

# Safety Assessment

to confirm the requirements of the European Cosmetics Regulation EU 1223/2009  
in accordance with chapter III, article 10 in the current valid version<sup>[1]</sup>

provided for the product

## LASHES Wimpern Wachstumsserum

**Formula number** **28897**

of the company

GL Beautycompany GmbH

performed by

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## Part A - Evaluation result

### LASHES Wimpern Wachstumsserum

Allowing for the general toxicological profile of the components, its chemical composition and the grade of exposition in compliance with the warnings and conditions of use at the regular and foreseeable application, the product is to be classified as safe and not harmful to the health.

The evaluation of the safety of the cosmetic product is based on the chemical composition of the formula (as found in the company and INCI formula subject to the inspection requirements of the raw materials and ready-made product), on the toxicological profile of the components (accessible toxicological and dermatological data of the raw materials, safety data sheets, as well as legal regulations regarding the raw materials), as well as the conditions of use as intended and unintended use as foreseeable within reason.

The grade of exposition results from the conditions of use with regard to the COLIPA guidelines as well as the directions for use on the product packaging. The voluntary and legally prescribed warnings as well as other consumer information are referred for safety measures, as far as they are part of the product packaging.

Responsibility for the observations on reclamations and possible misuse, as well as the resulting evaluations, lies with the distributor.

Compliance with the "Good Manufacturing Practice" takes place in accordance with the cosmetics GMP (DIN EN ISO 22716). It remains unaffected by the evaluation of the safety of the cosmetic product.

Evaluated on: 02.03.2022

Signature of the safety assessor:



Dipl. Chem. Dr. rer. nat. Martin Neubauer

## Teil C - Safety assessment of the cosmetic product

### 1. Conclusions from the safety assessment

The cosmetic product LASHES Wimpern Wachstumsserum, formula no.: 28897, has been evaluated according to Annex I of the EC Regulation 1223/2009 in its currently valid version. The product is to be evaluated as "SAFE" and harmless to health under consideration of the general toxicological profile of the components, the chemical composition and the degree of exposure, observing the warning notices and conditions of use under normal, reasonably foreseeable use. This product shall be clearly identified as a cosmetic product. Misuse as food is not to be expected due to the packaging design, the appearance and the smell. The product's formula was established and developed for the intended use as Eye care products (cream, gel, mascara, eyeliner, eye make-up, eye shadow, eyelash serum). The product does not contain any ingredients that are not suitable for this purpose. At normal and expected use, the product is no risk to health. The general impression of the finished product is that of a cosmetic product. It is not misleading to a use as a foodstuff, whether through the design of the labels, or through the form of the packaging, appearance or odor of the product. The product was tested for its time- dependent stability. Under normal and expected conditions of use and storage within the intended shelf life of the product, no health hazardous effects are to be expected due to instability.

All raw materials used must meet the requirements for consistent quality and purity set by cosmetic GMP. The distributor/producer/contract manufacturer must ensure this through suitable quality control measures. If limit values for unintentionally introduced impurities or toxically relevant substances describing a technically unavoidable concentration are known, these must be complied with by the distributor/producer/contract manufacturer and documented as part of quality assurance measures.

The microbiological quality of the cosmetic product was tested and the total germ count is under the limits prescribed by the SCCS. Pathogenic germs were not detected. The required germ reduction was achieved in the preservation efficacy test.

The product stability has been proven by stability tests. Under normal and expected conditions of use and storage, no adverse health effects due to instability are expected.

There is a confirmation by the packaging material supplier (see product information file) on the packaging material used. The present packaging material data do not suggest, that a migration of undesired components from the packaging into the product would occur, that the product is subject to variation from the packaging or that its safety is inhibited.

### 2. Warnings and instructions for use

Special warnings are not required. The present labels meet all labeling requirements. Special instructions for use have been omitted, since the product is clearly described as Eye care products (cream, gel, mascara, eyeliner, eye make-up, eye shadow, eyelash serum) and it can be assumed that the consumer will use the product correctly.

The product does not contain any substances that require special warnings or precautions on the label according to Regulation (EC) 1223/2009 for cosmetic products [1]. Furthermore, the product does not contain any substances which, due to their properties and their content in the final product, require special warnings or precautions on the label. Product-specific instructions (such as for sunscreens or for aerosol dispensers) are not required.

### 3. Explanatory statement

Safety margins of the individual raw materials, conclusion:

A safe cosmetic product generally exhibits safety margins of at least 100 for the individual raw materials. The raw materials used in the present formula were rated as safe in the applied concentrations regarding their toxicological profile, either through experts from the Cosmetic Ingredients Review (CIR), the European Food Safety Authority (EFSA), the Food and Drug Administration (FDA), International Fragrance Association (IFRA), or other national and international panels of experts.

The cosmetic product LASHES Wimpern Wachstumsserum, formula no.: 28897, is to be assessed as safe due to the exposition estimation and calculation (see section 7).

According to the regulation (EC) 1223/2009 for cosmetic products, this assessment is based on:

- the toxicological profile of the ingredients, accessible toxicological / dermatological documentation of the test on the raw material and the finished product, including microbiological tests, safety data sheets, legal regulations, generally binding international evaluations (e.g. by the Cosmetic Ingredients Review (CIR)), recommendations by authorities and associations, as well as the marketing experience
- the chemical composition of the raw material and the finished product
- tests on the raw material and the finished product
- the grade of exposition, which results from the product presentation and conditions of use

## 4. Final declaration

All statements and assessments made in this safety assessment were made according to current knowledge. Any subsequent modifications of the formula or the modification / addition of relevant data regarding the assessment of raw materials, the specification of raw materials, their minor constituents and / or the manufacturing process will void this assessment.

## 5. Literature

- (1) Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, in its currently valid version.
- (2) The SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 11th revision, The Scientific Committee on Consumer Safety, 31.03.2021.
- (3) 50th Amendment to the IFRA-Code of Practice, 30.06.2021.
- (4) Kosmetika - Inhaltsstoffe - Funktionen, IKW, 1998.
- (5) Wörterbuch der Kosmetik, Fey, H., Petsitis, X., WVG Stuttgart, 2004.
- (6) Cosmetic Raw Materials, chemical and physical specifications, toxicological data and safety data sheets, data base, data collection and archives of INCI-Experts GmbH, Hamburg.
- (7) Plants in Cosmetics, Vol I-III, Council of Europe, 2002.
- (8) Common Fragrance and Flavor Materials, Surburg & Panten, Wiley-VCH, 2006.
- (9) CIR-Compendium, Cosmetic Ingredient Review, Washington, 2005.
- (10) Teedrogen und Phytopharmaka, Ed. Max Wichtl, Wissenschaftliche Verlagsgesellschaft mbH, 2009.
- (11) Lehrbuch der Toxikologie, Ed. Marquardt & Schäfer, BI Wissenschaftsverlag, 1994.
- (12) Phytopharmaka nano, Sandra Leonhardt, Wissenschaftliche Verlagsgesellschaft mbH, 2012.
- (13) Heilpflanzenpraxis Heute, Siegfried Bäumler, Elsevier Urban & Fischer Verlagsgesellschaft mbH, 2007.
- (14) Guidance Document on Dermal Absorption, SANCO222/2000 rev. 7, 2004.
- (15) ISO 29621:2010, Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products, 2010.
- (16) Implementing Rules (2013/674/EU) on Guidelines referring to Annex I of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, 25.11.2013.
- (17) Cosmetic GMP - Good Manufacturing Practice, DIN EN ISO 22716:2008-12.
- (18) ECHA (European Chemicals Agency) 2012a. Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Updated version 2.1, November 2012. Consulted September 2015.
- (19) VO EU 10/2011, VERORDNUNG (EU) Nr. 10/2011 DER KOMMISSION vom 14. Januar 2011 über Materialien und Gegenstände aus Kunststoff, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen.
- (20) L298/39 COMMISSION RECOMMENDATION of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EG).
- (21) References INCI:
  - Pentylen Glycol: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/2101>
  - Propylene Glycol: <https://echa.europa.eu/registration-dossier/-/registered-dossier/16001>
  - Glycerin: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14481>
  - Trifolium Pratense Flower Extract: [https://www.bfr.bund.de/de/a-z\\_index/isoflavone-9777.html](https://www.bfr.bund.de/de/a-z_index/isoflavone-9777.html)
  - Arginine: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13725>
  - Alcohol denat.: <https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/16105>
  - Citric Acid: <https://www.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/15451>
  - Butylene Glycol: <https://echa.europa.eu/registration-dossier/-/registered-dossier/14962>
  - Phenethyl Alcohol: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13615>
  - Sodium Benzoate: <https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/14966>
  - Xanthan Gum: EFSA Journal 2017;15(7):4909
  - Gellan Gum: [https://www.fao.org/fileadmin/user\\_upload/jecfa\\_additives/docs/monograph16/additive-199-m16.pdf](https://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph16/additive-199-m16.pdf)
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  - Sodium Chloride: <https://www.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/15467>
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  - Lecithin: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/28377>
  - Bioflavonoids: EFSA Journal 2010; 8(9):1065
  - Glycine Soja Germ Extract: <https://pubmed.ncbi.nlm.nih.gov/15885867/>
  - Phenoxyethanol: <https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15160>
  - Caprylyl Glycol: <https://www.echa.europa.eu/de/web/guest/registration-dossier/-/registered-dossier/14120>

- Biotin: Blum et al., FCT, 153, (2021), 112267
- Rutin: Tiwari et al., Clinical Phytoscience (2020) 6:82
- Tocopherol: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/12703>
- Sodium Citrate: <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15303>
- Benzoic Acid: <https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/13124>

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