EN
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Answer given by Mr Breton
on behalf of the European Commission
(18.2.2022)

In the context of the COVID-19 pandemic, the Commission services have published detailed Guidance[1] to clarify the applicable EU legislation for alcohol-based solutions, gels, hand-cleaners, hand-disinfectants, namely Regulation (EC) No 1223/2009 on cosmetic products[2] and Regulation (EU) No 528/2012 on biocidal products[3]. In general, products containing an active substance and supplied with a primary biocidal purpose would in principle fall under the biocides legislation.

However, a personal health product, such as the ones to which the Honourable Member refers, presenting itself as 'antiseptic' or 'antibacterial' may, depending on the specific product, be a biocidal product, a cosmetic product, a medicinal product[4] or a medical device[5].

The decision on the classification of a specific product is to be taken on a case-by-case basis, taking into account all characteristics of the product, such as its presentation, ingredients, claims, and mode of action. The Commission services have published general guidance on the demarcation of those products[6]. Once classified, products should follow the requirements set out in the relevant EU legislation.

Manufacturers and other businesses may take contact with the appropriate national competent authorities in their Member State for further information and guidance, including on the classification of a product, where relevant. In particular, they can consult the European Chemical Agency (ECHA) website[7] and/or the national authorities listed on the Commission's website and being competent, for example, for cosmetics[8], medical devices[9], medicinal products[10] or biocidal products[11].

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[1] DocsRoom - European Commission (europa.eu)
[2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p.59); EUR-Lex - 32009R1223 - EN - EUR-Lex (europa.eu)
[3] 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 (OJ L 167, 27.6.2012, p.1); EUR-Lex - 32012R0528 - EN - EUR-Lex (europa.eu)
[4] EudraLex - EU Legislation | Public Health (europa.eu)
[5] Borderline products (europa.eu)
[6] DocsRoom - European Commission (europa.eu)
[7] Guidance on biocides legislation - ECHA (europa.eu)
[8] https://ec.europa.eu/docsroom/documents/45625
[9] https://ec.europa.eu/health/md_sector/contact_en and legislation: https://ec.europa.eu/health/md_sector/overview_en
[10] https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human
[11] https://circabc.europa.eu/w/browse/f5420b62-fa9f-4209-aaec-ec5b914e9a9f