



# Safety assessment

For the finished product

**Milky Body Wash**

According to Annex 1 of the Regulation (EC) No, 1223/2009

|                        |                                                                                                                                       |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Created on: 08.05.2025 | Recipenumber: MP, SG,28                                                                                                               |
| For                    | PureSource GmbH<br>Römerweg 21<br>86391 Stadtbergen                                                                                   |
| Safety assessor        | LEMIKOS GmbH<br>Sandra Haßler<br>Carl-Hans-Straße 5<br>51674 Wiehl/Germany<br>Tel: +49 (0) 2296 / 999 0300<br>E-Mail: info@lemikos.de |

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| <b>Milky Body Wash</b> |                       | <b>LEMIKOS</b><br>Die Kosmetikexperten |
| Status: 08.05.2025     | Author: Sandra Haßler |                                        |

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## **A. Safety information of the cosmetic product**

### **A.1 Safety information about the cosmetic product**

#### **A.1.1 Legal classification**

The present product is a mixture of Aqua, Sodium Laureth Sulfate, Sodium Chloride, Glycerin, Cocamidopropyl Betaine, Decyl Glucoside, Sodium Lauroyl Oat Amino Acids and other ingredients.

The product is used for shower gel.  
The present product is a RINSE-OFF product.

Thus the present product is a cosmetic product according to Article 2 (1) a of Regulation (EC) No 1223/2009. Cosmetic products are therefore products that are intended to come into contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity, specifically for the sole or mainly purpose to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

[Removed from this trade copy: production recipe and quantitative formula (A.2.1, A.2.2). Full report available to trade partners on request.]

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### A.2.3 Qualitative recipe

Ingredients:

Aqua, Sodium Laureth Sulfate, Sodium Chloride, Glycerin, Cocamidopropyl Betaine, Decyl Glucoside, Sodium Lauroyl Oat Amino Acids, **Centella Asiatica Extract, Xylitylglucoside, Parfum, Phenoxyethanol, Anhydroxylitol, Styrene/Acrylates Copolymer, Xylitol, Tetramethyl Acetyloctahydronaphthalenes, Disodium Edta, Aloe Barbadensis Leaf Juice Powder, Hexamethylindanopyran, Ethylhexylglycerin, Citrus Aurantium Bergamia Peel Oil, Limonene, Linalyl Acetate, Citronellol, Tetrasodium EDTA, Glucose, Pinene, Geraniol, Citric Acid**

Note: Ingredients in bold are below 1% and can be listed disordered.

Ingredients (PCPC):

Water, Sodium Laureth Sulfate, Sodium Chloride, Glycerin, Cocamidopropyl Betaine, Decyl Glucoside, Sodium Lauroyl Oat Amino Acids, **Centella Asiatica Extract, Xylitylglucoside, Fragrance, Phenoxyethanol, Anhydroxylitol, Styrene/Acrylates Copolymer, Xylitol, Tetramethyl Acetyloctahydronaphthalenes, Disodium Edta, Aloe Barbadensis Leaf Juice Powder, Hexamethylindanopyran, Ethylhexylglycerin, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Limonene, Linalyl Acetate, Citronellol, Tetrasodium EDTA, Glucose, Pinene, Geraniol, Citric Acid**

Note: For informational use only! Check for completeness before marketing.

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## **A.3 Physical /chemical properties of the raw materials**

### **A.3.1 Physical / chemical properties of the raw materials**

The physical-chemical properties of the raw materials are documented in the Product Information File. According to Article 11 of the Regulation (EC) No. 1223/2009 the Product Information File must be created separately. It contains all the data on raw materials, production method, proofs of effectiveness, etc. The Product Information File has to be stored for 10 years after the last production batch has been put on the market. Toxicological and safety-related data are listed below.

### **A.3.2 Physical / chemical properties of the finished product**

Consistency: liquid  
 Odour: as standard  
 Colour: as standard  
 Viscosity: -  
 pH-value: -  
 Density: -  
 Miscellaneous: -

### **A.3.3 Stability and shelf-life of the finished product**

The product is subjected to a stability test and/or storage test and/or durability test by the Manufacturer and/or client and/or responsible person. In doing so the usual storage conditions and external influences such as temperature, light and product aging have been considered. The product is stable in its current composition. Based on the stability test carried out and based on experience, the product has a shelf life of more than 30 months. A PAO of 12 M can be indicated.

|                        |                       |                                                                                    |
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## A.4 Microbiological quality and stability

### A.4.1 Microbiological quality

The following microbiological test is available for the product:

| parameter                    | Microbiological profile | Target value according to SCCS <100 for high-risk products/ <1000 for low-risk products |
|------------------------------|-------------------------|-----------------------------------------------------------------------------------------|
| Total aerobic bacteria count | <10 cfu/g               | <1000 cfu/g                                                                             |
| Specific pathogenic germs    | n.d.                    | n.d.                                                                                    |

### A.4.2 Microbiological stability

A germ-contamination test has been carried out. The testing was based on the DIN ISO 11930 in its current version respectively the requirements of the SCCS (Scientific Committee on Consumer Safety). The product was inoculated with *Staphylococcus aureus*, *Pseudomonas parvaeruginosa*, *Candida albicans* and *Aspergillus brasiliensis*. As a result, it was found that the product meets the adequate preservation, A criterion for topical use, according to the DIN ISO 11930. According to the requirements of the SCCS the number of germs has to be less than 1000 CFU/g. This requirement has also been met.

Date: 08.04.2025, SGS

## A.5 Impurities, traces, information about the packaging material

### A.5.1 Impurities/Traces

No substances are intentionally added as ingredients to the present cosmetic product which are prohibited in accordance with Annex II of Regulation (EC) No. 1223/2009. Unwanted substances or traces of substances in the ppm range (part per million, millionth) or ppb range (part per billion, billionth) are considered as contamination. Unintentionally, forbidden substances can be contained in cosmetic products as traces or impurities if they occur as technically unavoidable by-products in raw materials or packaging, e.g., due to storage and/or the manufacturing process and/or interactions between the ingredients and/or technically unavoidable by-products in raw materials.

|                        |                       |                                                                                     |
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In particular, traces of heavy metals, solvent residues, residual monomers, nitrosamines, other potential CMR substances or pesticides should be considered here.

Heavy metals and their compounds in cosmetic raw materials, for example, are prohibited in cosmetic products, but there are no specified maximum levels for cosmetic products in Regulation (EC) No. 1223/2009. And exposure to heavy metals generally plays a subordinate role compared to other sources (food, drinking water, breathing air, e.g. dust and smoking). They are to be expected in mineral raw materials, which are mainly used in decorative or powder cosmetics (BfR Statement 025/2006 of 05.04.2006)

Following a statistical monitoring study of cosmetic products, the Federal Office of Consumer Protection and Food Safety (BVL) has issued guideline values for the technical unavoidability of heavy metals. (see BVL Report 14.4 Reports on food safety 2018)

Based on the monitoring, the following heavy metal contents were defined as technically avoidable:

| Element              | General cosmetic products | Tooth paste        |
|----------------------|---------------------------|--------------------|
| <b>Lead (Pb)</b>     | <b>2,0 mg / kg*</b>       | <b>0,5 mg / kg</b> |
| <b>Cadmium (Cd)</b>  | <b>0,1 mg / kg</b>        | <b>0,1 mg / kg</b> |
| <b>Mercury (Hg)</b>  | <b>0,1 mg / kg</b>        | <b>0,1 mg / kg</b> |
| <b>Arsenic (As)</b>  | <b>0,5 mg / kg**</b>      | <b>0,5 mg / kg</b> |
| <b>Antimony (Sb)</b> | <b>0,5 mg / kg</b>        | <b>0,5 mg / kg</b> |

\* For the product groups make-up powder, blusher, eye shadow, kajal, incl. eyeliner and eyeliner as well as theatre, fan and carnival make-up: 5 mg/kg

\*\* For theatre, fan and carnival make-up: 2.5 mg/kg

According to the GESTIS substance database, the individual heavy metals are hardly or not at all absorbed; even in the worst-case scenario, absorption is less than 1%. <https://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index.jsp> The largest sources of absorption are food, breathing air and drinking water. In order to detect the heavy metals, it is pointed out that a hard, chemical digestion process (including strong acids and microwave digestion) is required for the analysis in order to dissolve the elements/heavy metals from the rock or the raw material itself, whereby a mineral raw material simultaneously loses its entire characteristic and loses its functionality.

Such a breakdown and therefore bioavailability does not occur when applied to the skin.

This means that traces of heavy metals are not bioavailable to the human organism because the element atoms are firmly incorporated into the lattice structure of the inorganic raw materials concerned.

Based on the documents submitted by the manufacturer, there are indications of minimal contamination by heavy metals of geogenic origin. However, these are technically unavoidable and do not jeopardise the safety, shelf life or quality of the finished product.

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Polycyclic aromatic hydrocarbons (PAH) are banned in cosmetic products, there are no fixed maximum levels in Regulation (EC) No. 1223/2009. For foodstuffs, a total limit value for 4 PAHs (benzo [a] pyrene, benzo [a] anthracene, benzo [j] fluoranthrene, chrysene) <10 µg / kg was specified in Regulation (EC) No. 835/2011, whereby the value for benzo [a] pyrene must not be larger than 2 µg / kg. Based on the documents submitted by the manufacturer and/or client and/or responsible person, there is no indication of contamination by PAHs that would affect the safety and quality of the finished product or impair its shelf life.

Residual solvent contents such as ethylene glycol or diethylene glycol are not present according to the certificate of analysis of the glycerine. The purity corresponds to pharmaceutical standards.

According to the manufacturer, 1,4 dioxane as an impurity of sodium laureth sulphate is within the limits of technical unavoidability. Further residual monomers and/or pesticides are not present in the documents submitted by the manufacturer and/or client and/or responsible person and therefore cannot affect the safety of the finished product or the shelf life either. Further possible impurities and traces can be found in the data of the submitted specifications and/or certificates of analysis.

Cocoamidopropylbetaine belongs to the group of amphoteric surfactants. It is used as a mild surfactant that is well tolerated by the skin to improve foam and improve the sensory texture. The classic contaminants are dimethylaminopropylamine and amidoamine as production residues. Cocoamidopropylbetaine is safe to use dermally. Both of these impurities can arise during manufacture and cause skin allergies. According to raw material data, contamination with amidoamine and contamination with dimethylaminopropylamine are indicated in the trace range and are technically unavoidable according to the manufacturer. As a result, it can be assumed that the two potential allergens are only found in trace amounts. So far, no market data has been collected, so that the use of this raw material can be considered safe.

Nitrosamines are various compounds that contain nitrogen. They can result from reactions with oxygen, nitrogen and water and are not permitted in cosmetic products. There are no direct limit values for cosmetic products, in toys there are limit values of 1mg/kg according to §6 Bedarfsgegenstände VO. According to the SCCS, a maximum nitrosamine content of 50µg/kg applies to the raw materials used, and the content of secondary amines in the raw materials should not exceed 5%. [https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_072.pdf](https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_072.pdf) . In the available batch-related specifications/certificates of analysis, no exceedance can be recognised.

Furocoumarins are phototoxic substances that occur naturally in certain plants, for example in the peel of citrus fruits. For cosmetic products that may be exposed to sunlight, a maximum value applies. Products that may be exposed to the sun may only contain quantities of less than 1

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mg/kg (=1 ppm/part per million). according to the data, the present formulation does not contain any furanocoumarins. ( Regulation of EDI, Switzerland)

In a statement from 2006, the Federal Institute for Risk Assessment (BfR) classified formaldehyde as a carcinogenic substance for the nasopharynx when inhaled, the harmful effect of which, however, depends on the concentration. In 2008, the European Commission classified formaldehyde as suspected cancer (Category 2). Formaldehyde falls under the category of "substance with carcinogenic (carcinogenic), mutagenic (mutagenic) or reproductive (toxic to reproduction) properties" (CMR substance). In 2014, the regulation on the classification, labeling and packaging of substances and mixtures (CLP regulation) was updated, stating that formaldehyde is now seen as a category 1B substance, i.e. as a carcinogen in animal experiments. This classification change came into force in 2016. In principle, according to Article 15 of the EU Cosmetics Regulation, the use of CMR substances in cosmetics is prohibited. The present product does not contain any raw materials that contain more than 0.001% free formaldehyde in the finished product.

Plasticisers, in particular the phthalates (esters of phthalic acid) used in some cases, are primarily used in plastics production to give brittle plastics an elastic and supple property, which means that they can be dissolved relatively easily in contact with cosmetic products. Due to their classification as probably toxic to reproduction, the EFSA [https://www.laves.niedersachsen.de/startseite/lebensmittel/ruckstande\\_verunreinigungen/phthalate-in-lebensmitteln-99796.html](https://www.laves.niedersachsen.de/startseite/lebensmittel/ruckstande_verunreinigungen/phthalate-in-lebensmitteln-99796.html) has therefore set a TDI (tolerable daily intake) for the three phthalates DEHP (diethylhexyl phthalate), DBP (dibutyl phthalate) and BBP (butyl benzyl phthalate).

The SCCS has also analysed with the safety of cosmetic products with phthalate impurities in a detailed statement and calculated the Margin of Safety (MoS) to ensure that they are harmless to health. According to the SCCS, traces of up to 100 ppm (mg/kg) of the phthalates DEHP, DBP and BBP are to be classified as harmless to health. [https://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_106.pdf](https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_106.pdf)

In the present formulation, the impurities have been considered and the product is considered safe for intended and reasonably foreseeable use by the consumer.

(see product information file)

## A.5.2 Nanomaterials and CMR-substances

No nanomaterials and no CMR substances according to Article 15 and Article 16 of Regulation (EC) No 1223/2009 are used in this product.

## A.5.3 Information about the packaging material

**Packaging material:** The packaging (primary packaging) is a 250ml plastic bottle with bamboo pump.

The present packaging information and specifications lead to the conclusion that no migration of undesirable components from the packaging in the product takes place or that the product can be changed by the packaging or that the safety of the product is impaired. In particular, traces of

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heavy metals, solvents and pesticides residues are considered. The packaging is in accordance with the legal provisions of the German Commodities Ordinance and Regulation (EC) 1935/2004 and/or Regulation (EG) Nr. 2023/2006 and/or Regulation b(EG) Nr. 10/2011 in its current version. (See product information file) The packaging material is suitable for the cosmetic product.

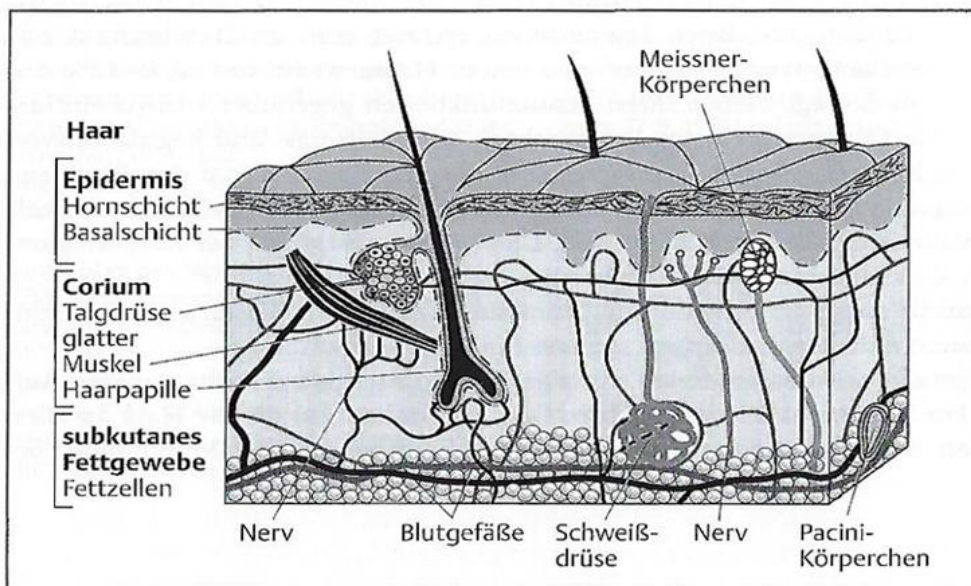
Date of declaration of conformity: see PIF

## A.6 Normal and reasonably foreseeable use

The product is used as shower gel. The product is used by adults.

### A.6.1 Estimation regarding absorption through the skin

The product is used as follows: Description of application: (see label) This results in an dermal absorption. Through the structure of the skin (stratum corneum, stratum granulosum, stratum spinosum, basement membrane, corium), chemical substances are absorbed differently. Resorption can be viewed as a multi-stage process:



Source: *Cosmetics and Hygiene*, Wilfried Umbach, 3rd edition, Wiley-VCH-Verlag

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1. The substance must be absorbed on the surface of the stratum corneum.
2. The substances must perfuse through the stratum corneum, depending on the molecular size and solubility.
3. You need to reach the epidermis.
4. The molecules must pass through the epidermis into the corium, where they reach other tissues in the body via the blood circulation.

Essentially, the physical laws of diffusion apply to this diffusion of substances (Fick's law). This means that a substance is absorbed depending on the molecular size and structure, solubility, time and thickness of the skin structure. (See Textbook of Toxicology, H. Marquardt and S.G.Schäfer, Spektrum publishing house). The absorption is estimated according to SCCS and generally applicable toxicological principles and is given in the following table:

| Flux (Jmax-µg/cm <sup>2</sup> /hour) | Molecular Weight in g/mol | Log Pow   | Max. Absorption in % |
|--------------------------------------|---------------------------|-----------|----------------------|
| negligible                           | > 600                     | <-1 or >5 | negligible           |
| <0,1                                 | > 300                     | <-1 or >5 | < 10                 |
| 0,1-1,0                              | 200-300                   | 2,0-2,5   | < 10                 |
| 1,0-10,0                             | 150-250                   | 1,0-2,0   | < 20                 |
| 10,0-100,0                           | 60-200                    | 0,5-3,0   | < 40                 |
| >100                                 | <150                      | 0,5-1,5   | < 80                 |

(Source: training documents of the DGK / IKW training for safety assessors from September 23rd to 24th, 2009)

Note: To estimate the dermal, oral or inhalation absorption, individual assumptions are made for each substance. Otherwise, a worst-case assumption generally applies.

## A.7 Exposure to the substances

### A.7.1 Basis of calculation

| Abbrevia-<br>tion in the<br>formulas | Explanation                                                                                                                                                                                                                            | Numeri-<br>cal value | Unit  | Literature<br>source/ In-<br>formation |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------|----------------------------------------|
| A                                    | The amount of use/days-dose is calculated according to Annex I, Part A.6 of Regulation (EC) No. 1223/2009 of the European Parliament and the SCCS Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation | 18.6700              | g/day | SCCS/ esti-<br>mation                  |

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| Abbrevia-<br>tion in the<br>formulas | Explanation                                                                                                                                                                                                         | Numeri-<br>cal value        | Unit                 | Literature<br>source/ In-<br>formation                                      |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|-----------------------------------------------------------------------------|
| F                                    | Frequency of use or duration and fre-<br>quency of use                                                                                                                                                              | 1.43                        | /day                 | SCCS/ esti-<br>mation                                                       |
|                                      | Normal and reasonably foreseeable<br>route of exposure                                                                                                                                                              | dermal                      |                      | Specification<br>of client/ spe-<br>cification of<br>label/ estima-<br>tion |
|                                      | Place of application                                                                                                                                                                                                | whole<br>body               |                      | Specification<br>of client/ spe-<br>cification of<br>label/ estima-<br>tion |
| C                                    | Percentage concentration of the toxico-<br>logically relevant substance in the final<br>product                                                                                                                     |                             |                      | see recipe                                                                  |
| BW                                   | Standard body weight of the target group<br>adults                                                                                                                                                                  | 60.0000                     | kg                   | SCCS/ esti-<br>mation                                                       |
| R                                    | Retention factor, designates the percen-<br>tage of the product that is in contact with<br>the skin (for long enough) for penetration<br>can take place, is composed of dilution<br>factors and distribution factor | 0.0100                      | -                    | SCCS/ esti-<br>mation                                                       |
| DAderm                               | Leave-on-Coefficient dermal                                                                                                                                                                                         | different                   | -                    | Worst case/<br>Estimation                                                   |
| TD<br>(NOAEL)                        | Toxicological data e.g. NOAEL If no data<br>on subacute/sub chronic toxicity are<br>available, an estimation by TTC concept<br>is performed or other data are used.<br>(Read Across)                                | See raw<br>material<br>data | mg/kg                | See raw ma-<br>terial data                                                  |
| SED (der-<br>mal)                    | Systemic exposure doses                                                                                                                                                                                             | See cal-<br>culation        | mg/kg                | Calculated                                                                  |
| MoS                                  | Safety distance                                                                                                                                                                                                     | See cal-<br>culation        | Wit-<br>hout<br>unit | Calculated                                                                  |

The safety margin is the ratio of the highest amount tolerated without adverse effects (NOAEL, no observed adverse effect level in mg / kg body weight) to the systemic exposure dose / SED

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of this substance. If there is no value for this, other literature sources must be used for consideration.

The MoS per ingredient is calculated as follows: (Safe, if MoS > 100)

$SED = A / \text{standard body weight (mg / kg bw / day)} \times C (\%) / 100 \times DA (\%) / 100$

$MoS = TD / SED$

[Removed from this trade copy: ingredient level exposure calculations and toxicological profiles (A.7.2, A.8). Full report available to trade partners on request.]

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## **A.9 Information on the cosmetic product**

### **A.9.1 Data on acute toxicity, inhalation toxicity and sensitization**

#### **A.9.1.1 Inhalation toxicity**

Inhalation of Milky Body Wash is not to be expected, neither with intended nor with foreseeable use. An assessment of the inhalation toxicity can therefore be omitted.

#### **A.9.1.2 Data on acute toxicity, inhalation toxicity and sensitization dermal**

Due to the toxicological profile and the compiled literature, as well as the fact that the raw materials have been used on the cosmetic market for years, the product can be considered safe in its composition. Acute toxicity values such as LD50 (rat, oral) and LD50 (rabbit, dermal) >2,000 mg/kg are available for some of the raw materials used in the product. Furthermore, NOAEL values are also available in some cases or there are skin compatibility tests, as well as assessments by CIR (Cosmetic Ingredient Review), the SCCS (Scientific Committee of Consumer Safety) or there is further literature available or the substances could be classified as acutely toxic harmless via other sources. Some of the substances are also regulated in Regulation (EC) No. 1223/2009. This means that neither the pure raw materials nor the finished mixture should be expected to pose an acutely toxic risk to the consumer under reasonable, foreseeable use due to interactions between the substances in this cosmetic product.

#### **A.9.1.3 Sensitization**

As an undesirable effect, contact allergies can occur whenever there is contact with a chemical substance of natural or synthetic origin. According to the current state of science and on the basis of the data available for the ingredients, no or only very minor and short-term effects are to be expected in the case of contact with the potential allergens in the product. In addition, the composition of the product does not give any scientifically justifiable indications that regular use of the present product poses a risk of sensitizing effects. The INCI indication of all ingredients on the packaging allows the consumer / user to identify allergens known to him and to avoid the product if necessary. An adequate risk minimization is achieved by regular evaluation of the cosmetovigilance data.

## **A.10 Undesirable effects and serious undesirable effects (Cosmetovigilance)**

This is a new formulation.

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## B. Safety assessment of the cosmetic product

### B.1 Safety assessment of the cosmetic product

#### B.1.1 Conclusion from the safety assessment

The cosmetic product Milky Body Wash of company PureSource GmbH is classified as

**SAFE**

for human health under normal and reasonably foreseeable use according to regulation 1223/2009 (EC).

This review is based in accordance with Annex I, Part B.3 of Regulation 1223/2009 on:

- **the toxicological profile of the ingredients**, available toxicological / dermatological documentation of raw materials and finished product testing, including microbiological tests, reporting form for poison control centers, safety data sheets, law regulations, generally binding international reviews, recommendations from authorities and associations and experiences of marketing;
- **the chemical composition** and concept of operations / finished product testing requirements, raw material testing requirements and physical / chemical tests, if required;
- **the level of exposure**, resulting from the conditions of use, as they are specified in the instructions. For security, please refer to the voluntary and statutory warnings and other information, as long as they are part of the product presentation.

The assessment according to the cosmetics GMP remains unaffected. This safety assessment was carried out on the basis of the present knowledge (state-of-the-art). Changes of the formulation or of the statutory provisions require a renewed security assessment.

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## B.1.2 Qualitative recipe

Ingredients:

Aqua, Sodium Laureth Sulfate, Sodium Chloride, Glycerin, Cocamidopropyl Betaine, Decyl Glucoside, Sodium Lauroyl Oat Amino Acids, **Centella Asiatica Extract, Xylitylglucoside, Parfum, Phenoxyethanol, Anhydroxylitol, Styrene/Acrylates Copolymer, Xylitol, Tetramethyl Acetyloctahydronaphthalenes, Disodium Edta, Aloe Barbadensis Leaf Juice Powder, Hexamethylindanopyran, Ethylhexylglycerin, Citrus Aurantium Bergamia Peel Oil, Limonene, Linalyl Acetate, Citronellol, Tetrasodium EDTA, Glucose, Pinene, Geraniol, Citric Acid**

Note: Ingredients in bold are below 1% and can be listed disordered.

Ingredients (PCPC):

Water, Sodium Laureth Sulfate, Sodium Chloride, Glycerin, Cocamidopropyl Betaine, Decyl Glucoside, Sodium Lauroyl Oat Amino Acids, **Centella Asiatica Extract, Xylitylglucoside, Fragrance, Phenoxyethanol, Anhydroxylitol, Styrene/Acrylates Copolymer, Xylitol, Tetramethyl Acetyloctahydronaphthalenes, Disodium Edta, Aloe Barbadensis Leaf Juice Powder, Hexamethylindanopyran, Ethylhexylglycerin, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Limonene, Linalyl Acetate, Citronellol, Tetrasodium EDTA, Glucose, Pinene, Geraniol, Citric Acid**

Note: For informational use only! Check for completeness before marketing.

## B.2 Warnings and instructions for use

### B.2.1 Warnings and instructions for use

The product contains no ingredients that may require special applications for cosmetic conditions or warnings on the label according to Regulation EC No 1223/2009. Furthermore, no ingredients are contained in the cosmetic product that require special application conditions or warnings due to their chemical properties. End product-specific information such as in aerosol packages are also not required.

**General note:** The label must be checked separately for legal conformity and was not checked as part of the safety assessment.

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## **B.3 Justifications**

### **B.3.1 Composition of the finished product**

According to the information in Part A, the composition of the product complies with the requirements of the Cosmetics Regulation EC 1223/2009. Impurities that may be present, such as pesticides, heavy metals, nitrosamines, pyrethroids, furocoumarins, polycyclic aromatic hydrocarbons, solvent residues, formaldehydes, etc., which may be unintentionally contained in the product, are known as far as they are available. Minimisation to zero cannot be achieved even with a careful selection of raw materials. Quality, properties, availability, compliance with GMP conditions, etc. were taken into account. Any traces of impurities are therefore technically unavoidable. This means that in individual cases, exceedances are possible, but this was considered and evaluated toxicologically as part of the assessment, so that the product is safe to use according to the current state of knowledge.

### **B.3.2 Normal and reasonably foreseeable use**

The normal and reasonably foreseeable use of this product as shower gel is clearly identified in the product description, labelling and presentation.

## **B.4 Undesirable effects and serious undesirable effects (Cosmetovigilance)**

This is a new formulation.

### **B.4.1 Packaging information**

According to the information and documents of the respective manufacturers listed in A.5, the primary packaging complies with the relevant requirements and recommendations and is thus suitable as packaging for the cosmetic product.

### **B.4.2 Stability and shelf life of the finished product**

With the tests carried out, the microbiological quality of the cosmetic product corresponds to the requirements of the SCCS Notes of Guidance, 12th revision, and is therefore rated as safe. On the basis of the storage tests carried out and the physical / chemical tests carried out, as well as the successful preservation stress test, the product is considered to be sufficiently stable and a shelf life of more than 30 months is considered to be justified.

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### **B.4.3 Raw materials, impurities, traces, toxicological profile**

All raw materials used in this product comply with the Cosmetics Regulation regarding its purity. The use in the specified amounts complies with the Cosmetics Regulation. The testing of raw materials showed that all limits and recommendations are complied with. The use of certain cosmetic ingredients is regulated in Annexes III to VI of Regulation (EC) No 1223/2009 and its amendments. The formula is thus to be evaluated as safe. All ingredients / raw materials used have been subjected to a toxicological safety assessment and comply with the requirements of the Cosmetics Regulation in terms of their purity and quantities. The examination of the ingredients / raw materials showed that all limit values and recommendations are adhered to. The use of certain cosmetic ingredients is regulated in Annexes III to VI of Regulation (EC) No. 1223/2009 and its supplements. The recipe is therefore to be assessed as safe in this regard.

The purity specifications which are required by Regulation (EC) No. 1223/2009 on cosmetic products, in particular residues of solvents, heavy metals and/or pesticides and/or other impurities are met in the raw materials used. The Certificates of Analysis and/or specifications and all other documents provided were checked and classified. None of the raw materials has residues which have a negative influence on the cosmetic product regarding the system toxic effects on humans or which affect the stability and durability of the product. The above raw materials were rated as safe for use in this product according to Regulation (EC) No 1223/2009 in the currently valid version.

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## C. Qualification of the safety assessor and approval of part B

### C.1.1 Validity

This safety assessment remains valid as long as no significant qualitative and / or quantitative changes in the recipe and in the application security and the scope of the relevant product are made, or a significant number of consumer complaints is present. Furthermore, this safety assessment remains valid until legal changes and / or new scientific knowledge.

**Note: Please check in principle your product information on labels, folding box, instruction leaflet etc. on legal compliance, since with this order only a safety assessment for your product was created.**

Nümbrecht, the 08.05.2025



state approved food chemist

Sandra Haßler

LEMIKOS GmbH

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### C.1.2 Curriculum Vitae of the safety assessor

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name                   | Sandra Marion Haßler geb. Freyer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Date of birth          | 18.09.1975                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Place of birth         | Nümbrecht                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Marital status         | married                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Professional education | 1996- 2000: Study of Food Chemistry at the "Rheinische Friedrich-Wilhelms-University" in 53012 Bonn                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Practical education    | <p>July 1995- December 1995: Company Sarstedt, equipment and disposables for medicine and science in 51588 Nümbrecht-Rommelsdorf</p> <p>January 1996- March 1996: Aggerverband, supplier of drinking water and sanitation in 51645 Gummersbach</p> <p>December 2000 - January 2001: BELKAW, Bergische Licht-, Kraft- und Wasserwerke in 51432 Bergisch Gladbach</p> <p>February 2001 - April 2001: working student Bayer AG in 51368 Leverkusen</p> <p>2001- 2002: professional practical year as prospective food chemist at the following locations:</p> <p>Eismann und Family GmbH &amp; Co KG in 40822 Mettmann</p> <p>Food Control Office city of Oberhausen in 46041 Oberhausen</p> <p>Chemistry and Geoscience Institute of the cities Essen and Oberhausen in 45127 Essen</p> |
| Occupation             | <p>2002- 2013: Food chemist for Hollywood Nails GmbH, An der Hasenjagd 10, 42897 Remscheid</p> <p>Responsible for product development, quality assurance, product labelling, Safety Assessor, Regulatory Affairs, dealing with authorities and associations, occupational safety,</p> <p>2010: Freelancer as Cosmetics Legal Advisor, Expert for regulatory affairs and Safety Assessor, member of the Society of German Chemists e.V. (GDCh), member of the DGK, German Society for Scientific and Applied Cosmetics e.V., member of the German Society for Toxicology e.V. (DGPT e.V.)</p>                                                                                                                                                                                          |
| Further education      | various seminars on hygiene, safety assessments of cosmetic products, CPNP, cosmetic law, GMP (Good Manufacturing Practice) and modelling means for artificial nails, Presentations at trade shows around the cosmetics law                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

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### C.1.3 Qualification of the safety assessor

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## Erlaubnisurkunde

**Frau Sandra Marion Freyer**

geboren am 18. September 1975 in Bierenbachtal

wird gemäß § 2 Abs. 1 des Gesetzes über die Berufsbezeichnung "Lebensmittelchemiker" vom 7. März 1978 (GV. NRW. S. 88/SGV. NRW. 2125) mit Wirkung vom heutigen Tage die Erlaubnis erteilt, die Berufsbezeichnung

**"Lebensmittelchemikerin"**

zu führen.

Köln, den 18. September 2002

Bezirksregierung

Im Auftrag

  
(Möck)

DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE  
UND ANGEWANDTE KOSMETIK E.V.



## CERTIFICATE

**Sandra Haßler**

Through her qualification according to Article 10, Paragraph 2 of the EC Cosmetics Regulation 1223/2009,

successful completion of the following DGK continuing education courses for safety assessors

Exposure to Cosmetic Products / Percutaneous Penetration  
Topical Safety, Immunology and Sensitization  
Metabolism, Kinetics and Structure-Activity Relationships  
Carcinogenesis and Mutagenesis  
General and Systemic Toxicology  
Reproduction Toxicology  
Microbiological Safety of Cosmetic Products

and her participation over the last five years in at least three DGK seminars for safety assessors or relevant further trainings

is certified as fulfilling the requirements of a

### DGK SAFETY ASSESSOR

Köln / Heidelberg, 30 November 2022

Dr. Andrea Weber  
President of the German Society for  
Scientific and Applied Cosmetics (DGK e.V.)

Prof. Dr. G. Eisenbrand  
Chairman of the Committee on  
Continuing Education for Safety Assessors

THIS CERTIFICATE IS VALID FOR 5 YEARS.

President: Dr. Andrea Weber  
Training: Dr. Jens Burfeindt

Secretary: Dr. Volker Wendel  
Networking: Britta Klebon

Treasurer: Dr. Sven Munke  
Communication: Moritz Steneberg

Professional groups: Dr. Nicole Braun



Rheinische  
Friedrich-Wilhelms-  
Universität Bonn



Institut für Ernährungs- und  
Lebensmittelwissenschaften  
IEL

IEL – Bioanalytik/Lebensmittelchemie, Endenicher Allee 11-13, 53115 Bonn

Prof. Dr. Matthias Wüst Bioanalytik/Lebensmittelchemie

To whom it may concern

Endenicher Allee 19 b  
53115 Bonn  
Tel.: 0228/73-2361  
Fax: 0228/73-3499  
matthias.wuest@uni-bonn.de  
www.lebensmittelchemie.uni-bonn.de

Bonn, 2019-03-22

This letter is to confirm that Mrs. **Sandra Haßler (maiden name Freyer)**, born September 18th 1975, has passed the first state examination in food chemistry at the University of Bonn in 2000. At this time neither diploma supplements nor transcripts in English language were awarded to the candidates. However, the grade "first state examination" is comparable to a M.Sc. degree and encompasses a course of study of 8 semesters with a workload of approximately 240 credit points according to the European Credit Transfer and Accumulation System (ECTS). The curriculum contains lectures and laboratory courses in organic, inorganic, physical, and analytical chemistry and food sciences.

Prof. Dr. Matthias Wüst  
(Head of the examination office)

Prof. Dr. Matthias Wüst  
Universität Bonn, IEL-Bioanalytik  
matthias.wuest@uni-bonn.de  
Tel.: 0228/ 73 - 23 61; Fax: - 3499  
Endenicher Allee 11-13; 53115 Bonn

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