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MICROBIOLOGICAL RISK ASSESSMENT AND SPECIFICATION

Products:

ZENISOAPBASE Lowsweat-C

ZENISOAPBASE Lowsweat-W

Product type: Glycerine soap base
Intended use: Raw material for manufacture of glycerine soap

1. Physicochemical characteristics

pH: 9.5–10.5
Water content: approximately 26%

The product is an alkaline soap base. Its pH range creates an environment generally unfavourable to the growth and multiplication of most bacteria, yeasts and moulds.

Although the product contains approximately 25% water, water content alone does not determine microbiological susceptibility. The microbiological risk is also influenced by pH, water activity, composition of the soap matrix, manufacturing conditions, storage conditions and the ability of microorganisms to survive and multiply in the product.

2. Microbiological specification

The following microbiological limits are established as internal quality specifications for the soap base:

Parameter	Specification
Total Aerobic Mesophilic Microorganisms (TAMC)	≤ 1,000 CFU/g
Total Yeasts and Moulds (TYMC)	≤ 100 CFU/g
Pseudomonas aeruginosa	Absent in 1 g
Staphylococcus aureus	Absent in 1 g
Candida albicans	Absent in 1 g
Escherichia coli	Absent in 1 g

These limits are established with reference to the principles of ISO 17516, Cosmetics — Microbiology — Microbiological limits.

This specification defines acceptance criteria and does not constitute a microbiological laboratory test report.

3. Microbiological risk assessment

The soap base has a pH of 9.5–10.5.

The alkaline character of the product substantially limits the ability of many microorganisms commonly associated with cosmetic contamination to grow and proliferate.

The product does not represent a neutral-pH aqueous cosmetic system. Although approximately 26% water is present in the formulation, the water is contained within an alkaline soap matrix whose physicochemical

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conditions are unfavourable for microbial growth.

On this basis, the soap base may be considered to present a **low microbiological risk**, subject to confirmation within the Cosmetic Product Safety Assessment.

4. Microbiological testing

No microbiological laboratory test results are claimed by this document.

Where required by the Cosmetic Product Safety Assessor, microbiological testing may be performed to verify compliance with the microbiological specification.

For products considered microbiologically low risk, routine microbiological testing may not be necessary where an adequate scientific justification is available.

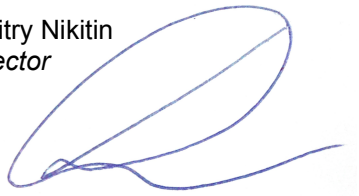
5. Conclusion

Based on the physicochemical characteristics of the soap base, particularly its alkaline pH of 9.5–10.5, the product is considered to have a low inherent susceptibility to microbial growth.

The established microbiological specification provides internal acceptance criteria for the product.

The final determination of microbiological risk and the necessity for microbiological testing and/or preservation challenge testing shall be made within the Cosmetic Product Safety Assessment of the finished cosmetic product.

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