Personal Care Preservatives and Biocides:

are we judging the book by its cover?

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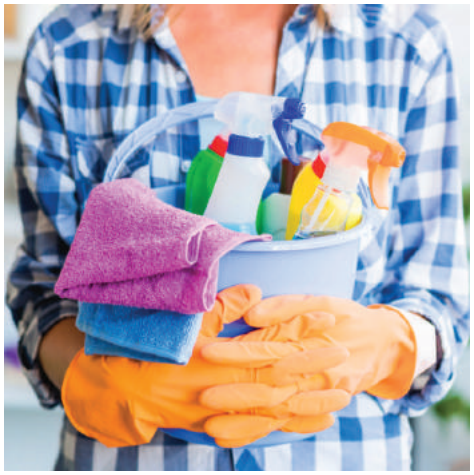
If it is true that our body is home for our soul, it is equally true that buildings we live and we work in become home for our lives. In my job, I deal with personal care products, and I do know how much consumers invest in their personal care (Cosmetic is a market sector under constant increase) (1). In my daily life, I also deal with household cleaning; as a consumer, what I have noticed is the increasing number of products and shops fully dedicated to house care and washing. Therefore, I assume that this sector is under a positive trend too; this is also confirmed by both Italian and European market data (2). Technically speaking, one of the crucial steps during the Personal Care formulation process is the preservation of the formula, fundamental to maintain the product integrity during its entire shelf life. On the other hand, I guess this is also the case of household products, which need the same level of protection from microbial contamination. In the personal care industry, ingredients approved to be used as prevention of microbial spoilage are ***Preservatives***, whereas in the household industry the same function is entrusted to ***Biocides***. Preservatives and Biocides… apparently, are very similar type of ingredients, with analogous efficacy and targets, but… Are they really so close? To answer this question, we have decided to compare Personal Care Preservatives to Biocides, starting from key points resumed in Table 1.



By analysing the table, what immediately stands out is the difference in terms of definition, application and targets: if Preservatives are ingredients exclusively used to prevent microbial (bacteria, yeasts, moulds) spoilage in cosmetic raw materials and finished products, Biocides have multiple scopes and targets: they can be both chemical substances and microorganisms used to destroy, deter, render harmless, or exert a controlling effect on any harmful organism (not only microorganisms); furthermore, it is important to distinguish biocidal active substances from biocidal products: the first ones mostly include chemical compounds, but can also be microorganisms; biocidal products contain one or more active substances and may contain other non-active co-formulants to ensure effectiveness.

The above mentioned difference in complexity between Preservatives and Biocides, obviously reflects not only in their definition, but also in the reference Legislation controlling these ingredients, in the procedures for their approval/authorization, as well as in the process that we will call "post-approval safety evaluation". First, referring to the **regulatory framework**, on one hand we have Personal Care Preservatives, whose regulation is limited to one of the annexes (Annex V) of the European Cosmetic Regulation 1223/2009; on the other hand, an entire Regulation (BPR 528/2018 + SMI) is dedicated in Europe to the approval, placing on the market and use of Biocidal Products and Active Substances. Second, regarding **authorization/approval**, procedures are completely different: if one would ask for the approval of a substance as new candidate in the Annex V of Cosmetic Regulation, he would discover that none of CPR articles defines the procedure for new Preservatives approval: on this issue the Cosmetic field relies on *SCCS Notes of Guidance* (3), complaining about some critical points that seem to limit the possibility for new preservative authorisation. Biocides approval is for sure a more complicated process, including two steps (1 -Active substance 2- Biocide product approval), which are regulated in Annex II and Annex III respectively of BPR; moreover, the approval of Biocides and Active Substances does not work at European level (as it is for Preservatives), but at single Member State level, and can vary from one to another.

Despite a dedicated and defined regulatory framework for new Active Substances/Biocides authorisation, also this process presents critical issues which are complained by the insiders, such as relevant economic investments, which leads to a limited Scientific Research in this fields; in addition to this, timelines for new substances approval is considered

as too long. The encountered difficulties in both fields reflects in the poor number of new Preservatives/Biocides approved and released in the market in recent years. Last, but not least, we think it is pertinent to discuss the existing difference in the process of **surveillance after the approval** of new Preservative/Biocides: in the Personal Care area it is only limited to specific requests of product safety assessment, that are generally submitted to the European Commission by relevant stakeholders (Member States, National Associations or Institutes); this assessment generally implies a *call of data* and subsequent evaluation, both performed by an impartial scientific committee (SCCS). For what concerns Biocides and Active Substances, their authorisation is time-limited (it lasts from 5 to a maximum of 10 years), after this period, a renewal procedure is needed.

TOPIC	PERSONAL CARE PRESERVATIVES Cosmetic Product Regulation	BIOCIDES Biocide Product Regulation
Definition	**Preservatives** means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product	**Biocidal product** means Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action; Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action; A treated article that has a primary biocidal function shall be considered a biocidal product
Field of application	Personal care raw materials and finished products;	Biocides and Treated Articles (means any *substance*, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products)
Target	Avoid microbial spoilage into raw materials and finished formula through inhibition of possible microorganisms growth (bacteria, yeasts and moulds)	**Disinfectants** (Human hygiene purposes, surfaces, materials, equipment and furniture, air, water not used for human or animal consumption, algaecides, textiles, tissues, masks and paints, Veterinary hygiene, Food and feed for humans and animals, Drinking water (both humans and animals); **Preservatives** (to prevent microbial and algal development of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices, rodenticide, insecticide or other baits (during storage and use) of films, coatings, paints, plastics, sealants, wall adhesives, binders, papers, art works, of wood (from organisms, including insects), of fibrous or polymerised materials, of masonry, composite materials, construction material, of liquids used in cooling and processing systems, of materials, equipment and structures, used in industrial processes (from slime growth), of fluids used for working or cutting metal, glass or other materials. **Pest control** (Rodenticides, Avicides, Molluscicides, vermicides, products to control other invertebrates not covered by other product-types, Piscicides, Insecticides, acaricides, products to control other arthropods, Repellents and attractants to control harmful organisms, other vertebrates **Other biocidal products** (Antifouling products, Embalming and taxidermist fluids)
Reference Legislation	REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on Cosmetic Products (CPR)	REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR) + SMI (*Subsequent Modifications and Insertions*)
Reference Authorities	European Commission; Member States; SCCS (Scientific Committee on Consumers Safety)	European Commission; Member States; ECHA (European Chemical Agency)
Procedure for new Preservative / Biocide approval	The procedure for inclusion of new substances into Annex V of CPR has to follow SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION Weak points of the procedure: - Animal Testing Ban and difficulties in covering all needed toxicological data; - Recently new molecules have been approved to be used as Preservatives by SCCS, even if not all SCCS Notes of Guidance endpoints were satisfied;	Authorisation is needed before to place on the market BIOCIDE; it implies two phases: 1) ACTIVE SUBSTANCE APPROVAL – Regulatory Framework: Articles 4 to 10 Annex II BPR - (a specific dossier is requested); if it is approved: 2) BIOCIDE PRODUCT APPROVAL - Regulatory Framework: Articles 17 to 23 Annex III BPR - (a specific dossier is requested) For both steps, Competent authorities, which are defined by every Member State, evaluate the dossier Weak points of the procedure: - The required economical investments are consistent; - Few Research on new substances; - Timing for approval are long; - In some cases, discrepancies in biocide products authorisation among different Member States occur;
"Free from" trend (Consumers perception)	Personal Care Preservatives belong to a positive list: Annex V of European Cosmetic Regulation 1223/2009 A no-sense marketing demonization has affected certain cosmetic ingredients in the past years (also Preservatives); great contribution to this discriminatory phenomenon was due to the use of the so called *"Free from"* claims	Biocide products approval make them part of a Positive list in BPR. This is positively perceived by insiders: end users are more focused on products efficacy, rather than their composition or specific ingredient absence. The market is not affected by *Free from* marketing trends
Safety assessment procedure (post approval)	In case of request to the European Commission, the SCCS is consulted by COM; SCCS can ask relevant parties to submit data in defence of the ingredient; SCCS is finally asked to provide its opinion on the safety of the ingredient	Authorisation of both Active Substances and Biocides are subjected to a predetermined time period (5 years to a maximum of 10 years); The procedures for renewal are indicated in Articles 12-16 of BPR (for Active Substances) and in Articles 45-46 of BPR (for Biocide products); it is necessary to demonstrate that conditions for authorization are still valid and a Dossier submission is requested
Efficacy evaluation	*Minimum Inhibitory Concentration test*: to evaluate the ingredient antimicrobial efficacy *Cosmetic Antimicrobial Challenge Test*: to evaluate the preservative performance in a specific finished product	Being grouped in four very different types of ingredients (Disinfectants, Preservatives, Pest Control and Other Biocidal Products – 22 Product Type in total, Biocides' efficacy is tested according to different protocols. Every Product Type has a set of tests to be satisfied, they are all listed into the *Guidance on the Biocidal Products Regulation - Volume II Efficacy - Assessment and Evaluation (Parts B+C)*
Efficacy enhancers	- Some ingredients of Personal Care finished formulas can boost the antimicrobial activity of preservatives; - Some Personal Care ingredients that does not belong to CPR Annex V, are recognized for peculiar antibacterial properties (i.e. Anti-dandruff; Deodorant)	Only Active substances reported in the following lists can be used to achieve biocide efficacy: -Active substances under revision (Delegated Regulation (EU) No. 1062/2014 and amendments) -Active substances list of the Union (https://echa.europa.eu/it/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances) - Active Substances list Annex I Regulation 528/2012 Some Co-formulant in Biocide products can boost Active Substance's efficacy or increase its bioavailability

Table 1. Personal Care Preservatives – Biocides comparison; Key points.

While working on this article, I had the opportunity to discuss some curious aspect of comparing Preservatives and Biocides with colleagues coming from the Biocide sector. What I found particularly curious was the difference in consumers' perception towards these two types of ingredients: in the Personal Care field, unfortunately, Preservatives often are not perceived as the guardian of microbial safety, but rather as dangerous ingredients: the feeling is that the marketing demonization has overpassed scientific truth, reaching end users that in some cases do not correctly interpret misleading marketing messages (see the "Free from" trends). On the contrary, in the Biocide field, end consumers are much more interested in products efficacy, rather than their composition (or ingredients absence). It seems that the inclusion of the ingredient in the positive list of approved active substances is not wrongly perceived as it happens with Preservatives, instead.

Curiously, there are some molecules that are approved to be used as both Biocides and Preservative, belonging to BPR list of approved active substances and Annex V of CPR: their use as Biocide and Personal Care Preservative is regulated, and thus they are considered safe and effective. Nevertheless, in the Cosmetic field, some of these ingredients are now more and more considered too dangerous to be used, and in some cases preferably avoided by producers. This does beg the question: does the diversity in weighting the same molecules depend on the application (probably, daily application of cosmetics directly on our skin led us to overdose our attention towards these products, in comparison to other items which we are in daily contact with, in any case) or are we simply judging the book by its cover?

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