Substantiation of Antibacterial/antimicrobial Caims for Cosmetic Products

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Introduction

A product applied on external parts of the human body, which is claimed as antibacterial or antimicrobial, can, from the legal point of view, be classified as either biocidal or as a cosmetic product. If, however, the claim or advertising explicitly refers to the treatment or the relief of an illness caused by bacteria/microorganisms the product has to be classified as a drug.

It is of critical significance to differentiate between a cosmetic product and a biocidal product that claims for the antimicrobial efficacy can be judged as secondary compared to the main cosmetic purposes in the sense of Art. 2, 1(a) of the Regulation (EC) No 1223/2009 [1]. If the product is classified as cosmetic product, adequate and verifiable proof of the claimed antimicrobial efficacy has to be provided with regard to the provisions made in Annex I, 3 of the VO (EC) 655/2013 [2]. Detailed legal requirements or binding normative standards regarding the kind and extent of such proof is, however, missing for cosmetic products. This position paper shall give proposals and assistance for choosing appropriate proof.

Requirements and Standards of other Areas

(Overview see **Tab. 1**)

The highest demands with respect to antimicrobial claims are found in normative standards for the testing of chemical disinfectants and antiseptics in the medical area. If a bactericidal efficacy shall be claimed in case of products for hygienic hand disinfection, the requirements of the European Norm EN 1040 (Phase 1, basic test), EN 13727 (Phase 2.1) and EN 1500 (Phase 2.2) have to be applied. Products for hygienic hand wash must

Chemical disinfectants and antiseptics the for medical, veterinary-medical and food area, microbicidal efficacy
EN 14885:2014, Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics
EN 1040, Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)
EN 13727, Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1)
EN 1500, Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 2)
EN 1499, Chemical disinfectants and antiseptics – Hygienic handwash – Test method and requirements (phase 2/step 2)
EN 12791, Chemical disinfectants and antiseptics – Surgical hand disinfection – Test method and requirements (phase 2, step 2)
EN 1276, Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)
EN 1650, Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)

Tab. 1 Requirements and norms in non-cosmetic areas

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fulfil the requirements of Phase 2.2 of norm EN 1499. The Phase 2.2 for testing products for surgical hand disinfection and surgical hand wash is given in norm EN 12791.
Test instructions are also available for chemical disinfectants (biocidal products) for application in the food area, industrial areas, households and public facilities. Products for hygienic hand wash should be tested according to norm EN 1276 (Phase 2.1) and EN 1499 (Phase 2.2), whereas testing of products which claim hygienic hand disinfection is described in EN 12791 (Phase 2.1).
If an additional fungicidal efficacy is claimed, tests for Phase 2.1 in accordance with EN 1650 must also be carried out.
A complete overview of all European norms for chemical disinfectants and antiseptics is provided in EN 14885.

Recommendations for Testing Cosmetic Products for which a Microbicidal, Microbiostatic or Antibacterial Resp. Antimicrobial Efficacy is Claimed

Cosmetic products with microbicidal, microbiostatic or antibacterial resp. antimicrobial efficacy are found in different product groups. Classical application areas are hand washing and mouth wash products, but also deodorants and products to treat skin impurities. Amongst the skin care products respective claims are mostly used in the foot care area, but also increasingly for body care products.
There are products, which, according to their application instructions, are used under conditions of a high load (application with or without water on skin which has not been pre-cleaned). Such products are, for example, hand washing products or wet tissues for hand cleaning without water. Products for the application under conditions of a low load (application on precleaned skin) are in case of respective application instructions e.g. deodorants and antibacterial facial tonics.

A differentiation has to be made between claims without specified efficacy against microorganisms:
antimicrobial: efficient against bacteria and fungi – an antiviral efficacy is not relevant for cosmetic products due to the differentiation from drugs
antibacterial: efficient against bacteria
antimycetic, antifungal: efficient against fungi

and claims which are either explicitly aimed at a killing effect (microbicidal, bactericidal or fungicidal) or at a growth inhibiting effect (microbiostatic, bacteriostatic or fungistatic). Claims such as "kills 99.9% of the bacteria" must also be understood as having a "killing effect".
When claiming a "killing effect", an efficacy as given in the norms for chemical disinfectants should be reached: this means a reduction of the microbial count by 3-5 log-units. If a growth inhibiting effect is claimed the count should be kept on the same level (minus the microbiological measuring inaccuracy) over the contact time as given by the respective type of application.
"Anti"- claims cannot be defined as scientific terms. The way of testing efficacy is not precisely determined. Minimum requirements for the use of such claims should therefore be applied with regard to the protection of the consumer from deceptive advertising. "Anti"- claims should be substantiated through quantitative proof of the killing or growth inhibiting efficacy in tests, which simulate conditions representing those given in the application instructions. In case of killing effects the test-result should show a reduction of the count (expressed as "log-reduction value") which is at least 2 log-units higher than the acceptable range of deviation for such microbiological testing (acc. EN 17516 [3]: 0.5 log).
The practice-relevance of the required reduction of 2 log-units cannot be verified in such a test-system. The same is also true for reduction-factors applied for the efficacy- testing of chemical disinfectants. The relevance of such reduction-factors with regard to the skin physiology can hardly be evaluated. Such tests should just be understood as test-models and cannot represent the reality in all aspects.

When defining and performing the tests, the following aspects should be observed:
- The product marketed with a specific claim must be identical to the product used in the test.
- Basic tests (e.g. acc. EN 1040) may help to evaluate the microbiocidal efficacy of an active agent or of a product under development. The results of such tests, however, cannot be used as proof of product-claims without additional tests correlated with the relevant application conditions.
- Accordingly, for such additional tests methods have to be chosen which are adapted to the instructed application of

Product-group	Test-organisms	Contact-time	Method based on
Handwash*	Reference-strains acc. EN	30 sec , 60 sec, 120 sec	EN 1040, EN 1276, if applicable: additional practice-tests (Phase 2.2)
Deo	*Staphylococcus spec.* *Corynebacterium spec.*	60 min, 8 hrs, 48 hrs**	EN 1040, EN 1276
Foot care (leave on)	*Epidermophyton floccosum* *Trichophyton mentagrophytes* *Trichophyton rubrum*	15 min, 30 min	EN 1275, EN 1650
Anti-spot-products	*Propionibacterium acnes*	30 sec , 60 sec, 120 sec	EN 1040, EN 1276
Wash-gel etc., Mask, leave on		5 min, 30 min, 60 min	
Mouth-wash/Dental creme	*Streptococcus mutans* *Streptococcus oralis* *Actinomyces odontolyticus*	30 sec , 60 sec, 120 sec	EN 1040, EN 1276
Anti-dandruff shampoo	*Malassezia furfur*	30 sec , 60 sec, 120 sec	EN 1040, EN 1276

* The minimum application time of 30 s has to be mentioned on the product.
** If an efficacy for a period of 48 hrs is used as a promotional claim.

Tab. 2 Recommendations for the selection of test-methods and relevant test-organisms of specific products or application areas and recommended contact-times

the product. The test-performance should respect the load resulting from the instructed application. Standardized methods for practice-tests (Phase 2.2) can only be used for selected product-types, e.g. hand-soap and hand cleaning-gel.

- The kind of application (rinse-off or leave-on) as well as the application area (e.g. face, hands, mouth and intimate area) must be taken into consideration.
- To prove the killing efficacy of products which are rinsed off the skin, it is recommended to used normative tests for biocidal efficacy and to adapt these tests with respect to the microbial spectrum, the contact time and the evaluation of cosmetic products. Growth inhibiting effects on microorganisms, however, cannot be examined in these tests, since the contact time on skin is usually shorter than the time needed for growth or inhibition of the microorganisms. For this group of products, it is advisable to perform additional practice resp. application tests in which the respective product is used according to the instructed application. Examples for application tests can be found in literature [4,5].
- For products, which stay on the skin, tests should be adapted in a way that the undiluted application of the product is taken into account.
- A justification for the selection of the test-system used should be included in the product-documentation.
- Recommendations for the selection of test-systems, relevant test-organisms for specific products or applications and recommended contact times are given in, **Tab. 2**.

Literature

[1] EC: REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

[2] EC: REGULATION (EC) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products

[3] DIN EN ISO 17516:2014: Cosmetics – Microbiology – Microbiological limits

[4] *Eigener U., Behrens U.*: Untersuchungen zur Wirksamkeit eines Hausdesinfektionsmittels; Hyg.+Med. 9, 267-269 (1984)

[5] *Eddy E.A.*: Sampling the bacteria of the skin; Handbook of Non-Invasive Methods and the Skin; CRS Press (2006)

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