

From Guidelines to Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products

Criterion	Description	Examples of claims (only illustrative and not exhaustive) and remarks
Evidential support	<p>Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them⁸, including where appropriate expert assessments.</p> <p>The responsible person⁹:</p> <ul style="list-style-type: none"> - Determines the appropriate and sufficient methodology to be used for claim substantiation. The appropriateness and relevance may be evaluated by the authorities as part of their market surveillance activities. - Determines the appropriate supporting evidence. Such evidence can be of different kinds and forms and must be justified where necessary in the product information file¹⁰. - Must hold appropriate and adequate scientific evidence to substantiate the claim made whether explicit or implied, with appropriate support. - May consult an expert who will provide the appropriate support. - Must ensure that the evidential support is still applicable when the formulation of the product changes. <p>Evidence for claim substantiation shall take into account state of the art practices (see Annex II on</p>	<p>Computers are now able to analyse and quantify skin coloration for even skin tone; this can also be done by trained observers using a grading scale.</p> <p>The presentation of results from in vitro or in silico studies should not suggest a result in vivo.</p>

⁸ See Annex II

⁹ See Articles 4 and 5 of Regulation (EC) No 1223/2009.

¹⁰ See Article 11(2) of Regulation (EC) No 1223/2009, listing the information to be included in the product information file (11(2)(d): 'where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product').

	<p>best practices).</p> <p>Where studies are being used as evidence, they shall be relevant to the product and to the benefit claimed, shall follow well-designed, well-conducted methodologies (valid, reliable and reproducible) and shall respect ethical considerations.</p> <p>The level of evidence or substantiation shall be consistent with the type of claim being made, in particular for claims where lack of efficacy may cause a safety problem, e.g. sun protection claims¹¹.</p> <p>Statements of clear exaggeration¹² which are not to be taken literally by the average end user (hyperbole) or statements of an abstract nature shall not require substantiation.</p> <p>A claim extrapolating (explicitly or implicitly) ingredient properties to the finished product shall be supported by adequate and verifiable evidence, such as by demonstrating the presence of the ingredient at an effective concentration.</p> <p>Assessment of the acceptability of a claim shall be based on the weight of evidence of all studies, data and information available depending on the nature of the claim and the prevailing general knowledge by the end users.</p>	<p>A claim <i>'this perfume gives you wings'</i> is hyperbolic, as no one would take it literally and expect to grow wings.</p>
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¹¹ See Recommendation 2006/647/EC of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto, OJ L 265, 26.9.2006, p. 39.

¹² See Article 5 of Directive 2005/29/EC ('(...) the common and legitimate advertising practice of making exaggerated statements or statements which are not meant to be taken literally is not considered as an unfair practice').