Cleansing, disinfection, sanification ... Let's make them clear!

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Skin is the largest organ we have, among its multiple functions, one of the most important is the protection of human body from external adverse factors and pathogens. Despite skin can be considered as one of our most precious safety guardians, sometimes even the skin needs enhancement and a little bit extra support in terms of protection against potential hazardous attacks.

We all experienced and are still going through an historical period where enhanced hygiene practices are warmly recommended by WW authorities, in order to prevent the transmission of Coronavirus, and so reduce as much as possible the spread of related COVID-19 disease. In Europe, recommendations came from the European Centre for Disease Prevention and Control: *"Washing of hands with soap and water ... or cleaning hands with alcohol-based solutions, gels or tissues..."*. As a logic consequence, since the first months of 2020, the use of hand cleaners and disinfectants in form of gels, hand wipes or other leave on products has increased dramatically. Number, types and brands of related available products in supermarkets, pharmacy, drug and/or personal care stores have risen significantly; at the same time, also some confusion emerged on products claims and reference regulations, not only among end users, but, in some cases, also among insiders. In lights of this, we considered it could be of interest to make stock of the situation and shed some light on wording, activities, related products and regulations when speaking of enhanced hygiene practises.

WORDING AND CLAIMS

Let's imagine you do not work in the Personal Care field or you have no knowledge about the existing difference between a Personal Care product, a Detergent and a Biocide. You need to provide you and your family with products to enhance hands hygiene practise; you go to the pharmacy/drug or cosmetic store and, on the counter, you find several types of packaging and small bottles claiming *sanitizing – disinfectant – antibacterial – antiviral – microbiocidal* – etc. efficacy. Questions naturally arise: which one is the best in terms of safety and protection? which one should I choose? Which is the difference among all these products?

First of all, there is a net difference between detergents and disinfectant/sanitizing products; while general soaps are cosmetics, other products such as alcohol-based solutions, gels, hand-cleaners, hand-disinfectants, etc. might require further clarifications and fall within regulations which differ from the Cosmetic one.

Detergent products are formulations intended to be used and rinsed off from the skin, with the purpose of cleaning, washing and improving aspect and odour of the washed body part. They are **Cosmetic** products.

Disinfectant/Sanitizing products are formulations intended to go beyond the general purpose of personal hygiene. They have to contain active substances with a primary biocidal purpose (i.e. intended to control harmful organisms); these active substances must be approved by competent authorities and make the finished formulation a Biocidal product.

The term Hygiene

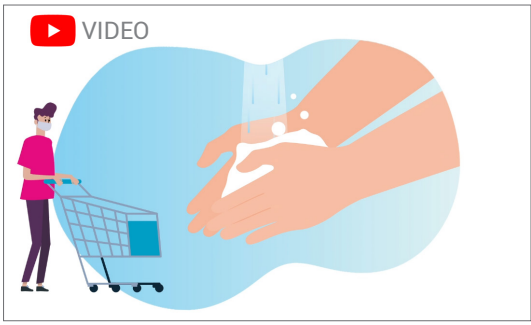
The use of the term hygiene can be associated with different meanings which range from simple cleanliness to disinfection; the real meaning depends on the context in which hygiene is used. When the term refers to 'personal hygiene' (products intended to clean and keep skin in good conditions) it usually relates to Cosmetic products. On the contrary, when *hygiene* is associated with 'disinfection', it is linked to biocidal products.

LEGAL FRAMEWORK

Product claiming is not the unique parameter that indicates which regulatory framework controls a finished product. **Claim** together with **product composition** and **purpose of use** are binding parameters to understand whether a finished formulation is:

- A **cosmetic product**, covered by the **European Cosmetic Regulation 1223/2009**
- A **biocidal product**, that falls within the **Biocidal Products Regulation 528/2012**

Claims are relevant indication of the purpose of the product; Claim is not only what's reported on the label, but also what is included in product specification, in technical sheet and advertisement.
In addition to this, claim has to be coherent with product composition and intended use. When the claim refers to the idea of cleaning and improving hand and body appearance, we are in the case of typical Cosmetic claim (e.g. hand cleaner) and the product falls within Regulation 1223/2009. On the contrary, when the claim relates to public health improvement through the control of infectious organisms, going beyond the general perception of personal hygiene, then the product



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is covered by Biocide Regulation 528/2012. Below, some typical Biocidal claims are reported:

-Antibacterial; Kills bacteria; Germicide
-Antiviral; kills viruses; Virokill

Purpose of use is strictly linked to product claiming. Products supplied with a main, primary or exclusive cosmetic purpose (i.e. cleaning or cleansing the skin) are covered by the Cosmetics Regulation. Differently, products with a primary biocidal purpose (i.e. intended to control harmful organisms) fall within the scope of the biocides legislation.

Product composition is another important parameter that discriminates Cosmetics from Biocides. In this case the differentiation is simple and linked to the presence, or absence, of the so called *active substances*; these have been assessed and approved under the Biocidal Products Regulation: products containing an active substance are not covered by the cosmetics legislation, but by Reg. 528/2012.

Regarding Italy, it is necessary to open a parenthesis on that class of products named *Presidi Medici Chirurgici* (PMC) – English literal translation: Surgical Medical Devices. PMC are intended for skin disinfection; they contain active substances not yet approved as Biocides, but still under examination in the "review programme" set out in Regulation (EU) No 1062/2014 (see Annex II).

SKIN AND SURFACES: DIFFERENT TARGETS, DIFFERENT PRODUCTS, DIFFERENT REGULATIONS

In the above paragraphs, we examined differences related to skin products, briefly:

To clean/wash our skin Personal Care products (EU Reg. 1223/2009)

To disinfect / sanitize our skin Biocidal products (EU Reg. 528/2012). Particular is the case of Italy, where *sanification* is achieved through Biocides, whereas *disinfection* is achieved through the use of PMC, as per Italian DPR. 392/1998

Now, what about surfaces treatment? As logic, the mechanism of action and consequently the type of needed products to achieve cleaning or disinfection of skin and inanimate surfaces are different. **Cleaning** of surfaces is achieved through the use of **Detergents**, which are regulated under Reg. 648/2004.

Disinfection/ Sanification of surfaces is again achieved through **Biocides** use.
In annex V of Biocidal Products Regulation 528/2012, clear differentiation is reported regarding product type (PT): products intended for skin application are known as PT 1, while those intended to be used on surfaces are PT2.

Needed effect	Target	Product to be used	Relevant legislation
Cleaning/Washing	Skin	Personal Care	Reg. 1223/2009
	Surface	Detergent	Reg. 648/2004
Disinfection/Sanification	Skin	PT1 Biocide	Reg. 528/2012
	Surface	PT2 Biocide	
Disinfection*	Skin*	PMC*	DPR. 392/1998*

*Italy only

Table 1. Type of products to enhance hygiene practices and related legislation.

Requirements	BIOCIDES	COSMETICS	DETERGENTS
Authorization (Competent Authorities)	Yes; it implies -Robust dossier (Stability + Efficacy tests) -Approval of Active Substance Supplier	No; CPNP notification is required, it implies PIF Production (Safety + Efficacy + Microbiological tests)	No
Technical Product Requirements	Efficacy, Stability, Safety (Human – Animal – Environment)	Efficacy, Stability, Safety (end user); Environmental Safety under REACH	Biodegradability
REACH regulation compliance	Yes, for all raw materials except Active Substances	Yes, for all raw materials	Yes, for all raw materials
Cost	Yes, payment of authorization fee	No fee (only testing costs)	No fee (only testing costs)
Approval timing	Long (2 years approx.)	Short/Immediate	Short/Immediate
Production plant	Quality system (art. 65 BPR)	Cosmetic GMP	Any specific requirement

Table 2. Biocides, Cosmetics and Detergents: differences before market release.

Table 1 summarizes type of products described in this article, and related legislation.

REQUIREMENTS BEFORE MARKET RELEASE

In order to have a deeper vision of the products we described in this article, it could be of interest to dig deeper with their description, through the analysis of needed processes and requirements before are released on the market.

Products that are subjected to major requirements are Biocides: their authorization is a long process that requires a robust dossier proving product's efficacy and stability; not only the active substance must be authorized by competent authorities, but also their suppliers. In addition to this, the authorization of the active substance also requires the payment of a fee. As for the production processes, they have to be compliant to a quality system.

If compared to Biocides, required procedures before the release on the market of Cosmetics and Detergents can be considered both lighter. Detergents are not subject to any authorization, whereas Cosmetics require a notification on CPNP (Cosmetic Product Notification Portal), that implies the submission of the Product Information File (PIF), a dossier including safety, microbiological and efficacy tests. Both Cosmetics and Detergents do not require any payment for their market release (except testing costs) and approval timing is definitely shorter. All the products, Biocides, Cosmetics and Detergents, must be compliant to REACH Regulation regarding raw materials used in formulation (with exception for Biocides active substances).

Table 2 lists and summarizes main differences in terms of requirements before market release.

REFERENCES

- Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.) – EU Commission document; created by GROW.R.2.DIR; published 30/03/2020
- https://www.complifegroup.com/news/surgical-devices-and-biocides/
- Normachem webinar – Come immettere nel mercato prodotti igienizzanti, detergenti o disinfettanti. 20th July 2020; www.normachem.it
- 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
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
- Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents.