Guidelines for the borderline between Biocides – Cosmetic Products – Medicinal Products for human use (Federal Agency for Medicines and Health Products)

This document was prepared by the Joint / Mixed Commission, chamber for human use products.[1]

This document serves as a guideline to help review the status/ classification of products which are on the borderline between Biocides, Cosmetic Products, Medicinal products without interfering with current and future laws and regulations in this area. According to the case law, each product must be assessed on a case by case basis. It is based on the Guidance documents and Manual of Decisions of the European Commission mentioned below (which are now obsolete as of 01/10/2015).

Note: The provisions of this accompanying document also apply to herbal products.

- Manual of Decisions for Implementation of Directive 98/8/EC Concerning the placing on the market of Biocidal Products – **OBSOLETE AS OF 01/10/2015**

  https://circabc.europa.eu/sd/a/d0155521-069e-4e8c-91cc-126006d32a83/Manual%20of%20%20%20decisions%20(obsolete%20as%20of%2001.10.2015)

G-Regs Note: The guidance provided through this Manual of Decisions is obsolete since 1 October 2015 – due to the fact that a new Biocidal Products Regulation ('BPR' Regulation (EU) No 528/2012[2]) has repealed and replaced the existing Biocidal Products Directive 98/8/EC ('BPD').

Best to use: Manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)) – Version 1 (Nov 2013)
http://ec.europa.eu/DocsRoom/documents/13033/attachments/1/translations/en/renditions/native or
http://ec.europa.eu/DocsRoom/documents/13033/attachments/1/translations/en/renditions/pdf

- Borderline between directive 98/8/EC concerning the placing on the market of biocidal product and directive 76/768/EEC concerning cosmetics products – **NO LONGER VALID**

G-Regs Note: European Commission has published a Guidance document: Borderline between the legislation for cosmetics and biocides http://www.gregsregs.com/downloads/EUborderlinecosmetics_biocides.pdf

- Borderline between Directive 98/8/EC concerning the placing on the market of biocidal product, Directive 2001/83/EC concerning medicinal products for human use and Directive 2001/82/EC concerning veterinary medicinal products – **NOT RELEVANT TO COSMETICS**

  https://circabc.europa.eu/sd/a/51ca9945-167d-411f-9763-92e634af9e1c/Biocides-2002-01%20-%20Borderline%20with%20(veterinary)%20medicinal%20products.pdf (Version 08/01/2008)

- Guidance Document on the demarcation between the Cosmetic Products Directive 76/768/EEC and the Medicinal Products Directive 2001/83 as agreed between the Commission Services and the Competent Authorities of Member States:

  http://ec.europa.eu/DocsRoom/documents/13032/attachments/1/translations/en/renditions/pdf

Main European Legislation on the subject:

- Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products - Date of end of validity: 11/07/2013

  REPLACED AND REPEALED BY: REGULATION (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[3]

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4]

- Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market - Date of end of validity: 31/08/2013

  REPLACED AND REPEALED BY: 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[5]

[1] The commission consists of a chamber (or office) for products for human use and a chamber for veterinary products
[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:en:PDF
[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2009R1223:20130711:EN:PDF
[4] Consolidated Version: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_consol_2012_en.pdf
[5] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0528&qid=1447954709028

DISINFECTANTS / ANTISEPTICS (for personal use)

Overview

These products can generally fall under two different statuses/ classifications, namely that of a biocide or a medicinal product. The status that will apply depends on the claims, the purpose, and product composition.

Medicinal: These products fall under the law on medicinal products and can only be presented with therapeutic indications as approved during the granting of marketing authorisation in accordance with the Medicines Act of 25 March 1964 and its implementing decrees (G-regs: under Art. 9(1) it is forbidden to advertise medicinal products for which a Marketing Authorisation has not yet been granted).

Biocides: These products can not in any case be presented with therapeutic indications. Normally, only the general disinfectant properties can be recognized/ attributed. They fall under the status of biocide as "Biocidal products for human health" (Product type 1 of Annex V of the RD of 22/05/2003 concerning the placing on the market and use biocidal products). Such a product meets the definition of "biocide" if:

It is an active substance and preparation containing one or more active substances, put up in the form in which they are supplied to the user, intended to fight against harmful organisms (fight against = destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means) – (Taken from Art. 1(1) RD 22/05/2003)

G-Regs Note: Royal Decree of 22 May 2003[6] has been repealed by RD 8 May 2014 (Art. 49) with the exception of Arts 50-65 and Annexes XII and XIII; - Royal Decree 8 May 2014[7] (relative to the making available on the market and use of biocidal products) supplements the Biocidal Products Regulation (EU) No 528/2012 and implements the transitional measures laid down in Article 89 of Regulation (EU) No 528/2012.

The definition of biocidal product is contained in Art. 3(1) BPR:

"(a) '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."

Note: Annex V still contains the types of biocidal products covered by the Regulation – product Type 1 is still: Human Hygiene (under Main Group 1 – Disinfectants) - Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

If the antiseptic properties are incidental/ ancillary (G-regs: i.e. inherent) to the main purpose of the product, it is possible that the product falls within the classification/ status of a cosmetic product. See in relation to this also, the examples below on soaps and cleansing gels.

It is therefore possible that two products containing the same active ingredient fall under two different statuses, this depending on the indications used.

SPECIFIC EXAMPLES:

- **Mouthwashes with the indication/ claim: "Antiseptic"** *("antiseptique" / "antiseptisch")*

What status do they have?

According to the Guidance document (Doc-Biocides-2002/01 Version 08.01.2008 – referenced above), these products may in effect be considered as biocides when it is indicated that the product has general disinfectant properties for hygiene purposes without therapeutic indications/ claims. The terms "antiseptic *(antiseptique / antiseptisch)*, "antibacterial" *(antibactérien / antibacterieel)*, "disinfectant" *(disinfectant / desinfecterend)* can be used in this case. Terms such as "gingivitis" *(gingivite / gingivitis)*,"periodontitis" *(parodontite / paradontitis)*, "inflammation of the gums" *(inflammation de la gencive / tandvleesontsteking)* are therapeutic indications and puts the product in the category of medicinal products.

- **Skin Disinfectants**

When disinfectants for skin are used for general hygiene, these products without therapeutic indication/ claim (nl version uses claim) may fall under the definition of biocide. These products may refer to a pathogen (a disease agent / causative agent – such as bacteria etc) but in no case to a disease, which would constitute a therapeutic indication/ claim.

E.G. A hand sanitizer used in a hospital may possibly have the statement: "active/ working against the hepatitis B virus" (= pathogen) ('actif contre le virus de l'hépatite B' / 'effectief tegen hepatitis-B-virus') BUT NOT "Protects against Hepatitis B" (= Disease) ('protège contre l'hépatite B' / 'profylactisch tegen hepatitis B')

E.G. The products for hand disinfection of those active in the food industry fall under the status of biocide

- **Alcohol based gels**

Alcohol based gels with an active concentration of alcohol of approximately 60% to 80% (V/V)[8] are generally considered as biocides, as it is the recommended concentration to achieve an optimal disinfecting effect. If therapeutic indications/ claims are presented, these gels can fall under the definition of a medicinal product. If in doubt, the product should be evaluated/ assessed on a case by case basis by the competent authorities, an evaluation during which all aspects of the product will be examined.

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[6] http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2003052246&table_name=loi

[7] http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&table_name=loi&cn=2014050879

[8] Or between 520 and 735 mg /g expressed in weight / weight (based on "Alcoholometric Tables" of the European Pharmacopoeia)

- **Soaps and Liquid soaps** *(Savons et savons liquids / Zepen en vloeibare zepen)*

In the case of soaps and liquid soaps, if a term / statement of the type "antibacterial", "antiseptic" or "disinfectant" is included in the trade/ brand name, the biocidal function cannot be regarded as a secondary property (unlike in the case of deodorants) and the product falls under the status of biocide and not under that of cosmetics. If they mention therapeutic or prophylactic properties, soaps of this type are considered medicinal products.

- **Disinfectants on the skin before surgery**

Due to the fact that the main objective of these products is to prevent infection of the surgical wound, they are regarded as medicinal products, regardless of the indications presented / claims used. The purpose / goal of these products is sufficient to consider them as medicinal products. However, products for disinfecting the hands of healthcare professionals will fall under the definition of a biocide.

- **Disinfectants for wounds**

These are automatically considered medicinal products because their main goal is to prevent infection.

Note: Disinfectants for the disinfection of medical devices fall under the status of biocide in the case of a General disinfection. Products intended for a specific device themselves can also be a medical device. For details refer to Guidance document: MEDICAL DEVICES: Guidance document: Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf

Pest Control Products

Products against lice

In accordance with the manual of decisions mentioned above, products such as shampoos, lotions, etc. are considered medicinal products if they are used to effectively kill lice, since a lice infestation is considered a disease. If the function is not achieved by a pharmacological, immunological or metabolic action, the product may fall within the definition of a medical device.

If there is a repellent (to prevent infestation by lice), it falls under the definition of a biocide. In this case, no therapeutic indication such as "pediculosis" can however be mentioned.