Wrong cosmetic preservation and related adverse effects

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In our previous article (Pellegrino M., "The importance of personal care preservation" – Jan/April) we spoke about the importance of preservatives use in Personal Care products. Preservatives are substances added to a finished formulation to prevent microbial spoilage in it. Many cosmetics contain water and other ingredients that can constitute nutrients for bacteria and fungi; to avoid the contamination risk, it is essential to protect the formulation, and here the Annex V of the European Cosmetic Regulation 1223/2009 comes in help. The annex provides a detailed list of all admitted preservatives, together with indications on how to use them, in order to maintain the formula protected from microbes and safe to be used.

Despite the above, personal care preservatives have been under a negative and not-scientifically based marketing pressure. A clear example of this sort of preservatives demonization is the use of the claim *Preservatives free*, which is now banned from finished cosmetic products. The adverse marketing pressure against preservatives is not only no sense from a scientific and technical point of view, even worst it can be also dangerous in regards to finished products safety, that actually should be the first parameter when releasing a cosmetic product on the market. This article is meant to briefly introduce potential adverse effects related to inaccurate product preservation.

UNDESIRABLE CONSEQUENCES OF INACCURATE PRESERVATION

It can happen that preservatives are wrongly dosed in a finished Personal Care product; in other cases, the choice of suitable molecules from Annex V is not correct (the molecule could be not stable in the formula, it could not work at a specific pH values, the molecule could

not properly solubilize and disperse in the formulation, …); it can also happen that some formulators try to substitute preservatives with other ingredients not belonging to Annex V, but supposed to have a similar effect. These are all examples of inaccurate product preservation. The choice of a suitable preservative system should be always based on experimental trials and good knowledge of the formulation and of ingredients compatibility. Inaccurate preservation can be the cause of finished product spoilage and contamination. The presence of bacteria and fungi infecting the product can lead to a number of undesired effects: first, from formulative point of view, the formulation can lose its original texture and organoleptic properties can change, becoming unpleasant in some cases. This would be doubtless a considerable bad reputation for the producer. Nevertheless, in some cases, even if the product is contaminated by microbes, it is not visible to the naked eye. This translates in a danger for the end user, because the application of a spoiled product could cause adverse health effects.

Perhaps it is not known that the number of recalls of cosmetics in EU, due to microbial contamination, doubled between 2014 and 2016 (1). A research made in 2018 on RAPEX (European Commission, Rapid Alert System for dangerous non-food products) revealed how the number of notifications, due to microbiological risk, has increased by 20% in the years 2014-2017, if compared to the period 2010-2013; in addition to this, cosmetics were in the top 3 of most notified products class in several EU member states (2).

Regarding US market, 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).

Products' recall from the market surely corresponds to a damaged reputation for the producer. Nevertheless, as stated above, what is even more risky is the fact that a spoiled finished product could cause number of diseases in end users.

When there are no apparent changes in microbiologically contaminated products, it is possible that consumers keep on using them. Microorganisms responsible for cosmetic contamination cover the whole microbial spectrum, from Gram positive and negative bacteria, to yeasts and moulds; they are all potential 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; bacterial conjunctivitis and the highly contagious infections caused by *Staphylococcus* species (folliculitis, carbuncles and toxic epidermal necrolysis are some examples) are other 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).

INACCURATE PRESERVATION SOMETIMES MEANS OVEREXPOSURE

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 (6). 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 all depends on concentration. This toxicological basic principle 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 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 caused by the overexposure: bacteria overexposed to

some chemicals may develop resistance, while consumers may develop skin problems. 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 (7). The overexposure issue, is not only related to preservatives: a recent publication, for instance, revealed allergic contact dermatitis caused by Argan Oil (8), well known in the cosmetic market, as a multifunctional natural ingredient.

PROPER PRESERVATION MEANS SAFE

The European Cosmetic Regulation 1223/2009 imposes safety of finished cosmetic products as a key parameter before the release on the market. Preservation of the formulation is a crucial step during the formulation process, to avoid microbial spoilage and prevent the product to get contaminated with all potential adverse effects here reported.

Would you ever drive a car with no safety belts on? Would you ever go on holyday leaving your home with the door and windows open? We are used to protect what we hold dear, ourselves, families and dears. In the same way, the use of Personal Care preservatives protects the cosmetic formulations, preventing as much as possible microbial spoilage. It is fundamental that the product we decide to use, before working on our appearance, is safe for our skin. Luckily, the Personal Care field can count on good guardians as preservatives! They work to guarantee us safe and effective cosmetics.

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