PRODUCTIP GUIDE FOR SUPPLYING THE EU MARKET WITH HAND GEL OR SANITISING WIPES

Hand Gel

Biocide and/or Cosmetic?

Any Anti Bacterial or similar claims?

YES

NO

Perception of consumer that it is working as a biocide - even without “anti” claim?

YES

NO

Any claim that the product protects or nourishes the skin?

YES

NO

C.
Biocidal as well as a Cosmetic Product

A.
Biocidal Product

Any claim that the product protects or nourishes the skin?

YES

NO

B.
Cosmetic Product

Perhaps a detergent

See This Guide and The 5 Key Questions on page 10

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A WORLD IN WHICH PRODUCTS CAN BE TRUSTED

Before you read any further we would like to make one thing clear. Getting involved with products that are covered under the Biocide Regulation, the Cosmetics Regulation, or both, may not be your everyday product compliance process. It is complex. It involves paperwork, time, money, patience. There are no quick routes to the market.

HANDGEL - Biocide or Cosmetics or both?

source EU document: CA-Jul13-Doc.5.1.h

What looks like an everyday product proves to be very complex from a regulatory point of view. When you think about it, it is in contact with your skin. Not once but many times. It should eliminate bacteria, viruses, but keep you healthy. Serious business.

A Biocides are covered by Biocide Regulation (EU) 528/2012.

A Regulation means that it has been adopted unchanged as national legislation in all Member States. There is however still a lot of involvement of national authorities for biocides. The European Chemical Agency (ECHA) has a central role.

What is the definition of a biocidal product?

"Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render-harmless, prevent the action of or exert a controlling effect on any harmful organism by chemical or biological means."

Biocides work because they have one or more so-called Active Substances. There are 3 categories of Active Substances from an approval point of view:

1. Existing Active Substances being evaluated for approval (Existed before the regulation became active)
2. Approved Active Substances
3. New Active Substances being evaluated for approval

This is relevant because these 3 cases create different hurdles if you want to access the market. To give you an idea. To get new Active Substances approved and authorised can take years and cost millions. This is relevant because companies that have approved and authorised Active Substances have something to fight for.

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There are 22 so-called Product-Types. Active Substance shall be approved to be used in one or more of these Product Types.
The following 3 Product Types are relevant in case of hand gel.

Product Type 1 (PT1): Human Hygiene
Product Type 2 (PT2): Surface Disinfection
Product Type 3 (PT3): Disinfection of surfaces that come in contact with food and or feed

All 22 Product Types can be found here:
https://echa.europa.eu/regulations/biocidal-products-regulation/product-types

B Cosmetics are covered by the Cosmetic Product Regulation (EC) 1223/2009.

What is the definition of a cosmetic product?

"Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours"

So are there no grey areas?

There are products that are only regulated through the cosmetics legislation. These products might contain an active substance, a preservative, for the sole purpose of preserving the cosmetic product itself. That is, without giving a biocidal function to the product. The cosmetic legislation regulates what preservatives are allowed.

There are products that are only regulated through the biocide regulation. These are products that make a claim to control public health through the control of infectious organisms such as “disinfecting”, “anti-bacterial”. Cheese is cheese unless you sell it as “anti-mouse cheese”: you have turned it into a biocide (rodenticide).
So it is a mix of claim and expected use.

Important: The Covid-19 crisis has substantially shifted the perception of expected use

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There are also products that are regulated through both the cosmetics and the biocides legislation. For example mosquito repellent sunscreen.

The fact that a biocide is used on the skin does not necessarily make it a cosmetic product. And the fact that good hygiene (washing hands) will contribute to fight bacteria does not make any cleaning cosmetic a biocide.

In order to determine which type of product is covered by what regulation the following logic applies:

In particular, where a biocidal product is supplied with a claim to protect public health through a control of infectious organisms, which would go beyond the general knowledge of personal hygiene as a contribution to public health, considering the reasonable expectations of the average consumer, that function is likely to be of primary importance, in which case the product has to be regulated under the biocides legislation.

On the other hand, a public health claim relating to a function that has nothing to do with biocidal action, such as that of protecting the skin from the sun, does not attribute a primary biocidal function to a product.

What is important is “considering the reasonable expectations of the average consumer ..” That *reasonable expectation* for sure has changed in the last months during the Covid-19 crisis.

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C What if it is both a biocide and a cosmetic product?

Comparing hand rinse-off products with leave-on products makes things more clear.

Examples of presumed classification for hand and body rinse-off products (soap)

Labelled Claim	Cosmetic		Biocide
Physically clean / visually clean	✔		
Daily use, suitable for dry, and sensitive skin	✔		
Unique antibacterial formulation	✔	and/or	✔
Germ kill	✔	and/or	✔
Kills 99.9% of the bacteria			✔
Antibacterial	✔	and/or	✔
Natural ~~antibacterial~~	✔	and/or	✘*
Hygienically clean	✔	and/or	✔

* biocide products may not have the claim “natural”. The complete text says: “The advertising of a biocidal product shall not mention ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’, ‘natural’, ‘environmentally friendly’, ‘animal friendly’ or any similar indication”

That means natural soap as cosmetic product is possible but never as biocide, therefore never in combination with any claim that creates the perception that it has a biocidal function.

Why are there “and/or” situations?

This has to do again with the reasonable expectation. Are these products that are specifically targeted to a use where the biocide function is more relevant? Packaging, marketing materials, positioning in the supply chain, it all shall be considered.

When it is clear from an assessment of all product characteristics that the product is mainly intended to protect public health through biocidal action, which would go beyond the general knowledge of personal hygiene as a contribution to public health considering

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the reasonable expectations of the average consumer in the market in question, the product cannot be considered as a cosmetic and will have to comply exclusively with the biocide legislation.

In the absence of any such (biocidal) claims, and if the assessment of all product characteristics shows that the main intended (and understood) function of the product is only to clean, the product is a cosmetic product and will have to comply exclusively with the cosmetic legislation.

Examples of presumed classification for hand and body leave-on products

Labelled Claim	Cosmetic		Biocide
Handcleaner	✔		
Physically clean / visually clean	✔		
Antibacterial			✔
Kills a wide range of germs			✔
Kills bacteria			✔
Antiviral, kills viruses, virokill			✔
Hand/body sanitizer			✔
Disinfection of hand or other body parts			✔
Hygienically clean			✔

It should be noted, however, that in the case of hand or body leave-on products, it is more likely that the product will have a disinfecting action, as the removal of dirt will not be as efficient as in the case of a rinse-off product. In addition, these products are often presented as implicitly preventing the spread of diseases.

In this case, therefore, it is all the more important that all the characteristics of the product, including the expected perception of the consumer, are taken into account. This has to be kept in mind when designing labelling, packaging, advertisement, websites, where you

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place the product in a store, in an online store. Again, the expected perception of the consumer surely has changed in the recent months due to the Covid-19 crisis.

Conclusion. Leave-on hand gel is within the scope of the biocide legislation and could, if claims are made that it also nourishes / protects the skin, also be in the scope of the cosmetic legislation.

Note that “Natural” shall NEVER be used in combination with a biocide function! The official text reads:

“*The advertising of a biocidal product shall not mention ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’, ‘natural’, ‘environmentally friendly’, ‘animal friendly’ or any similar indication.”*

See also EU Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.) (available in all relevant languages)

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What is the route to market?

Is there a fast track procedure available for hand gel?

Yes there is, several Member States have already granted permissions to pharmacies or companies that are producing disinfectants, but there are limitations and conditions.

We recommend to read information on this in:
https://echa.europa.eu/nl/covid-19

This is NOT a fast route to market if you have never been involved in production of biocide or cosmetic products and or making these products available to the EU market.

Three cases and available routes

Biocides work because they have one or more so-called Active Substances. There are 3 categories of Active Substances from an approval point of view:

1. Existing Active Substances being evaluated for approval (Existed before the regulation became active) for example ethanol to be used in Product Type 1, 2 or 4.

   >> go to CASE 1 on page 9

2. Approved Active Substances for example propan-1-ol, propan-2-ol, hydrogen peroxide, for Product Type 1, 2 or 4.

   >> go to CASE 2 on page 9

3. New Active Substances being evaluated for approval, for example active chorine generated from sodium chloride by electrolyse for Product Type 1

   >> go to CASE 3 on page 10

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CASE 1

Company wants to place **ethanol based products** on EU/EEA/Swiss/UK market.

The responsibility for fulfilment of the requirements of the Biocide Regulation is with an EU company. In case of a non-EU company the EU importer has to ensure approval of active substances and authorisation of the biocidal product.

Ethanol is still under evaluation. Authorisation to make the product available needs to be obtained at the relevant authority in each Member State.

http://echa.europe.eu/support/helpdesks

CASE 2

Company wants to place **isopropanol (propan-2-ol) based products** on EU/EEA/Swiss/UK market. Isopropanol is already approved to be used as active substance in Product Types 1, 2 and 4.

The responsibility for fulfilment of the requirements of the Biocide Regulation is with an EU company. In case of a non-EU company the EU importer has to ensure approval of active substances or authorisation of the biocidal product.

Each product that is using the approved active substance must be authorised prior to be made available on the market. Contact the helpdesks for the member states where you want to sell the product. You need to prepare technical documentation, packaging, labeling, and so on. A technical file created in ProductIP helps you to collect, structure and share that documentation.

Overview National Helpdesk Contact Details

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Producers of the active substance have to be on the so-called article 95 list:
https://echa.europa.eu/information-on-chemicals/active-substance-suppliers

Fast track to add a production source for propan-1-ol or -2-ol to the article 95 list.
https://echa.europa.eu/documents/10162/28801697/accelerated_te_propanol_isopropanol_en.pdf/fe8d0741-3271-2938-1da8-f0e06b2aba8d

CASE 3

Company wants to place a new Active Substance based products on EU/EEA/Swiss/UK market, for example **active chlorine generated from sodium chloride by electrolyse.** This Active Substance is new and has to pass approval.

The responsibility for fulfilment of the requirements of the Biocide Regulation has to be with an EU company. In case of a non-EU company the EU importer has to ensure approval of active substances or authorisation of the biocidal product.

Biocidal products can be placed on the market following the approval of the active substance(s) and the authorisation of the products.

However Member States may, in exceptional situations, permit products on its market that do not comply with the biocidal regulation under Article 55(1). Such authorisation would only permit access to the market of the relevant Member State for a limited time.

Overview National Helpdesk Contact Details

The 5 Key questions to ask when you start

1. What is/are the Active Substances and their approval status for the Product Type?
2. Who is/are the suppliers of these Active Substances?
3. Are these suppliers listed on the Article 95 list?
4. Is the actual biocidal product itself registered in each Member State you want to sell?
5. Is all information in the relevant language(s) for these Member State you want to sell?

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FAQ

Q1 What is this Article 95 Obligation?

A1 The supplier of the active substance used in a biocidal product, or the supplier of the biocidal product has to be included in the Article 95 list.

Q2 Do all the companies need to be on the Article 95 list?

A2 No. Within the same supply chain only one has to be listed. Note that you still need to list your biocidal product with each Member State.

Q3 And what if we are not the original applicant for the active substance?

A3 You will need to submit an application to ECHA to be included in the Article 95 list. You could say that this is request to get a co-license. Fees will be applicable.

Q4 How can I quickly place on the EU market hand rub formulations recommended by the World Health Organisation (WHO)?

A4 See CASE 1 on page 9 for ethanol based products.
See CASE 3 for propan-1-ol, propan-2-ol or hydrogen peroxide based products.

Q5 How can I quickly place on the market alcohol based sanitisers?

A5 It depends on the Active Substance. Determine this first and next see if your route is covered by CASE 1, 2 or 3.

Q6 What about other types of sanitisers?

A6 It depends on the Active Substance. Determine this first and next see if your route is covered by CASE 1, 2 or 3.

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Q7 Do I need to register the substances in a biocidal product under REACH?

A7 Approved Active Substances as well as existing Active Substances pending approval are exempted from REACH registration. All other substances used for production of biocidal products are subjected to REACH registration if the manufactured or imported product is over 1 tonne/year per company.

Q8 Is it possible to get a temporary permit to sell biocidal products in the EU market in order to manage the COVID-19 outbreak?

A8 Not in the EU market in one go. However, the Competent Authority of a Member State may permit for a limited period the use of a biocidal product under the supervision of that Competent Authority. There are daily changes to these exceptional rules and derogations, contact the national helpdesk or competent authority for up-to-date information.

Q9 What about nano materials?

A9 A dedicated risk assessment is needed when the nano-form of the active and non-active substances are used in a biocidal product. Products containing nano-materials are excluded from the simplified authorisation procedure.

Q10 What is this R4BP register at ECHA?

A10 R4BP 3 is the central hub through which all biocides applications are made. It provides functions which enable the industry and the authorities to comply with the legislative requirements and exchange information between them.

https://echa.europa.eu/support/dossier-submission-tools/r4bp

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Information on the product / packaging?

The product and packaging will have to carry in Member State language:

- Every active substance and its concentration;
- Authorisation number;
- Name and address of the Authorisation Holder;
- Name or trademark and address of the EU business entity placing the product on the market;
- Biocide function - what does it do - on what Product Types;
- Instructions for use;
- Traceability information / charge number / expiry date;
- Most likely additional CLP statements and pictograms.

(Not intended to be a full detailed checklist)

What if hand gel is just, or also, a cosmetic product?

The cosmetic regulation is complex enough on its own. Cosmetics require a Responsible Person to sign off on the compliance of the product. If you don't have one in your company, you will need to find a 3rd party that is willing to do it on your behalf.

Cosmetic products have to be notified at the Cosmetic Product Notification Portal (CPNP)
https://webgate.ec.europa.eu/cpnp/public/tutorial.cfm

A technical file created in ProductIP helps you to collect, structure and share that documentation. (Note, there is no interface with CPNP)

The cosmetic regulation has a positive list of ingredients that you will have to choose from. Ditto for the preservatives you are allowed to use.
This can be found in the Cosmetic Ingredient Database called **CosIng**.
https://ec.europa.eu/growth/sectors/cosmetics/cosing_en

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The product and packaging will have to carry in Member State language:

- Ingredient list from International Nomenclature Cosmetic Ingredient (INCI);
- Description of the cosmetic function;
- Instructions for use;
- Precautions;
- Name or trademark and address of the EU business entity placing the product on the market;
- Best Before Date / Period After Opening;
- Traceability information / charge number;
- Possibly CLP warnings and symbols;
- Contents;
- Country of origin for non-EU producers.

(Not intended to be a full detailed checklist)

See also the guide provided by Cosmetics Europe: https://cosmeticseurope.eu/library/8

What about sanitising wipes?

Sanitising wipes will be regarded as a biocidal product for the same reasons as for hand gel. It all depends on claims made and or perception of the consumer. It is unlikely these products are considered to be a cosmetic product. They might be considered a detergent as well, covered by the detergent legislation.

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How can ProductIP help?

Via our web-based solution you can instantly create a comprehensive regulatory checklist for non-food consumer products. This checklist is the core of a so-called technical file. Invited suppliers can upload the compliance evidence directly into this technical file. You sign off the references in the regulatory checklist with the uploaded information; certificates, test reports, declarations, bill of materials, etc. When relevant for the product you can create a CE declaration with a mouse click.

These technical files enable you to demonstrate to authorities, consumers, other stakeholders, that you are in control of product compliance in a way that is in line with the regulatory framework.

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