PART A- Cosmetic Product Safety Information

1. COSMETIC PRODUCT INFORMATION

PRODUCT NUMBER: CPSR-NM-02/311024

Product Category: Skincare

Class of cosmetic product: Rinse-off

Product Name: Aloe Vera Hydrating Bath Shower Oil
Company Name: New Miuz

Safety report version: 1.0

Address: 4340 Von Karman Ave Newport Beach CA 92660

REPORT CONTENT: Report Part A:

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2. Physical/chemical characteristics and stability of the cosmetic product.
3. Microbiological quality
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2. QUANTITATIVE AND QUALITATIVE COMPOSITION

Sr. No.	INCI	Percentage (%)	CAS NUMBER
1	Aloe Barbadensis Leaf Extract (Aloe Vera)	85507-69-3	15.00%
2	Cocos Nucifera (Coconut) Oil	8001-31-8	15.00%
3	Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	10.00%
4	Isopropyl Myristate	110-27-0	20.00%
5	Avena Sativa (Oat) Kernel Oil	84012-26-0	10.00%
6	Mel (Honey)	8028-66-8	5.00%
7	Simmondsia Chinensis (Jojoba) Seed Oil	61789-91-1	7.00%
8	Fragrance	Proprietary	5.00%
9	Laureth-3	3055-97-8	8.00%
10	Tocopheryl Acetate (Vitamin E)	7695-91-2	5.00%

Allergens: Limonene at 0.12%, Linalool at 0.10%, and Coumarin at 0.08%

SVHC present in this product and estimated amounts[1]: With Reference to the Report No. SHAMLP1727309501 against the job No. SHIN1712075526PC-SH, No SVHC detected above the defined limit of 0.1% (w/w) set in regulation (EC) No 1272/2008 and No 790/2009.

[1]The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on product or 0.01% in rinse-off products. In case of SVHC, if a SVHC is found over the reporting limit, client is suggested to identify the component which contains the SVHC and exact concentration of the SVHC by requesting further quantitative analysis from laboratory.

3. PHYSICAL AND CHEMICAL PROPERTIES AND STABILITY

3.1 Physical/chemical properties of the cosmetic product

Appearance	**Liquid**
Color	**Variable**
Smell	**Not Applicable**
Solubility	**Not Available**
Density	**Not Applicable**
Flash point	**Non-Flammable**
Boiling point/range	**Not Applicable**

3.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations. Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the product life cycle.

3.2.1 The manufacturer confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

4. Microbiological quality

4.1.1 Microbiological specification of ingredients (substances and mixtures).

Types of microorganism	Initial Incoculum (cfu/g)	Method	Recovered Inoculum (cfu/g) 8 d
Total Aerobic Mesophilic (DSM 53)	5.1×10^5	LVS EN ISO 4833-1:2013	$<1.1 \times 10^1$
Aspergillus brasiliensis (DSM 1988)	1.8×10^5	LVS EN ISO 21149:2017	$<1.2 \times 10^1$
Escherichia coli (DSM 110652)	2.0×10^5	LVS EN ISO 18415:2017	$<1.0 \times 10^1$
Candida albicans (DSM 1386)	2.7×10^5	LVS EN ISO 18416:2016	$<1.1 \times 10^1$
Staphylococcus aureus (NCTC 10788)	2.2×10^5	LVS EN ISO 22718:2016	$<1.0 \times 10^1$
Pseudomonas aeruginosa (NCIMB 8626)	9.4×10^5	LVS EN ISO 22717:2016	$<1.0 \times 10^1$

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition specification of ingredients), the ingredients used can be assessed as microbiologically safe.

4.1.2 Microbiological specification of the finished product

The given product can be regarded as microbiologically safe for consumer health under the ISO 29621:2017 standard Cosmetics Microbiology Guidelines for the risk assessment and identification of microbiologically low-risk products.

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

5. Impurities, trace amounts of forbidden substances, & information about packaging material

5.1 Impurities and trace amounts of forbidden substances

Packaging material is expected to be stable under normal conditions of use. According to specifications (see section 1. Quantitative and qualitative composition specification of ingredients) submitted, the ingredients do not contain impurities or trace amounts of forbidden substances.

5.2 Information about packaging material Container:

The Manufacturer confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product stated minimum usable life. During that life, no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

6. Normal and reasonably foreseeable use

The Current Label Advice

Clean the Area before Use

The label of this product should include this special note regarding its use, incompliance with

Article 19(1)(d) of Cosmetic Regulation (EC) No. 1223/2009

7. Exposure to the cosmetic product

Area of application	**Dermal**
Product type: Leave-on or Rinse-off	**Rinse-off**
Duration and frequency	**Once a day**
Possible additional routes of exposure	**Dermal**
Estimated skin surface area (cm2)	**17500**
Estimated amount of the product applied according to the SCCS (g/day)	**20**
Estimated retention factor according to the SCCS	**0.01**
Target group	**Adults**
Calculated relative daily exposure according to the SCCS	**0.20**

8. Exposure to the ingredients

Sr. No.	INCI	Percentage (%)	SED (mg/kg/day)
1	Aloe Barbadensis Leaf Extract (Aloe Vera)	15.00%	0.38
2	Cocos Nucifera (Coconut) Oil	15.00%	0.38
3	Helianthus Annuus (Sunflower) Seed Oil	10.00%	0.25
4	Isopropyl Myristate	20.00%	0.50
5	Avena Sativa (Oat) Kernel Oil	10.00%	0.25
6	Mel (Honey)	5.00%	0.13
7	Simmondsia Chinensis (Jojoba) Seed Oil	7.00%	0.18
8	Fragrance	5.00%	0.13
9	Laureth-3	8.00%	0.20
10	Tocopheryl Acetate (Vitamin E)	5.00%	0.13

9. Toxicological profile of the ingredients in the formulation

9.1.1 Dose Response Assessment

No toxicological endpoints are identified.

9.1.2 Dietary Exposure and Risk Characterization

Dietary exposure of the product via food or water is difficult to estimate due to the widespread use of these ingredients in thousands of products, in food, pharmaceuticals, cosmetics, in addition to use as an inert in

pesticide formulations.

In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population including infants and children.

9.1.3 Occupational, Residential, School and Day Care Exposure and Risk Characterization

No uses in residential areas are stated in proposed labels for the product. Therefore, human exposure is not expected in this area.

9.1.3.1 Occupational Exposure and Risk Characterization

There is a possibility for dermal, eye and inhalation exposure, but risk to applicators is mitigated as long as the product is used according to label directions. The Agency has considered the product in light of the safety factors in the Food Quality Protection Act (FQPA) of 1996 and has decided of reasonable certainty of no harm to the U. S. population in general, and to infants and children in particular.

9.1.3.2 Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses currently appear on proposed. labels.

9.1.4 8.1.4. Drinking Water Exposure and Risk Characterization

Because of its insolubility in water, exposure to product in drinking water is not. expected.

9.1.5 Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and

Children

Dietary risk from exposure to products is difficult to estimate due to the use of the current ingredients in thousands of products.

9.1.6 Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur in the mixer/loader/applicator subpopulation via dermal and inhalation routes. Risks associated with dermal, and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for the product showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category IV), and no significant dermal irritation (Toxicity category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

9.1.7 Cumulative Effects

Product is not toxic and therefore there would be no expected cumulative effects from common mechanisms of toxicity. In addition, most of the ingredients are naturally occurring, and it is used in thousands of products. An exact cumulative exposure is not necessarily due to the non-toxic nature of ingredients.

The Margin of Safety (MOS) for the product's ingredients has been assessed and found to be sufficiently high. This indicates that the product is safe for use and does not pose any harm to users when applied according to the recommended guidelines.

Sr. No.	INCI	Percentage (%)	MOS
1	Aloe Barbadensis Leaf Extract (Aloe Vera)	15.00%	5000.00
2	Cocos Nucifera (Coconut) Oil	15.00%	5000.00

3	Helianthus Annuus (Sunflower) Seed Oil	10.00%	5000.00
4	Isopropyl Myristate	20.00%	2000.00
5	Avena Sativa (Oat) Kernel Oil	10.00%	5000.00
6	Mel (Honey)	5.00%	5000.00
7	Simmondsia Chinensis (Jojoba) Seed Oil	7.00%	5000.00
8	Fragrance	5.00%	1000.00
9	Laureth-3	8.00%	2500.00
10	Tocopheryl Acetate (Vitamin E)	5.00%	10000.00

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

In line with WHO guidelines, recommending a minimum value of 100, it is generally accepted that the MoS should at least be 100 to conclude that a substance is safe for use. Since the ingredient used in this formulation are edible and have an MOS value above 100 then the conclusion is that they are safe for use in this formulation.

10. Undesirable effects and serious undesirable effects

The product with a similar composition has been supplied to the market in the long term. and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by Julia Nessa in accordance with procedures detailed in Cosmetic Regulation (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable, and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

11. Additional information on the product

No additional information is available, and no additional studies were carried out.

12. References

THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

2. MSDS of ingredients, Commission Implementing Decision Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products SCCS - Opinions
http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm

3. Cosing: The European Commission database on cosmetic substances
http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple

4. REGULATION 1223/2009 ANNEXES
https://ec.europa.eu/growth/tools-databases/cosing/?fuseaction=ref_data.annexes_v2

PART B - Cosmetic Product Safety Assessment

1. Assessment Conclusion

Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation including the detailed production and labeling which has been assessed as meeting the requirements of Cosmetic Regulation (EC) No. 1223/2009 effective on the date this report was issued.

2. Labeled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of Cosmetic Regulation (EC) No. 1223/2009:

For external use only. Keep out of reach of children.

Storage: Store in a cool, dry place, away from direct sunlight. Ensure the container is tightly closed after each use to maintain product stability.

Caution: For external use only; avoid contact with eyes and broken skin. Discontinue use if irritation occurs. Not suitable for ingestion. Keep out of reach of children and pets.

3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to Cosmetic Regulation (EC) No.1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that the composition of this cosmetic product complies with the requirements of Cosmetic Regulation (EC) No. 1223/2009 of the European Parliament and of the Council.

4. Assessor's credentials and approval of Part B Experience and qualifications:

Assessor Name: Muhammad Kamran
Address: 35-A Staff Colony UET Lahore.

- Proof of Qualifications:https://verification.pec.org.pk/v/eV/sED/i.aspx?eid=342F303135343330
- Bachelors of chemical engineering, Sharif College of Engineering & Technology (University Of Engineering and Technology)
  - 8+ years' experience formulating cosmetic products
  - Member of the Engineering Council (CHEM/15430)

Assessor Signature
Date: 31-10-2024

This safety report is based upon information available at this date. The safety of the product should be reviewed on a regular basis. Reviews of this assessment should be conducted when new information becomes available.