

**TECHNICAL DOCUMENT ON THE SCOPE OF APPLICATION OF THE
COSMETICS REGULATION (EC) NO 1223/2009 (ARTICLE 2(1)(a))**

**Product claims of leave-on hydro alcoholic hand gels
in the context of COVID-19 pandemic**

Agreed by the Sub-Working Group on Borderline Products

(12 November 2020)

PLEASE NOTE: THIS TECHNICAL DOCUMENT WAS PREPARED BY THE SUB-WORKING GROUP ON BORDERLINE PRODUCTS AND THEN ENDORSED BY THE WORKING GROUP ON COSMETIC PRODUCTS. IT IS NOT A EUROPEAN COMMISSION DOCUMENT AND CANNOT BE REGARDED AS REFLECTING THE OFFICIAL POSITION OF THE EUROPEAN COMMISSION.

THIS DOCUMENT SHALL ONLY SERVE AS “TOOL” FOR THE CASE-BY-CASE APPLICATION OF UNION LEGISLATION BY THE NATIONAL COMPETENT AUTHORITIES AND NATIONAL COURTS.

THE VIEWS EXPRESSED IN THIS DOCUMENT ARE NOT LEGALLY BINDING; ONLY THE EUROPEAN COURT OF JUSTICE CAN GIVE AN AUTHORITATIVE INTERPRETATION OF UNION LAW.

This technical document aims at detailing the product claims which would not support the classification of leave-on hydro alcoholic hand gels (hereinafter “hand gels”) as cosmetic products¹.

It was agreed by the Sub-Group on Borderline Products on 8 October 2020 and then endorsed by the Working Group on Cosmetic Products via written procedure on 23 October 2020 and in its meeting on 12 November 2020.

This technical document should be read taking into account the *Borderline Manual*² and the “*Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants*”³ as it aims to complement these documents. Even if the classification of each product shall be conducted on a case-by-case basis, taking into consideration all characteristics, product claims (to be intended as text, names, trade marks, pictures and figurative or other signs) can, nevertheless, be a strong indication of the main purpose of a product.

Recital 51 of Regulation (EC) No 1223/2009 on cosmetic products provides that “*the consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic*”.

Article 20 of Regulation (EC) No 1223/2009 on cosmetic products (governing “*Product Claims*”) further provides that “*In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have*”.

In light of the above, this technical document contains examples of product claims that are likely to cause the perception that a hand gel has mainly a biocidal function and that should, consequently, be considered misleading when affixed on hand gels placed on the market as cosmetic products. In this context, there should be no explicit or implicit biocidal claim on cosmetic products, irrespective of the medium or type of marketing tool used for the products concerned (e.g. leaflets, internet). All examples listed below are illustrative and the list is thus not exhaustive.

¹ This document focuses on claims that are likely to cause the perception that a hand gel has mainly a biocidal function and is not intended to discuss claims that are likely to cause the perception that a hand gel shall be classified as a medicinal product in accordance with Directive 2001/83/EC.

² Manual of the Working Group on Cosmetic Products (Sub-group on Borderline Products) on the Scope of the Application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)), version 5.2 (September 2020). Available at: <https://ec.europa.eu/docsroom/documents/42850>.

³ Available at: <https://ec.europa.eu/docsroom/documents/40523>.

Labelling elements that would not support a main cosmetic function of leave-on hydro alcoholic hand gels (not to be used on cosmetic products)

Claims (and their variations):

- antibacterial, antimicrobial, antiviral, virucide, antifungal (and their attributes, such as ‘antiviral properties’, ‘antibacterial ingredients’, ‘inhibits bacterial growth’);
- disinfecting, disinfectant, disinfection, sanitizer, sanitizing;
- antiseptic;
- kills X% bacteria/viruses/microbes;
- decontaminating;
- formulation recommended by the World Health Organisation (WHO);
- anti-COVID-19, anti-coronavirus, anti-SARS.

References or allusions to:

- infection, pandemic, diseases;
- COVID-19, coronavirus, SARS-CoV-2;
- microorganisms, bacteria, viruses, pathogens, germs, fungi;
- disinfection;
- medical use;
- percentage of alcohol in the product;
- safe hands.

Pictures or graphical elements of:

- (corona)virus, bacteria, microbes;
- (red) cross (when suggesting a medical connotation);
- shield (when indicating protection against microorganisms);
- STOP sign (when indicating preventing/controlling the spread of a disease or infection or microbes);
- any sign related to hospital, pharmacy, ambulance, first aid, etc;
- CLP pictograms.