COSMETIC PRODUCT SAFETY REPORT

According to EC Regulation 1223/2009 and SCHEDULE 34 of The Product Safety and Metrology etc. (amendment etc.) (EU Exit) Regulations 2019

100% Natural Premium Dead Sea Bath Salt

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SAFETY ASSESSOR

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PART A - COSMETIC PRODUCT SAFETY INFORMATION

Product name	100% Natural Premium Dead Sea Bath Salt
Shade names	/
Product type	Bath product
Formula number	100
Category of the product	Bath product
Physical form of the product	Solid
Target population	Adults
Primary site of application	Body area
Packaging type and size	250g/ 1kg/ 25kg PET sachet
Manufacturer name and address	Jordan
Producer name and address	Jordan

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INCI name	Trade name	CAS	EINECS/ELINCS	% active in the raw material	Concentration in the final product	Function
MARIS SAL	Dead Sea Bath Salts	None	None	100	100	Skin Conditioning

2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

a. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF SUBSTANCES OR MIXTURES

Substance (INCI) / Mixture	Chemical NAME	Physical form	Molecular weight (g/mol)	Water Solubility /Solubility	Partition coefficient	Absorption spectra (UV absorbers)
MARIS SAL	**Not available**	**Solid (crystals)**	**Not available**	**Not available**	**Not available**	**Not applicable**

b. PHYSICAL/CHEMICAL CHARACTERISTICS OF THE FINISHED COSMETIC PRODUCT

Test	Specifications	Results
Appearance	(In-house) White or Transparent Granular.	Pass
Odor	Characteristic	Pass
Density (g/ml)	0.95 – 1.1	Pass
pH	6.5 – 8.0	Pass

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c. STABILITY OF THE COSMETIC PRODUCT

The physical stability of the finished product is justified based on the stability report document, which is ensuring that no changes in the physical state of the finished product occur during transport, storage or handling of the product.

The stability testing was performed according to the accelerated method (6 months at 40°C). The results below were obtained:

Test	Specification	Time (Months)			
		ZT	1	3	6
Description	White or Transparent Granules	Comply	Comply	Comply	Comply
pH (10% dispersion)	6.0-9.0	7.6	7.7	7.6	7.6
Total Aerobic Bacterial Count	NMT 100 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Total Yeast and moulds	NMT 100 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Pseudomonas aeruginosa	Absent per 1 g	Absent	Absent	Absent	Absent
Staphylococcus aureus	Absent per 1 g	Absent	Absent	Absent	Absent
Escherichia Coli	Absent per 1 g	Absent	Absent	Absent	Absent
Candida albicans	Absent per 1 g	Absent	Absent	Absent	Absent

Based on the test results, the date of minimum durability is equal to 36 months.

3. MICROBIOLOGICAL QUALITY

a. MICROBIOLOGICAL QUALITY OF SUBSTANCES AND MIXTURES

Substances and mixtures susceptible to microbial growth (water-based mixtures, protein-rich materials, plant or animal raw materials)	Present
Raw materials which do not support microbial growth (organic solvents)	Not present

b. MICROBIOLOGICAL QUALITY OF THE FINISHED COSMETIC PRODUCT

According to the 'Guidelines on Microbiological Quality of the finished product' (SCCS Notes of Guidance), the following limits apply:

Category 1: Products specifically intended for children under 3 years, eye area and mucous membranes.

Category 2: Other cosmetic products.

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Types of microorganism	Products specifically intended for children under three years of age, the eye area or the mucous membranes	Other products
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould)	**≤ 1 x 10^2 CFU per g or ml [a]**	**≤ 1 x 10^3 CFU per g or ml [b]**
Escherichia coli	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Pseudomonas aeruginosa	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Staphyloccocus aureus	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Candida albicans	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, Interpretation of results, results considered out of limit if **a > 200 CFU/g or ml,** **b > 2 000 CFU/g or ml.** NOTE When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used.		

(Source: The SCCS Notes of Guidance for testing of cosmetic ingredients and their safety evaluation, SCCS/1602/18, October 2018)

This product was evaluated according to the category 2, and the following results were obtained:

Microbial Content		
• Total Aerobic Bacterial Count	(In – house) <100 CFU/g	Pass
- Molds and yeast Count	<100 CFU/g	Pass
• E – Coli	Absent	Absent
• Candida albicans	Absent	Absent
• Pseudomonas aeruginosa	Absent	Absent
• Staphylococcus aureus	Absent	Absent

The results show, that the microbiological purity of the product is acceptable and meets the criteria listed above.

This cosmetic product does not require challenge testing because it does not contain water. In case water activity is very low it can be assumed that there will be no growth of microorganisms and therefore this product may be considered a low-risk product.

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4. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

a. IMPURITIES AND TRACES

This product is manufactured according to Good Manufacturing Practice (ISO 22716). Ingredients used throughout must be of high quality (it is assumed that only cosmetic, pharmaceutical or food grade ingredients are used) and (where specified) they have to meet purity criteria listed in the Cosmetics legislation. In case there are any prohibited impurities, they must be technically unavoidable under the conditions of a good manufacturing practice. Information provided on ingredient purity can be found in the certificates of analysis and are held in the Product Information File and are acceptable.

b. THE RELEVANT CHARACTERISTICS OF PACKAGING MATERIAL

The product is packaged in a 250g/ 1kg/ 25kg PET sachet. These packaging components are widely used for consumer products. They are non-porous to inks and adhesives and are unlikely to react chemically with this product. They are considered to be safe since there is no evidence of possible migration of packaging components into the product.

5. NORMAL AND REASONABLY FORESEEABLE USE

This product is a rinse-off bath product intended to be used by adults on daily basis.

Instructions for use written on the label	Bath: Dissolve 1-2 cups of salt, soak for 20 minutes. Foot care: Dissolve 1/2 cup in warm water, soak feet for 10 minutes.
Precautions for use written on the label	For external use only. Avoid contact with eyes. Discontinue use if irritation occurs.

A clear explanation of the normal intended use and the reasonably foreseeable use is provided on the product label and therefore a mistaken use (not a misuse) is not recognisable.

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6. EXPOSURE TO THE COSMETIC PRODUCT

Product Type:	Bath Salt
Targeted Population:	Adults
Estimated daily amount applied (g):	300*
Skin Surface Area of Application/cm2:	16340*
Calculated daily exposure (g/day)	30
Calculated relative daily exposure (mg/kg bw/day):	500
Amount Per Unit Area of Skin per day mg/cm2/day:	1,8
Exposure time:	20-30min*
Frequency of application:	1/week*
Part of the body exposed:	Area body, area head *

* Bath product, RIVM

7. EXPOSURE TO THE SUBSTANCES

INCI	Retention factor	POD	SED	MoS
MARIS SAL	0.1	not available	500	/

Calculations of Margin of Safety (MoS) have been determined for all ingredients where this is possible from published toxicity information. The method used to do this is:

SED (whole product)*% ingredient = SED (ingredient)

MoS = NOAEL (ingredient)/SED (ingredient).

In every case, the MoS is >100 which is considered to be acceptable. In addition, calculations are also presented to show how much each ingredient is below the recommendations of the industry (CTFA) and those required by European cosmetic legislation. All ingredients fall below any recommended maxima.

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8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

INCI name	MARIS SAL
Restriction	None
General description	Naturally occurring substances, inorganic salts derived from sea water. There are no adverse effects expected or reported from the use of this material.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 3000 mg/kg
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not available
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

Perfume compliance to IFRA regulations:

This product is fragrance free.

9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

The product is available on the market. No undesirable effects have been reported till now.

10. INFORMATION ON THE COSMETIC PRODUCT

- The product has not been tested on animals
- The product does not contain CMR, nanoparticles...
- Additional testing:/

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PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

1. ASSESSMENT CONCLUSION

The cosmetic product 100% Natural Premium Dead Sea Bath Salt can be assessed as **SAFE** for normal and reasonably foreseeable use by the European Cosmetics Regulation (EC) No 1223/2009 (as amended) and SCHEDULE 34 of The Product Safety and Metrology etc. (amendment etc.) (EU Exit) Regulations 2019.

2. LABELLED WARNINGS AND INSTRUCTIONS FOR USE

The following instructions for use and warnings are written on both, primary and secondary packaging:

Instructions for use written on the label	Bath: Dissolve 1-2 cups of salt, soak for 20 minutes. Foot care: Dissolve 1/2 cup in warm water, soak feet for 10 minutes.
Precautions for use written on the label	For external use only. Avoid contact with eyes. Discontinue use if irritation occurs.

The labelled instructions for use and the general description of the product indicate the explicit use of the finished product as a rinse-off bath product intended for daily use. A reasonably foreseeable mistaken use additional to this use (not a misuse) is not recognisable

3. REASONING

a. SAFETY EVALUATION OF SUBSTANCES AND/OR MIXTURES

The margin of safety, which takes into account all systemic toxicity endpoints, has been calculated for each of the ingredients used in this cosmetic product. All ingredients (where the NOAEL value was available) have a sufficiently large MoS (>100), which is supporting the safety of the finished product. Specific exposure consideration for the targeted consumer group (adults) has been taken into account as documented in the exposure and MoS calculation.

b. SAFETY EVALUATION OF COSMETIC PRODUCT

Stability data

The stability data (microbiological and physical-chemical stability) of the formula after storage meet the previously specified characteristics. They confirm the sufficient stability of the formula. The shelf life for the final product is 36 months. Based on the above-mentioned the product is rated as safe.

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Packaging

The package consists of a 250g/ 1kg/ 25kg PET sachet. The packaging of the product is made to protect the product during shelf life and use and to enable the safe use of the product. No interaction with packaging material is expected as the packaging compatibility with the formulation was confirmed during its stability test. Based on that the packaging is rated to be suitable and safe for this specific product type. This package does not contain hazardous materials that require special markings or labelling on the shippers.

Normal and reasonably foreseeable use

A reasonably foreseeable mistaken use (not a misuse), is not recognizable.

Undesirable effects and serious undesirable effects

From the market launch until today the complaint statistics as documented in the Consumer Response System (CRS) of the manufacturer of this product show no remarkable consumer complaints regarding undesirable effects or serious undesirable effects in general.

Information on the cosmetic product

The product is a rinse-off bath product intended to be used by adults on daily basis.

The packaging of the cosmetic product should include the following information in indelible, easily legible and visible lettering:

- Brand name
- Name of the product
- Function of the cosmetic product (unless it is clear from its presentation)
- Ingredients list (ingredients present **in more than 1%** in the end product should follow in the same order as here): **MARIS SAL**
- Particular precautions for use:For external use only. Avoid contact with eyes. Discontinue use if irritation occurs.
- Instructions for use: Bath: Dissolve 1-2 cups of salt, soak for 20 minutes.
- Foot care: Dissolve 1/2 cup in warm water, soak feet for 10 minutes.
- Date of minimum durability (for products with minimum durability ≤ 30 months) or PAO (for products with minimum durability > 30 months)

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- Nominal quantity (except for packaging containing less than 5 grams or 5 millilitres, free samples and single-application packs)
- Batch number or the reference for identifying the cosmetic product
- Responsible person's name and address
- Manufacturer name and address
- Products' country of origin

SUMMARY

The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment and an assessment of the final cosmetic product.

All statements in this safety assessment were elaborated on the recent level of knowledge. Every change in the formulation or changes and/or additional information of relevant data respectively will require an immediate re-evaluation of this safety assessment.

Concerning skin tolerance, the final product is expected to be well tolerated and to have good cosmetic acceptability.

Safety assessor: Tjaša Grum, MBiochem

Signature:

We confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use. Its composition complies with EC Regulation 1223/2009 and SCHEDULE 34 of The Product Safety and Metrology etc. (amendment etc.) (EU Exit) Regulations 2019

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