

Functional Skin Care

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What's the meaning of

Functional - Skin – Care

- first condition: it is **safe**!
- help the skin and its physiological function
- with claim (=function) support
- mainly topical application
- **but** it is not pharmacies

How can it be done?

- with the claims which can be proofed with scientific data
- Example from euroup
- difference between China and other countries

COLIPA GUIDELINES

Efficacy Evaluation of Cosmetic Products

- "These guidelines aim to assist the cosmetics industry to comply with the applicable European regulations for the efficacy evaluation of cosmetic products. Because **methodologically sound research is essential for the efficacy evaluation**, these guidelines provide an overview of established testing methodologies. ...
- The use of studies substantiating product efficacy in product communication, as well as the use of other information sources that are not pertinent to this document (e.g. data found in the literature such as that available on key raw materials) are..."

Claim Support

- Needs to meet legal and regulatory requirements regarding the safety and efficacy of the cosmetics to protect consumers against misleading and overpromising claims
- COPLIA Guideline „Guidelines for the evaluation of the efficacy of cosmetic products“ aim to assist the cosmetic industry to comply with the applicable European regulations

Cosmetic Claims

According to COLIPA GUIDELINES:
Efficacy Evaluation of Cosmetic Products

- A cosmetic claim is any public information, which primarily provided for marketing purposes
 - On the content
 - The nature
 - The effect
 - The properties, or
 - The efficacy of the product

Cosmetic Substantiation

- In vitro
 - Often first step
 - Screening
 - Proff-of-concept
 - No meaningful in vivo endpoint
 - Penetration studies
- In vivo
 - Realistic conditions
 - Consumer relevant
 - Also to reconfirm in vitro results

In vivo Study options

- Bio-instrumentation
- Clinical evaluations
- Self-assessment

The Nature of experimental Studies

Q1/2012) BDF Praxis = draft from Cosmetics Europe (COLIPA)

- **Dermatologically tested**

→ the product underwent tests conducted under the supervision of a dermatologist who has to sign the report

→ Cosmetics Europe (draft): Court (European Court of Justice in Case C-99/01) clarified that the average consumer's expectation of such a claim is that the product underwent tests intended to study its effects on the skin and that the results of those tests were positive and showed that the product was well tolerated

- **Clinically tested**

→ the product underwent tests conducted in a (day-) hospital under the supervision of a dermatologist or physician who has to sign the report (advisory opinion of Gerhardt, 2004)

→ Cosmetics Europe (draft): refers to the expertise, process or conditions under which the tests were carried out / tested on humans under the supervision of relevant professional experts (physicians or other suitably qualified professionals). it may refer to a specific efficacy of the product or to skin tolerance.

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The Nature of experimental Studies

Q1/2012) BDF Praxis = draft from Cosmetics Europe (COLIPA)

- **Tolerance tested**

→ Cosmetics Europe (draft): means that the product underwent tests intended to study its tolerance on a target group and that the results of those tests were positive and the product was well tolerated by this group

- **Tested under medical supervision**

→ the product underwent tests conducted under the supervision of a physician (gynecologist, ophthalmologist, pediatrician) who has to sign the report

→ Cosmetics Europe (draft): indicates that the product underwent tests conducted under the supervision of a medically qualified professional. it may refer to a specific efficacy of the product or to skin tolerance

Thanks!

- **LIST OF COMMON CRITERIA FOR CLAIMS** which may be used with respect to cosmetic products according to article 20 of regulation (EC) 1223/2009
- hier wird unter anderem ein Vorschlag für die Definition der "[nature of experimental studies](#)" erarbeitet (zB "clinically tested" oder "dermatologically tested")
- **Problem:** International gibt es derzeit keine gültige Vereinheitlichung, d.h. jedes Land hat andere Anforderungen an den Claimsupport, von einfacher Erklärung bis hin zu notariell beglaubigten Reports externer klinischer Studien.
- **Aber:** In einigen Regionen / Ländern gibt es Bestrebungen in Richtung klinische Prüfung (Clearcast, NDA, Registrierungsbehörden).

Formulating Claims

- A claim can be a
 - Word
 - Sentence or paragraph
 - Drawing or image

Cosmetic Advertising

- Described as the promotion of cosmetics and beauty products
 - On the package or the pack insert, but also
 - Through a variety of media