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COSMETIC PRODUCT SAFETY REPORT

Bulk name: Benevi Hydroderm Gesichtsfluid
Formulation number: 1735/06

Product name: BENEVI HYDRODERM Gesichts-Fluid

Reference number: 130015.02

Customer: Benevi Med GmbH & Co. KG

Inspected batch number of manufacture: LOT 51202

By order of: Dr. Sacher Kosmetik GmbH
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COSMETIC PRODUCT SAFETY REPORT SUMMARY

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Description of the cosmetic product.....	3
Part A Cosmetic product safety information	4
1. Qualitative and quantitative composition of the cosmetic product.....	4
2. Physical/chemical characteristics and stability of the cosmetic product.....	4
3. Microbiological quality	4
4. Impurities, traces, information about the packaging material.....	5
5. Normal and reasonably foreseeable use	5
6. Exposure to the cosmetic product	5
7. Exposure to the substances	5
8. Toxicological profile of the substances	6
9. Undesirable effects and serious undesirable effects	6
10. Information on the cosmetic product	6
Part B Cosmetic product safety assessment	7
1. Assessment conclusion	7
2. Labeled warnings and instructions of use in accordance with Article 19 (1) (d).....	7
3. Reasoning	8
4. Assessor's credentials and approval of part B.....	8



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Cosmetic product safety report is performed according to article 10 annex I of the regulation (EC) No 1223/2009 of 30 November (Official Journal of the European Union L342/59).

Description of the cosmetic product

Bulk name: Benevi Hydroderm Gesichtsfluid

Formulation number: 1735/06

Product name: BENEVI HYDRODERM Gesichts-Fluid

Reference number: 130015.02

Type of cosmetic product: Leave-on-product

Packing: Paperbox

Container: 50 mL- plastictube with screw cap (HDPE/PP; Food Grade quality)

Description of content:

The cream is soft hydrating and suitable for dry and impure skin. Recommended for women as well as men. Category 5 according to IFRA/IKW.

Recommended application:

Apply once a day on the cleansed skin and let it work in.



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Part A *Cosmetic product safety information*

1. Qualitative and quantitative composition of the cosmetic product

The qualitative and quantitative composition of the cosmetic product, including chemical identity of the substances and their intended function is listed in chapter 4 and 6 of the cosmetic product safety information. Information of suppliers about identity and composition of the substances of the cosmetic product are existing in an electronic data bank.

2. Physical/chemical characteristics and stability of the cosmetic product

The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product are listed in chapter 5 resp. chapter 1. The stability of the cosmetic product under reasonably foreseeable storage conditions is documented by means of stability tests. The period of time after opening for which the product is safe is established by means of an assessment system based on physical stability tests and chemical as well as microbiological analysis.

3. Microbiological quality

The microbiological specification of the substances or mixtures and the cosmetic product are listed in chapter 5. The results of the preservation challenge tests (chapter 6.4.) satisfy the demands of the European Pharmacopoeia for topical products.



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4. Impurities, traces, information about the packaging material

The purity of the substances and mixtures was examined on basis of the present material data sheets. There was no indication of forbidden substances.

The relevant characteristics of the packaging material, in particular purity and stability, were examined. There was no indication of concern for the human health.

5. Normal and reasonably foreseeable use

The cream is applied once a day after cleansing onto the skin (Recommendation of the producer).

6. Exposure to the cosmetic product

Data on the exposure to the cosmetic product (in relation to the site(s) of application, the surface area(s) of application, the amount of product applied, the duration and frequency of use, the normal and reasonably foreseeable exposure route(s) and the targeted population(s)) are given in chapter 6.1 of the cosmetic product safety report.

Secondary exposure (e.g. non-intended inhalation or ingestion) is not expected.

7. Exposure to the substances

Data on the exposure to the substances contained in the cosmetic product are listed in chapter 6.2 of the cosmetic product safety report.



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8. Toxicological profile of the substances

The toxicological profile of all substances contained in the cosmetic product is listed in chapter 5. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitization and photo-induced toxicity is performed. All significant toxicological routes of absorption are considered as well as systemic effects.

The margins of safety (MoS) based on no observed adverse effect level (NOAEL) resp. ADI-values are calculated. Any read-across, if necessary, is substantiated and justified. The source of information is identified as shown in chapter 5.

Particular consideration is given to any possible impacts on the toxicological profile due to particle sizes, impurities and interaction of substances.

9. Undesirable effects and serious undesirable effects

Up to now no undesirable or serious undesirable effects are known as laid down in chapter 6.6.

10. Information on the cosmetic product

Studies from human volunteers (patch test on injured skin) underline skin tolerability of the cosmetic product.



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Part B ***Cosmetic product safety assessment***

1. Assessment conclusion

In consideration of the requirements of Article 10 and in particular Annex I as well as the knowledge of the formulas of similar products the present product complies with Article 3.

Under normal or reasonably foreseeable conditions of use, the product is safe for human health.

2. Labeled warnings and instructions of use in accordance with Article 19 (1) (d)

In view of the exposure of the product/substances and the toxicological profile of the substances particular warnings and instructions of use in accordance with Article 19 (1)(d) are not necessary.



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3. Reasoning

Margins of safety (MoS) based on NOAEL data are listed in part A of the Cosmetic Product Safety Report. The margins of safety of all examined substances fulfill the minimum value of 100.

If available, ADI data were taken into account for the estimation of the systemic burden. If no ADI data are available PADI values resp. Threshold of Concern of EFSA were taken into concern.

The calculated values of all examined substances are less than 50 % of the ADI data, resp. PADI or EFSA data.

4. Assessor's credentials and approval of part B

The assessor is in possession of a diploma in chemistry and biology and shows a more than 30 year's profession experience in the fields of research, teaching and official inspection.

Since 1999 he has absolved numerous courses of instructions to reach the qualification of a safety assessor.

Prof. Dr. rer. nat. Dettmar von Wachtendonk
Official food inspector

Eschweiler, 25.04.2016

- Former chemistry director –
of

Chemisches und Lebensmittel-Untersuchungsamt Aachen