COSMETIC PRODUCT SAFETY REPORT

Conforming to

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

REPORT REFERENCE NUMBER: MAF-AP-0323-01 SKBA

RESPONSIBLE INDIVIDUAL:

ALBENA PANTELEEVA

Health from the nature

26 The Larches

Carterton

OX18 3GH

Oxfordshire

United Kingdom

PRODUCT BEING ASSESSED: Skin Balm – "Calendula Balm"

CATEGORY OF PRODUCT & INTENDED USE: Cosmetic balm for regular application to the skin of the body. Leave on product.

REPORT PART A

1. Quantitative and qualitative composition of the cosmetic product(s) (including the chemical identity of substances in the formulation).
2. Physical/chemical characteristics and stability of the cosmetic product(s), including impurities, traces, and packaging material information.
3. Microbiological quality of the product(s).
4. Normal and reasonably foreseeable use of the product(s), target populations and warnings.
5. Product and substance exposure information.
6. Undesirable and serious undesirable effects.
7. Toxicological profile and analysis of substance – including MoS.
8. Information on the cosmetic product(s).

REPORT PART B

9. Assessment conclusions.
10. Labelled warnings and instructions of use.
11. Reasoning.
12. Assessor's credentials and approval of Part B

This report is valid only for the use by the person named as the Responsible Person for the products specified in the assessment. Any deviations from the formulations specified in this report ARE NOT VALID and will not be covered by this assessment.

All manufacture of products must comply with standard of good manufacturing practice as detailed in the relevant legislation.

All raw material specifications and finished product specifications must comply with any restrictions (purity etc.) detailed in REGULATION (EC) No 1223/2009

Any deviation from the prescribed formulation and list of permitted ingredients is NOT covered by this safety report.

MSDS sheets for all materials used must be included by the manufacturer as part of Safety Report Part A – additional information on raw materials (Identification and function) - http://ec.europa.eu/consumers/cosmetics/cosing/

MAF Cosmetic Consultants and the assessor named within accept no responsibility or liability for the misuse of this document or for any product produced outside of the specified formulation.

REPORT PART A

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT(S) (INCLUDING THE CHEMICAL IDENTITY OF SUBSTANCES IN THE FORMULATION)

PRODUCT FORMULATION: The following table details the formulation of the product.

PRODUCT FORMULATION			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX CONC. (w/w %)**
COCONUT OIL	COCOS NUCIFERA OIL	C	[redacted]
SUNFLOWER OIL	HELIANTHUS ANNUUS SEED OIL	C	
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	D	
BEESWAX	CERA ALBA	E	
SHEA BUTTER	BUTYROSPERMUM PARKII BUTTER	E	
CALENDULA	CALENDULA OFFICINALIS FLOWER	F	

2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT(S) INCLUDING IMPURITIES, TRACES, AND PACKAGING MATERIAL INFORMATION.

PHYSICAL AND CHEMICAL PROPERTIES:

The colour and fragrance are characteristic of the fragrance and colourants used in the formulation (if any).

For detailed information regarding the physical and chemical characteristics of the raw materials please refer to the MSDS in the product information file (PIF) and Section 7 of this document.

The exact pH of the product has not been empirically determined but based on the understanding of similar products the expected pH is 3.5-4.5.

STABILITY AND REACTIVITY:

The product is expected to be nominally stable at ambient storage conditions – to be confirmed by manufacturer based on observation of previous products made.

No major interactions are expected - possible interaction between labile components of fragrance materials (esters, alcohols) - no resulting components that are likely to alter the toxicity profile of the initial ingredients.

A suggested shelf life of at least 30 months applies to the product. A PAO of 6 months applies to this product.

INGREDIENT PURITY:

Specific purity criteria do not apply. The purity of the ingredients in the formulation(s) is specified – where appropriate – in the MSDS documents in PIF. Pharmaceutical, food or cosmetic grade ingredients are used in the manufacture of the product(s). The manufacturer is responsible for ensuring the purity of the ingredients used and the quality of the raw materials.

PACKAGING MATERIAL:

No specific requirements. Inert cosmetic/food grade packaging must be used. The manufacturer is responsible for ensuring the suitability and quality of the packaging material.

3. MICROBIOLOGICAL QUALITY OF THE PRODUCT(S).

The product(s) is anhydrous and has a low activity of water, and – under normal conditions of storage and/or use – does not support microbial growth. Product(s) is a Category 2 product:

For any cosmetic product classified as a "Category 2 Product", the total viable count (TVC) the TVC for aerobic mesophilic microorganisms should not exceed 1000cfu/g or mL of product. In addition, the pathogens Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans should not be detectable in 1g or 1mL of the product.

Microbiological quality testing was performed on the raw materials by the primary manufacturer. Further, specific microbiological testing is not required, nor recommended for this product(s).

4. NORMAL AND REASONABLY FORESEEABLE USE OF THE PRODUCT(S), TARGET POPULATIONS AND WARNINGS.

The product is a cosmetic balm. It is intended for frequent application to the skin of the whole body.

It is a leave on product.

It is intended to be used by the general population.

The product is not intended for, nor is marketed for use on babies, infants, and children under 3 years of age.

The product(s) is not intended to be used on mucous membranes or on the eye area. There is no other reasonable or foreseeable use for this product(s).

There is no specific requirement for warnings required for the product labelling, however a general statement that these products are for external use only, should not be applied to the eye area, mucous membranes, broken or irritated skin is recommended. It is also recommended that a statement advising to discontinue use in the case of irritation should also be include.

5. PRODUCT AND SUBSTANCE EXPOSURE INFORMATION.

Exposure (under foreseeable conditional use) is by dermal absorption only. The retention factor of 100% has been applied (as per The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th Revision), and all calculations have been based on typical exposure values (as per RIVM Report 320104001/2006).

AREAS OF SPECIFIC EXPOSURE

Inhalation – not relevant for this type of product.

Dermal – this product is intended for use on the skin of the face and body.

Eye – not relevant for this type of product.

Ingestion – not relevant for this type of product.

EXPOSURE OF PRODUCT; BODY					
PRODUCT AMOUNT PER APPLICATION[1] (G)	**POTENTIAL FREQUENCY OF USE[1] (PER DAY)**	**MAXIMUM DAILY PRODUCT USE (G)**	**RETENTION FACTOR[2]**	**MAXIMUM DAILY PRODUCT EXPOSURE (MG)**	**DAILY SYSTEMIC EXPOSURE DOSE (SED)† (MG/KG/DAY)**
5	1	5	1	5000	**83.333**

SUBSTANCE EXPOSURE DATA: BODY				
INGREDIENT CONCENTRATION BAND	**MAX. CONCENTRATION (% w/w)**	**DAILY SUBSTANCE EXPOSURE (mg/day)**	**SED (mg/kg/day)**	**LED (mg/kg/day)**
A (75-100)	**100**	5000	83.333	**5.00E+01**
B (50-75)	**75**	3750	62.5	**3.75E+01**
C (25-50)	**50**	2500	41.667	**2.50E+01**
D (10-25)	**25**	1250	20.833	**1.25E+01**
E (5-10)	**10**	500	8.3333	**5.00E+00**
F (1-5)	**5**	250	4.1667	**2.50E+00**
G (0.1-1)	**1**	50	0.8333	**5.00E-01**
< 0.1%	**0.1**	5	0.0833	**5.00E-02**

1: Product amount per application, frequency of use and surface area exposed RIVM report 320104001/2006, H. J., Bremmer. 2: Retention factor THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 11TH REVISION. †: Mean body weight used 60kg. ‡: Based on the product amount per application

6. UNDESIRABLE AND SERIOUS UNDESIRABLE EFFECTS

There were no undesirable or serious undesirable effects reported at the time this report was prepared. A record must be kept of any reported undesirable effects, and they must be notified to the relevant competent authority.

Based on the understanding of products of this type (and the raw materials used to produce them) it is not expected that any adverse effects will occur as a result of the normal, prescribed use of this product.

7. TOXICOLOGICAL PROFILE AND ANALYSIS OF SUBSTANCES – INCLUDING MoS.

The NOAEL values for each ingredient in the products assessed within this report were obtained. The margin of safety (MoS) value was determined for each ingredient using the following formula (as defined by the SCCS):

$$MoS = \frac{NOAEL}{SED}$$

For the purposes of this toxicological assessment, a MoS of >100 is considered acceptable. Any ingredients with a MoS of less than 100 will have specific justification for their approval (if such approval is granted).

NOAEL values were obtained from published, repeat dose toxicity studies.

The following table details the NOAEL and MoS values for each relevant substance included in the formulations.

In addition to calculating the MoS, the TTC (threshold of toxicological concern) was determined where relevant. The following TTC apply to compounds, where relevant:

Cramer Class I	30ug/kg/day
Cramer Class II	9ug/kg/day
Cramer Class III	1.5ug/kg/day

Where the TTC is exceeded for a specific substance, justification for deeming it “safe” will be provided.

MoS OF SUBSTANCES ASSESSED IN THIS REPORT.

The MoS was calculated for each substance used in each of the formulations covered in this assessment; the MoS for each substance was >100; the assessment determined that each of the substances was satisfactorily safe when used as specified by each of the formulations detailed in this report. Any substance with a MoS of >1000 is considered safe and non-toxic.

PROHIBITED AND RESTRICTED SUBSTANCES, AND ALLERGENS:

There are no substances in the formulations of each of the products defined as prohibited by Annex VI of Regulation (EC) No. 1223/2009.

Any allergens present in the essential and/or fragrance oils used in any of the formulations that exceed 0.001% must be indicated on the labelling of the product(s). The manufacturer is responsible for calculating the allergens present and determining which – if any – must be included on the labelling.

8. INFORMATION ON THE COSMETIC PRODUCT(S).

There are no specific or medicinal claims made by the products. The product is intended for general cosmetic use by general consumers and does not contain any novel or previously unused cosmetic ingredients. All the ingredients used in the formulation for each of the products are widely used in cosmetic preparations and are generally considered safe for use in this type of cosmetic product.

TOXICOLOGICAL PROFILE OF INGREDIENTS		
INCI NAME	**TOXICOLOGICAL PROFILE**	**MoS**
BUTYROSPERMUM PARKII BUTTER	Considered safe as cosmetic ingredient (CIR, 2017, https://doi.org/10.1177%2F1091581817740569). No toxicological significance.	>100
CALENDULA OFFICINALIS FLOWER	Considered safe as a cosmetic ingredient: (https://journals.sagepub.com/doi/pdf/10.1177/1091581810384883) Mainly comprised of carbohydrates, lipids and fatty acids, phenolic compounds, flavonoids, tannins and steroids. Studies have shown (CIR) that calendula and calendula extracts are not dermal or ocular irritants or sensitisers, there were also no observable effects in chronic and sub chronic toxicity studies up to doses of 4600mg/kg. TTC: no concern for rinse-off products. Not known to be a dermal sensitiser, a mutagen or carcinogenic.	>100
CERA ALBA	No toxicological significance. Beeswax is inert, it is used as a food additive and is considered safe for use as a cosmetic ingredient. Refined beeswax must be used in cosmetic formulations to minimise the potential for microbial growth.	>100
COCOS NUCIFERA OIL	Cocos Nucifera Oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, Cocos nucifera L., Palmaceae. Physical Properties: Appearance: white to cream solid (est) Food Chemicals Codex Listed: No Flash Point: > 200.00 °F. TCC (> 93.33 °C.) Soluble in: oils water, 1.079e-012 mg/L @ 25 °C (est) Insoluble in: water Considered safe as a cosmetic ingredient (https://doi.org/10.1177/1091581811400636) No toxicological significance Oral/Parenteral Toxicity: Not determined Dermal Toxicity: Not determined Inhalation Toxicity: Not determined	>100
HELIANTHUS ANNUUS SEED OIL	Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/sites/default/files/Helianthus%20annuus.pdf) Sunflower oil is the second most used edible oil – there are no toxicological concerns and no toxicological significance.	>100

	Sunflower oil is not know to be a dermal irritant, an ocular irritant, a skin or ocular sensitiser and it is not a know phototoxic ingredient.	
THEOBROMA CACAO SEED BUTTER	Theobroma Cacao Seed Butter is a yellowish white solid material obtained from the roasted seeds of the Cocoa, Theobroma cacao L., Sterculiaceae. Considered safe as a cosmetic ingredient (https://doi.org/10.1177/1091581811400636) No toxicological significance	>100

There are no substances contained within the formulation considered to be acutely toxic (either via dermal and/or oral exposure). There are no know dermal or ocular irritants or sensitisers. There are no phototoxic compounds. There are no known CMR compounds.

[1]: Toxicological risk is calculated using a number of parameters and is determined either by using published, peer-reviewed studies or determined computationally. The TTC values, presence of Cramer Compounds and the CMR activity of the compounds are assessed to assign a "toxicological risk category" to each component of the product(s):

1) Low/limited toxicological significance: edible and inert substances with a NOAEL value of >1000mg/kg/day (or with no NOAEL value determined due to limited toxicological concern). Includes Cramer Class I compounds, no structural alerts and no CMR activity.

2) Limited toxicological significance: Functional components with a NOAEL of 100-500mg/kg/day. Cramer classes I and II, with limited structural alerts. No determined CMR activity.

3) Moderate toxicological significance: Functional and active components with a NOAEL of 50-100mg/kg/day. Cramer classes I and II with no structural alerts. No CMR activity at the levels used in the formulation.

4) High toxicological concern: components with NOAEL of <50mg/kg/day. Cramer class II and III compounds and compounds with known or potential CMR activity.

REPORT PART B – *SKIN BALM*

RESPONSIBLE PERSON DETAILS: **ALBENA PANTELEEVA**

Health from the nature

26 The Larches

Carterton

OX18 3GH

Oxfordshire

United Kingdom

9. ASSESSMENT CONCLUSIONS

Each of the products assessed by this report (specified in Part A) have been deemed safe for the prescribed use (**as a skin balm**). These products satisfy the requirements as specified in Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

10. LABELLED WARNINGS AND INSTRUCTIONS OF USE

No specific requirements for product labelling (other than as described in the next section). Labelling must comply with Regulation (EC) No. 1223/2009 as amended. It is recommended that general safety guidelines are included, e.g., avoid contact with the eyes, if irritation occurs discontinue use, do not use on broken or irritated skin etc.

ALLERGENS – LABELLING DECLARATION

If any of the 26 allergens specified in the EC Directive 2003/15/EC are present in a leave on product (as is the case for these products) in a concentration of 0.001% or greater, then they must be specified on the product label.

PRODUCT INGREDIENTS: *Cocos Nucifera Oil, Helianthus Annuus Seed Oil, Theobroma Cacao Seed Butter, Cera Alba, Butyrospermum Parkii Butter, Calendula Officinalis Flower.*

11. REASONING

All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

- The quantitative and qualitative composition
- Physical/chemical characteristics and stability of substances
- Microbiological quality
- Impurities, trace materials and packaging used
- The normal and reasonably foreseeable use of the product(s)
- Exposure to the product(s) (local and systemic)
- Exposure to the substances (local and systemic)
- Toxicological profile of the substances – including MoS and NOAEL values
- Undesirable and serious undesirable effects
- Any other information relevant to the product

The NOAEL and MoS were calculated using published, peer-reviewed studies of oral, dermal, systemic etc. toxicity of each of the ingredients included in the formulation(s). Where no peer reviewed data were available, suitable cross-over data were obtained. Various sources were used to obtain the required data, including PubMed, COSMO database, CIR and SCSS etc. Full details of the sources used can be provided upon request.

12. ASSESSORS CREDENTIALS AND APPROVAL OF PART B

This product meets the requirements of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019 and is approved.



Michael Ford, **BSc (Hons), MRes, AMRSB**

NAME:	Michael Ford, MAF Cosmetic Consultants
QUALIFICATIONS:	BSc (Hons) Biochemistry, MRes Biochemistry, AMRSB
ADDRESS:	18 Campion Close, Newport, NP20 5DR
DATE:	19/03/2023

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

It is hereby certified that

Michael Peter David Ford

has been conferred the award of
Bachelor of Science
in Biochemistry

Second Class Honours Division One

21 July 2020

Ardystir drwy hyn fod

Michael Peter David Ford

wedi cael dyfarniad
Baglor mewn Gwyddoniaeth
mewn Biocemeg

Anrhydedd Ail Ddosbarth, Adran Un

21 Gorffennaf 2020

Vice Chancellor
Is-Ganghellor

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CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

It is hereby certified that

Michael Peter David Ford

has been conferred the award of
Master of Research

Distinction

07 October 2021

Ardystir drwy hyn fod

Michael Peter David Ford

wedi cael dyfarniad
Athro Mewn Ymchwil

Rhagoriaeth

07 Hydref 2021

Vice Chancellor
Is-Ganghellor

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