me, not knowing the effect that these last words would have had upon me! I was thinking about different markets from the cosmetic one, and here what I saw: in our daily life, safety of products we choose is usually one of the key parameters for the selection of the right product, and this becomes a successful marketing tool for the related industry. Let's think about the automotive: in the history of this sector, many security systems have been introduced as car optional, bringing the vehicle to a superior premium class, if compared to competitors (airbag system is an example). Hopefully, many of these car safety tools became legally binding, and thus accessible to all customers. What about cosmetics? The impression is that nowadays opposite trends are driving the Personal Care market, where product safety seems to be undermined: whilst preservatives should be the guardian of formula safety, they are actually perceived as nasty ingredients; *Preservative-free* has incredibly become an appealing marketing tool. What is happening? For sure we wouldn't drive a car claimed "*Seat belts free*", we want to feel safe on our four-wheeled-second-house, we spend a lot of time on it, less in any case than the time cosmetics are on our skin...So why are we demonizing cosmetic safety tools like preservatives? What has happened to our idea of protection?

DID YOU KNOW THAT ...? UNDESIRABLE CONSEQUENCES OF INACCURATE PRESERVATION

Inaccurate product preservation, causing microbial spoilage of the formula, can lead to a number of undesired effects; from damages to producers' reputation, to more serious problems, such as adverse effects on the end user.

Perhaps it is not known that the number of recalls of cosmetics in EU, due to microbial contamination, doubled between 2014 and 2016 (1).



Going into detail, we have analysed the past 14 years reporting of the *European Commission, Rapid Alert System for dangerous non-food products (RAPEX)*. Generally speaking, cosmetics have been constantly present in the list of notified products. In particular, the number of notifications, due to microbiological risk, has increased by 20% in the past four years, if compared to the period 2010-2013. Enlarging 2017 data, cosmetics were in the top 3 of most notified products class in several EU member states (e.g. Germany, Estonia, Portugal, Slovenia and Finland); interestingly, in Italy, 23% of all received notifications (not only cosmetics) were due to microbiological risk (2). If we quickly take a look at the situation in US, thanks to FDA weekly enforcement reports, we have 645 microbiologically-related recalls over the period 2004-2011. Among the non-sterile recalls (22%), approximately 1/3 were due to cosmetics and soaps (3). It is evident that a product recall from the market corresponds to the worst business card for every company. But, please, it is not just a matter of reputation! The major problem, potentially caused by spoiled cosmetics, lies in the number of diseases that this can stimulate in end users.

Unfortunately, in some cases, there are no obvious changes in microbiologically contaminated products, thus it is possible that consumers keep on using contaminated cosmetics. Microorganisms responsible for cosmetic contamination cover the whole microbial spectrum, from Gram positive and negative bacteria, to yeasts and moulds, all these are potentially cause of skin diseases. Aspergillosis, caused by the mould *A. brasiliensis*, is only one of the possible examples, followed by various skin candidiasis linked to *Candida* and related yeasts (some of the readers maybe have suffered from athlete's foot, vaginal yeast infection or nail fungus), bacterial conjunctivitis and the highly contagious infections caused by *Staphylococcus* species (folliculitis, carbuncles and toxic epidermal necrolysis are some examples). There are numbers of reported cases, characterized by various degree of gravity, where domestic, professional and even hospital contaminated products were sources of problematic reactions. Microbial contamination can provoke skin and eye recoverable diseases (for instance bacterial corneal ulcer developed after minor corneal trauma with contaminated mascara applicator (4)). In extreme cases, the repeated

use of contaminated products turned into human death: it is upsetting the case of new born babies' infections caused by the hospital use of a contaminated shampoo, which, in the worst case, caused a baby death from meningitis and septicemia (5). Isn't it crazy to die for a contaminated product, and, at the same time, keep buying cosmetics claimed "preservative free"?

Did you know that it is possible to die because of water? It has been reported that drinking more than 5 litres of water in few hours can lead to human death (7). It is extreme, of course, but it epitomizes the dose dependent effect of *all* molecules:



we tend to consider toxic only very hazardous synthetic chemicals; actually, every molecule is potentially toxic: it is all about concentration! This is also valid for preservatives, and overexposure is a possible adverse effect related to inaccurate preservation: trying to avoid formula contamination and following a totally non-scientific approach, some producers adopt the "as much as it is permitted" method when dosing the preservative system, not considering that preservative effect is dose dependent. Preservative excess is not only a waste, but also a putative source of additional problems; at the same time, it is well recognized that a restricted number of molecules is nowadays used to preserve a much bigger variety of cosmetics (6). As a result, the final consumer is in potential danger of overexposure to some preservatives, because of their overdosing, as well as the cumulative effect caused by the use of multiple products containing the same preservative. Hence, the overexposure to non-risky cosmetic ingredients can turn innocuous substances into problematic ones. Methylisothiazolinone can be considered an example: personal care, household products and paints are potential sources of consumers' exposure to this preservative, responsible for a significant increase of allergic contact dermatitis in recent years (8). The overexposure issue, is not only related to preservatives: a recent publication, for instance, revealed allergic contact dermatitis caused by Argan Oil (9), well known in the cosmetic market, as a multifunctional natural ingredient.

No need to panic! All personal care ingredients, regulated and admitted by the European Cosmetic Regulation 1223/2009, are safe under intended condition of use; it is evident that overexposure to some of them can become problematic.

BASICS STARTING POINT FOR ACHIEVING SUCCESSFUL COSMETICS: PROPER PRESERVATION

When developing a new cosmetic, the selection of a suitable, safe and effective preservative system should be one of

the basics step. All major advanced engineering mega-buildings have to start from the foundations; similarly, in order to develop innovative cosmetics, it is essential to start with a stable and safe formula, before adding inventive and unique functional and active ingredients.



By following simple suggestions, it is easy to adopt a safe, effective and economically sustainable Preservative system, avoiding all risks related to inaccurate preservation. First: it is important to focus on the molecules quality to obtain good efficacy by lowering its dosage; second: synergistic combination can help in boosting preservation efficacy by reducing the dosage and last, but not list, dosages: preservative efficacy is dose-dependent, let's think about it when formulating!

WHY NOT BET ON POSITIVE COMMUNICATION? SAFE MEANS SUCCESSFUL!

We have realized how important is to properly preserve cosmetics, in order to avoid all risks related to product spoilage or overexposure. We know that a correctly preserved product is a safe product to be used. Let's think about communication: maybe positive messages about preservatives, as guardian of cosmetics safety, can be the key of success, as it happens in other markets: If you wouldn't buy a car claimed "Seat-belts free", would you ever buy a cosmetic "safety free"?

Starting from July next year, it will be not possible anymore to use misleading *free-of* marketing claims; it is the right moment to communicate something more, instead of less: what about having safe preservation in the spotlights? Not stressing anymore on their absence, but claiming preservative's secure presence in the formula. Customers would be happy to know that the product they put on their skin has been properly protected and preserved, avoiding any type of adverse effects for their health!

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