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Data Sheets for the Evaluation of the Efficacy of Active Substances in Cosmetic Products

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Labelling and advertising of cosmetic products are comprehensively regulated in the European Cosmetics Regulation 1223/2009 [1] in conjunction with the “Claims Regulation” VO (EU) 655/2013 [2].

The protection of the consumer from being misled by advertising claims of a cosmetic product is essential in the regulations.

Misleading advertising in cosmetics may result from the use of only traces of certain ingredients whose efficacy is generally known to consumers and which are intensively advertised on the product, in the media or on the internet.

The following questions need to be addressed:

- When is such advertising of a supposed active substance in the product dishonest?
- Which substances are perceived by consumers as active substances and can actually give rise to consumer deception?
- At what concentrations can effective concentrations be assumed?

The Cosmetic Products Working Group of the Lebensmittelchemische Gesellschaft (LChG), a sub-society of the Gesellschaft Deutscher Chemiker (GDCh), has been dealing with these questions for about 30 years. Results are data sheets for the evaluation of the efficacy of active substances in cosmetic products.

These data sheets are available free of charge on the website of the GDCh [3].

Individual cosmetic ingredients such as vitamins can have certain functions, for example anti-oxidant efficacy, which is only achieved by these ingredients alone in an overall formulation. If such an ingredient is used in an extremely low concentration and only its indication in the list of ingredients (INCI list) is required by law, a boastful claim of its anti-oxidative efficacy would be a deception of the consumer. The prominent indication of the substance in the product name (substance X cream) or in special prominence on the product (now with substance X) is also a deception, because the efficacy known to be associated with this substance is thereby implied and advertised in a deceptive manner.

If, on the other hand, a substance is emphasized in advertising, the concentration of which is low, while the efficacies generally known for this substance are also achieved by other substances in the formulation, a possible deception is less obvious as a result. This is because unlike medicinal products, whose efficacy is usually based on a single active ingredient, the efficacy of cosmetic products is usually the result of the interaction of all substances in the formulation. In order to assess a possible misleading effect, the overall presentation of the product must be taken into account in each case (case-by-case decision).

The aim of research and development by cosmetics manufacturers is to achieve effective overall formulations. The effectiveness of these overall formulations is investigated and documented using a variety of methods. A cosmetics manufacturer does not need to know the exact contribution of individual ingredients to the overall effect. In order not to fall under the suspicion of deceptive advertising of ingredients known for their efficacy, such as vitamins, hydroxy acids or propolis, manufacturers can orientate themselves on the information in the data sheets.

When paying attention to the information in the data sheets, manufacturers should also think about the stability of the ingredients. If one of the ingredients described in the datasheets is used in sufficiently high concentrations during production, but is degraded to a certain extent during storage due to stability problems, a concentration that is too low for efficacy claims may be found when the concentration is checked by control authorities months after production. This can result in a complaint, and this can happen even if the corresponding advertising emphasis is only to be found in the small print on the reverse side. Just like stability, possible antagonistic effects of other components of the formulation that may adversely affect efficacy must also be considered.

To date, data sheets on the following substances have been published by the working group:

- Allantoin
- Urea
- Honey

- Hydroxy acids and other organic acids with comparable effects
- Camomile
- Panthenol
- Propolis
- Selected proteins
- Vitamin A and its esters
- Vitamin E
- Vitamin C
- Niacinamide (Vitamin B3)

Another data sheet provides guidance on claims regarding pH values for cosmetic products.

Each of the data sheets must be considered in conjunction with the general notes on the application of the data sheets. These general notes can also be found on the GDCh website [3].

The data sheets have not only been repeatedly reviewed and revised. New data sheets on additional substances are also compiled and published by the working group through litera-

ture searches in scientific publications as well as in information from raw material manufacturers and compilation of the data. Aloe vera is the most recent substance in the collection, for which a data sheet has just been published and posted on the working group's website.

LITERATURE

- [1] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as amended
- [2] Commission Regulation (EU) No 655/2013 establishing common criteria for substantiating claims relating to cosmetic products of 10 July 2013, as amended
- [3] www.gdch.de/netzwerk-strukturen/fachstrukturen/lebensmittelchemische-gesellschaft/arbeitsgruppen/kosmetische-mittel.html

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