

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 (1)

provided for the product

LASH MAX HYALURONIC MASCARA

Formula number:

AME08901B-FP-19

of the company

GL Beautycompany GmbH

performed by

INCI-Experts GmbH · Gehlengraben 2 · D-22415 Hamburg · www.inci-experts.de

LASH MAX HYALURONIC MASCARA

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: 17.08.2021

Signature of the safety assessor:



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

Part C - Safety assessment of the cosmetic product

1. Conclusions from the safety assessment

The cosmetic product LASH MAX HYALURONIC MASCARA, Rezeptur-Nr.: AME08901B-FP-19, is to be classified as safe and not harmful to health, 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 present product is clearly recognizable as a cosmetic product. Misuse as a foodstuff is not to be expected due to the packaging design, appearance and odor.

The product's formula was established and developed for the intended use as make-up. It 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.

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. At the microbiological challenge tests, the required germ reduction was achieved.

The product stability was verified through stability testing. Under normal and expected conditions of use and storage, no adverse effects on the health are to be expected due to instability.

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 label meets all the requirements of labeling. Particular instructions for use were omitted, since the product is clearly described as a make-up and it can be assumed, that the consumer will use the product as intended.

The product contains no substances which make pursuant to Regulation (EC) 1223/2009 on cosmetic products [1] special warnings or precautions on the label required. Next, the product does not contain substances which require special warnings or precautions on the label due to their characteristics and their content in the final product. Product-specific information, such as for sunscreen products or aerosols, 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 LASH MAX HYALURONIC MASCARA, Rezeptur-Nr.: AME08901B-FP-19, 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) Verordnung (EG) Nr. 1223/2009 des Europäischen Parlaments und des Rates vom 30. November 2009 über kosmetische Mittel, in der aktuell gültigen Fassung.
- (2) The SCCS's Notes of Guidance for the Testing of Cosmetic ingredients and their safety evaluation, 9th revision, The Scientific Committee on Consumer Safety, 29.09.2015.
- (3) 48th Amendment to the IRFA-Code of Practice, 10. Juni 2015.
- (4) Kosmetika - Inhaltsstoffe - Funktionen, IKW, 1998.
- (5) Wörterbuch der Kosmetik, Fey, H., Petsitis, X., WVG Stuttgart, 2004.
- (6) Kosmetik-Rohstoffe, chemisch-physikalische Spezifikationen, toxikologische Daten und Sicherheitsdatenblätter, Datenbank, Datensammlung und Archiv der 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 Bäuml, Elsevier Urban & Fischer Verlagsgesellschaft mbH, 2007.
- (14) Guidance Document on Dermal Absorption, SANCO/222/2000 rev. 7, 2004.
- (15) Cosmetic products, 2010.
- (16) Durchführungsbeschluss (2013/674/EU) über Leitlinien zu Anhang I der Verordnung (EG) Nr. 1223/2009 des Europäischen Parlaments und des Rates über kosmetische Mittel, 25.11.2013.