



We create chemistry

Personal Care

Quality & Regulatory Product Information

Eumulgin® SML 20

PRD 30527797

Date: 01 Mar 2022

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® = Registered trademark of BASF in many countries ™ = Trademark of BASF

Care Chemicals

With the rising complexity of the regulatory environment and customers' growing demand for product quality and safety worldwide, companies need to provide information related to an increasing number of different regulatory and quality topics.

At the same time fast information flow is a key requirement for success.

In order to assist you in a rapid execution, BASF Personal Care established a Quality & Regulatory Product Information package (Q&R PI) which will provide you with a comprehensive summary of all required regulatory, quality, and safety information.

We have gained positive feedback from a large number of our customers who were able to accelerate their submission process. We are convinced that this package will also support you in your daily business.

If you have any further questions or need additional support, please contact your BASF sales representative.

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1. Identity and Registrations

INCI Name

Polysorbate-20

- Refer to corresponding statement Composition Sheet and Source
- Refer to corresponding Statement for the listing status of the product INCI names in China

Microplastic

- Based on information concerning the raw materials, production process and equipment used, in general polymers are not expected to be present neither are intentionally added in the product. Consequently, the product is not be regarded as microplastic according to ECHA's upcoming microplastic restriction.
- Refer to corresponding statement

Product description

- Refer to corresponding Technical Information
- Refer to corresponding Scientific and/or Marketing Brochure

Composition

- Refer to corresponding Composition Sheet
- Refer to corresponding statement Composition Sheet and Source

Compliance with Chemical Inventories

Compliance with the European Union's Chemicals Legislation (REACH), Regulation (EC) 1907/2006

- Refer to corresponding statement

Compliance with Chemical Inventories

- Refer to corresponding statement

Approval for cosmetic uses

Compliance with European Union cosmetics legislation

- We hereby confirm that the cosmetic ingredient marketed by BASF complies with the relevant requirements of the Cosmetics Regulation (EC) 1223/2009, as amended, under typical conditions of use.

Specific approvals

- UV Filters: refer to corresponding statement
- Hair Dyes: refer to corresponding statement

2. Product specification

- Refer to corresponding Specification Sheet

3. Manufacturing

Type of manufacturing process

- Chemical reaction
- By purification of a natural product
- By fermentation
- By extraction
- Blend
- Other:
- Refer to corresponding Composition Sheet and Source
- Refer to corresponding statement Manufacturing Procedure

Irradiation

- Based on information concerning the raw materials, production process, and equipment used radioactive material is not expected to be present.
- Refer to corresponding statement

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4. Raw materials

Based on our current knowledge, raw materials used in the manufacture of the product are:

- of vegetable origin
 - Derived from non-genetically modified plant.
 - GMO-free (not containing genetically modified DNA)
- of animal origin, refer to corresponding statement
- of mineral oil/natural gas origin (Petrochemical feedstock and/or synthetic)
- Inorganic
- Refer to corresponding Composition Sheet and Source
- Refer to corresponding statement Details of Origin

5. Stabilization of the Product

- Preservatives :
 - Antioxidants:
 - Sequestering/Complexing agents :
 - Others :
-
- There are no additives in this product
 - Refer to corresponding Composition Sheet and Source
 - Refer to corresponding Technical Information

6. Biodiversity related frameworks (e.g. Nagoya Protocol, CITES)

- Based on our current knowledge the product and/or its components is out of scope of the access and benefit-sharing obligations laid down in the Nagoya-Protocol, as implemented by EU-Regulation 511/2014
- Based on our current knowledge the product is in scope of the access and benefit-sharing obligations laid down in the Nagoya-Protocol, as implemented by the EU-Regulation 511/2014

Based on our current knowledge the product and/or its components are derived from species listed in the Appendices of CITES (Convention on International Trade in Endangered Species)

- No
- Yes, a statement is available on request.

7. Certification

- Certified according to ISO 9001/2015
- Refer to corresponding statement
- Refer to product specific Kosher, Halal or other certificates - when applicable
- Other:

8. By-products and impurities

- a) Residual solvents, heavy metals, pesticides, aflatoxins/mycotoxins, polycyclic aromatic hydrocarbons, residual monomers, phthalates, glycol ethers, allergens, other impurities
- Refer to corresponding Product Purity Profile

b) CMR substances

- Based on our current knowledge about the raw materials, production process, and equipment used CMR substances according to Annex VI of the CLP Regulation (EC) 1272/2008) are not likely to be present.
- May contain the following CMR substances:
Ethylene oxide <= 1 ppm, 1,4-Dioxane <= 1 ppm

The presence of traces of the listed CMR substances, stemming from raw materials used and/or being formed in the manufacturing process of the product in question, is not intended and is technically unavoidable.

In accordance with Article 17 of the Cosmetics Regulation (EC) 1223/2009 such traces of CMR substances are accepted.

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c) Proposition 65

- Based on our current knowledge about the raw materials, production process, and equipment used substances listed in The Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") are not likely to be present.
- Refer to corresponding statement.

9. Nanomaterials

Nanomaterials are defined in the Cosmetics Regulation (EC) No. 1223/2009 as follows:

'Nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm'

- The product and/or its components is not considered to be a nanomaterial under this definition.
- The product and/or its components is considered to be a nanomaterial under this definition. A statement is available on request.
- The product and/or its components is subject in a national Nano-inventory list. A statement is available on request.

10. Microbiological information

- The stability of a product against microbial attack is characterized by using either the water activity [aw] value, the specified pH-value, the alcohol content or a challenge test. Based on this appraisal and taking into account industrial hygiene measures, the total count of cells being able to multiply in the product is specified as

<= 100 CFU/g, incl. the absence of pathogenic indicators

acc. Ph. Eur. 5.1.4 category 2 [cutaneous use resp.] / DIN EN ISO 17516 when determined by total plate count (e.g. Ph. Eur. 2.6.12, DIN EN ISO 18415) or most probable number.

References

Cosmetic Microbiology, 2006; Edited by Philip A. Geis, Ph.D.; CRC Press, Boca Raton, FL 33487-2742; ISBN 0-8493-1453-4.

Microbial Quality Assurance in Cosmetics, Toiletries and Non-Sterile Pharmaceuticals, 1996 Second Edition Edited by R.M. Baird with S.F. Bloomfield; Taylor & Francis ISBN 0-7484-0437-6.

- DIN EN ISO 11930:2012; Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product
- DIN EN ISO 17516:2014; Cosmetics - Microbiology - Microbiological limits
- DIN EN ISO 18415:2011; Cosmetics - Microbiology - Detection of specified and non-specified microorganisms
- DIN EN ISO 29621:2010, Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products

- Refer to corresponding extended Microbiological Stability statement
- Refer to corresponding Specification Sheet

11. Safety and Environment Information

Product-specific Information on Animal Testing

- For the purposes of the European Cosmetics Regulation (EC) No. 1223/2009, no animal testing has been carried out by or on behalf of BASF on the product/ingredients after 11th March 2009 and after 11th March, 2013 (extended deadline for animal testing for repeated dose, reproductive toxicity or toxicokinetics). Refer to separate statement.
- Toxicological information available upon request
- Ecotoxicological information: Refer to Safety Data Sheet

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12. Selected Sustainability Standards, Policies and Procedures

For more information please visit the following websites:

<https://www.carecreations.basf.com>

<https://www.basf.com/global/en.html>

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