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-AB-1223-01 BEBA

RESPONSIBLE INDIVIDUAL:

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PRODUCT BEING ASSESSED: Beard, Hair, Moustache & Skin / Body Balm

CATEGORY OF PRODUCT & INTENDED USE: Cosmetic balm for application to the beard / facial hair, and 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 BASE FORMULATION: The following table details the formulation of the product base.

PRODUCT BASE FORMULATION			
INGREDIENT NAME / TRADE NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC (%)**
COCONUT OIL	COCOS NUCIFERA OIL	C	[redacted]
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	D	
SUNFLOWER SEED OIL	HELIANTHUS ANNUUS SEED OIL	D	
BEESWAX	CERA ALBA	E	
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	E	
SWEET ALMOND OIL	PRUNUS AMYGDALUS DULCIS OIL	E	
CALENDULA FLOWER	CALENDULA OFFICINALIS FLOWER	G	
CHAMOMILE FLOWER	CHAMOMILLA RECUTITA FLOWER	G	
PEPPERMINT LEAF	MENTHA PIPERITA LEAF	G	
NETTLE LEAF	URTICA DIOICA LEAF	G	

PRODUCT VARIANT FORMULATION(s): The following table details the formulation of the product variant(s).

FINAL PRODUCT VARIANT 1 FORMULATION			
INGREDIENT NAME / TRADE NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC (%)**
COCONUT OIL	COCOS NUCIFERA OIL	C	[redacted]
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	D	
SUNFLOWER SEED OIL	HELIANTHUS ANNUUS SEED OIL	D	
BEESWAX	CERA ALBA	E	
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	E	
SWEET ALMOND OIL	PRUNUS AMYGDALUS DULCIS OIL	E	
CALENDULA FLOWER	CALENDULA OFFICINALIS FLOWER	G	
CHAMOMILE FLOWER	CHAMOMILLA RECUTITA FLOWER	G	
PEPPERMINT LEAF	MENTHA PIPERITA LEAF	G	
NETTLE LEAF	URTICA DIOICA LEAF	G	
FRANKINCENSE ESSENTIAL OIL	BOSWELLIA CARTERII OIL	G	
VETIVERT ESSENTIAL OIL	VETIVERIA ZIZANOIDES ROOT OIL	G	
RED MANDARIN ESSENTIAL OIL	CITRUS RETICULATA PEEL OIL	G	

FINAL PRODUCT VARIANT 2 FORMULATION			
INGREDIENT NAME / TRADE NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC (%)**
COCONUT OIL	COCOS NUCIFERA OIL	C	[redacted]
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	D	
SUNFLOWER SEED OIL	HELIANTHUS ANNUUS SEED OIL	D	
BEESWAX	CERA ALBA	E	
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	E	
SWEET ALMOND OIL	PRUNUS AMYGDALUS DULCIS OIL	E	
CALENDULA FLOWER	CALENDULA OFFICINALIS FLOWER	G	
CHAMOMILE FLOWER	CHAMOMILLA RECUTITA FLOWER	G	
PEPPERMINT LEAF	MENTHA PIPERITA LEAF	G	
NETTLE LEAF	URTICA DIOICA LEAF	G	
VETIVERT ESSENTIAL OIL	VETIVERIA ZIZANOIDES ROOT OIL	G	
CEDARWOOD ESSENTIAL OIL	CEDRUS ATLANTICA BARK OIL	G	

FINAL PRODUCT VARIANT 3 FORMULATION			
INGREDIENT NAME / TRADE NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC (%)**
COCONUT OIL	COCOS NUCIFERA OIL	C	[redacted]
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	D	
SUNFLOWER SEED OIL	HELIANTHUS ANNUUS SEED OIL	D	
BEESWAX	CERA ALBA	E	
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	E	
SWEET ALMOND OIL	PRUNUS AMYGDALUS DULCIS OIL	E	
CALENDULA FLOWER	CALENDULA OFFICINALIS FLOWER	G	
CHAMOMILE FLOWER	CHAMOMILLA RECUTITA FLOWER	G	
PEPPERMINT LEAF	MENTHA PIPERITA LEAF	G	
NETTLE LEAF	URTICA DIOICA LEAF	G	
LILY OF THE VALLEY FRAGRANCE (CRAFTOVATOR)	PARFUM	G	

FINAL PRODUCT VARIANT 4 FORMULATION			
INGREDIENT NAME / TRADE NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC (%)**
COCONUT OIL	COCOS NUCIFERA OIL	C	[redacted]
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	D	
SUNFLOWER SEED OIL	HELIANTHUS ANNUUS SEED OIL	D	
BEESWAX	CERA ALBA	E	
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	E	
SWEET ALMOND OIL	PRUNUS AMYGDALUS DULCIS OIL	E	
CALENDULA FLOWER	CALENDULA OFFICINALIS FLOWER	G	
CHAMOMILE FLOWER	CHAMOMILLA RECUTITA FLOWER	G	
PEPPERMINT LEAF	MENTHA PIPERITA LEAF	G	
NETTLE LEAF	URTICA DIOICA LEAF	G	
LAVENDER ESSENTIAL OIL	LAVANDULA ANGUSTIFOLIA OIL	G	

FINAL PRODUCT VARIANT 5 FORMULATION			
INGREDIENT NAME / TRADE NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC (%)**
COCONUT OIL	COCOS NUCIFERA OIL	C	[redacted]
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	D	
SUNFLOWER SEED OIL	HELIANTHUS ANNUUS SEED OIL	D	
BEESWAX	CERA ALBA	E	
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	E	
SWEET ALMOND OIL	PRUNUS AMYGDALUS DULCIS OIL	E	
CALENDULA FLOWER	CALENDULA OFFICINALIS FLOWER	G	
CHAMOMILE FLOWER	CHAMOMILLA RECUTITA FLOWER	G	
PEPPERMINT LEAF	MENTHA PIPERITA LEAF	G	
NETTLE LEAF	URTICA DIOICA LEAF	G	
BERGAMOT ESSENTIAL OIL	CITRUS AURANTIUM BERGAMIA FRUIT OIL	G	
FRANKINCENSE ESSENTIAL OIL	BOSWELLIA CARTERII OIL	G	
RED MANDARIN ESSENTIAL OIL	CITRUS RETICULATA PEEL OIL	G	
LAVENDER ESSENTIAL OIL	LAVANDULA ANGUSTIFOLIA OIL	G	
PEPPERMINT ESSENTIAL OIL	MENTHA PIPERITA OIL	G	

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 cannot be empirically determined due to its anhydrous nature.

STABILITY AND REACTIVITY:

Based on our understanding of products of a similar nature, it can reasonable be assumed that the product will remain nominally stable at ambient storage conditions – to be confirmed by manufacturer based on observation of previous products made. At the point of completing this assessment, no results of stability tests have been made available; the manufacturer is obligated to perform stability tests and record the observations in their product information file.

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 12 months applies to this product. This shelf life may have to be re-evaluated depending on the results of the stability testing performed by the manufacturer.

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).

Assessment of the microbiological quality and risk of the product has been assessed using the guidelines specified in ISO 29621 and as described in NoG (SCCS/1647/22).

NoG (SCCS/1647/22) / ISO 29621 specifies the minimum microbiological standards of cosmetic products (i.e., the qualitative limits in a finished cosmetic product of the specified microorganisms):

TYPE OF MICROORGANISM	PRODUCTS SPECIFICALLY INTENDED FOR CHILDREN UNDER 3 YEARS OF AGE, THE EYE AREA OR MUCOUS MEMBRANES (Category 1)	OTHER PRODUCTS (Category 2)
TOTAL AEROBIC MESOPHILIC MICROORGANISMS (BACTERIA PLUS YEAST AND MOULD)	**≤ 1 x10² CFU per g or ml**	**≤ 1 x10³ CFU per g or ml**
Escherichia coli	Absence in 1g or 1ml	Absence in 1g or 1ml
Pseudomonas aeruginosa	Absence in 1g or 1ml	Absence in 1g or 1ml
Staphylococcus aureus	Absence in 1g or 1ml	Absence in 1g or 1ml
Candida albicans	Absence in 1g or 1ml	Absence in 1g or 1ml

The product is a Category 2 product.

Low microbiological risk products are not required to have specific microbiological quality testing or preservative efficacy testing. Low risk products are defined (in ISO 29621) as:

- Product with a pH of more than 10 or less than 3.
- Products that are anhydrous.
- Products that have significant content of alcohol (>20%), polar solvents (>10%) or other substances that create a hostile environment that inhibits the growth or survival of microbes.

This product is anhydrous. These conditions are considered to create an environment sufficiently hostile to inhibit the survival and growth of microbes.

The area of application of the product is not considered to increase the microbiological risk of the product, i.e., it is not applied on mucous membranes, it is not applied to the eye area and is not intended to be applied on broken or irritated skin.

Based on the above we have deemed the product to be of a sufficiently low risk that specific testing of the microbiological quality of the product is not required.

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

The product is a cosmetic balm for application to the beard / facial hair, the hair and the skin of the 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 12th 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 beard / facial hair, hair & body.

Eye – not relevant for this type of product. Use on the eye area should be avoided.

Ingestion – not relevant for this type of product.

EXPOSURE OF PRODUCT; HAIR / FACIAL HAIR					
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)
0.4	1	0.4	0.1	40	**0.6667**

SUBSTANCE EXPOSURE DATA: HAIR / FACIAL HAIR			
CONCENTRATION BAND	CONCENTRATION (%)	DAILY SUBSTANCE EXPOSURE (mg/day)	SED (mg/kg/day)
A (75-100)	100.00	40	**0.666666667**
B (50-75)	75.00	30	**0.5**
C (25-50)	50.00	20	**0.333333333**
D (10-25)	25.00	10	**0.166666667**
E (5-10)	10.00	4	**0.066666667**
F (1-5)	5.00	2	**0.033333333**
G (0.1-1)	1.00	0.4	**0.006666667**
H (<0.1)	0.10	0.04	**0.000666667**

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 12TH 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**
BOSWELLIA CARTERII OIL	Contains 0.6% limonene; major bioactive component of the essential oil. NOAEL (EFSA) = 300mg/kg	>100
CALENDULA OFFICINALIS FLOWER	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Calendula Officinalis Flower Extract is an extract obrained from the flowers of the Calendula, Calendula officinalis L., Compositae CAS#: 84776-23-8 EC#: 283-949-5 FUNCTION: Skin conditioning. 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. Short-Term Oral Toxicity Ichimaru Pharcos Co Ltd18reported a study in which groups ofdd-mice (number not stated) were given a mixture ofC offici-nalisflower extract, butylene glycol, and water (neither con-centrations nor relative proportions given) daily for 14 daysat 5, 10, or 20 mL/kg. No animals died and the LD50wasreported to be greater than 20 mL/kg.Hindle et al38conducted a study of the use of calendula mealin the diet of 8- to 13-week-old crossbred pigs at levels of 2%,6%,10%,or20%for 37 days. A control group received dietwith no calendula meal. There were 8 animals per group andduplicate groups were tested for a total of 18 animals at eachexposure/control level. Only castrated or female pigs wereused. Calendula meal was prepared from the kernel fractionof seeds from which the hulls had been removed. The dailyweight gain was highest for the 2%group, significantly higherthan the control. As the percentage of calendula meal in the dietincreased, weight gain decreased and, at the 20%level, was lessthan the control. Blood levels of hematocrit, hemoglobin, oxy-genated hemoglobin, creatinine, and zinc were unchanged bycalendula meal in the diet at any level and aspartate amino-transferase (AST), alanine aminotransferase (ALT), and lactatedehydrogenase activities were within the normal range as well.Silva et al39reported an oral study in which a hydroalcoholicextract ofC officinaliswas given to female Wistar rats (10 pergroup). The hydroalcoholic extract of the dried flowers of Cofficinaliswas supplied by Simo˜es Laboratory, RJ, Brazil (lotNo 02.001) and concentrated by evaporating the solvent. Thematerial was resuspended in distilled water and stored in ali-quots at20C.Daily doses of 0.25, 0.5, and 1.0 g/kg of the Calendula extractwere given for 30 days. The control group received distilledwater only. The animals were observed for signs of toxicity,body weights were recorded weekly, and water and feed con-sumption were monitored. Animals were fasted for 12 hoursafter the last treatment, anesthetized, and blood collected forevaluation. Biochemical analysis included glucose, blood ureanitrogen (BUN), creatinine, AST, ALT, total cholesterol, trigly-	>100

	cerides, alkaline phosphatase (ALP), total and direct bilirubin,total protein, albumin, and globulin. Hematological parametersincluded erythrocytes, leukocytes, platelets, hemoglobin, hema-tocrit, mean corpuscular volume (MCV), mean corpuscularhemoglobin (MCH), mean corpuscular hemoglobin concentra-tion (MCHC), and differential leucocyte counts. After blood col-lection, animals were killed, and the brain, heart, liver, kidneys,adrenal glands, spleen, uterus, and ovaries were removed,weighed, and evaluated for external signs of toxicity.Treatment did not have a statistically significant effect onbody weight gain, or consumption of water or feed. No clinicalsigns of toxicity were observed in any treated animals and allsurvived. Biochemical parameters were not significantly dif-ferent from controls, except that the BUN level was elevatedin the high-dose group (51.2+1.6 mg/dL) compared with con-trols (41.4+2.3 mg/dL), and ALT activity was elevated at alldose levels. Several statistically significant differences werenoted in hematological parameters. The number of neutrophilswas reduced in the low- and high-dose groups compared withcontrols, but not in the middle-dose group. The lymphocytecount was elevated in the high-dose group compared with con-trols. The number of monocytes was reduced in the middle- andhigh-dose groups. No external signs of toxicity were observedin any organ, and there were no organ weight differencesbetween treated and control animals. The authors concludedthat the data supported an absence of toxicity for this Calendulaextract; however, they also suggested that the elevated BUNand ALT could be signs of possible renal and hepatic overload,which should be further investigated.	
CEDRUS ATLANTICA BARK OIL	Acute oral toxicity using read across from Cedarwood Texas oil distilled: (similar to OECD TG 401): LD50 >5000 mg/kg bw Skin irritation in vitro using read across from Cedarwood Texas oil distilled (OECD TG 439): irritating Skin corrosion in vitro using read across from Cedarwood Texas oil distilled (OECD TG 431): not corrosive. Eye irritation in vitro using read across from Cedarwood Texas oil distilled (OECD TG 438): not irritating. Skin sensitisation using read across from Cedarwood Texas oil distilled (OECD TG 429): sensitising. Ames test using read across from Cedarwood Texas oil distilled (OECD TG 471): negative	>100
CERA ALBA	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Beeswax CAS#: 8012-89-3 EC#: 232-383-7 FUNCTION: Emollient, Film forming 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
CHAMOMILLA RECUTITA FLOWER	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Matricaria Recutita Flower Oil is the essential oil distilled from the flowers of the plant, Matricaria recutita, Compositae (syn: Chamomilla recutita, Compositae) CAS#: 84082-60-0 EC#: 282-006-5 FUNCTION: Perfuming The acute oral and dermal toxicity of Anthemis nobilis, ext. (Chamomile oil), was evaluated using 10 rats and 4 rabbits, respectively (strains and sex unspecified). The animals were administered a single dose of 5 g/kg bw, and were then observed for 14 days. There were no mortalities. The acute oral and dermal LD50 was reported to be > 5 g/kg bw (Johnson et al., 2017). No relevant acute inhalation toxicity data were identified, or are needed.	>100

	No in vitro skin or eye irritation studies are available or required. The skin irritating potential of Anthemis nobilis, ext., (Chamomile oil) was assessed in rabbits in a in vivo study conducted according to French national protocols and compliant with GLP. 0.5 mL of a 20% (v/v) solution of the test material was applied to the clipped skin of 6 male New Zealand white rabbits, for 24 hours under occlusive coverage. Application sites were scored for erythema and oedema 30 minutes and 48 hours after removal of the occlusive capsule (i.e. 24 and 72 hours after application of the test item). The primary cutaneous irritation index was reported to be 0.29 (maximum 8), corresponding to a non-irritant substance (Clement, 1988). The eye irritating potential of Anthemis nobilis, ext., (Chamomile oil) was assessed in rabbits in a in vivo study according to French national protocols and compliant with GLP. 0.1 mL of a 20% (v/v) solution of the test material was instilled into the conjunctival sac of the right eye of each of 6 male New Zealand white rabbits, without rinsing. The eyes were examined for effects on the conjunctiva, iris and cornea 1 hour, and 1, 2, 3, 4 and 7 days after instillation of the test item. The mean ocular irritation index was reported to be 0.33 (maximum 110) after 2 days, and 0 after 3 days, corresponding to a non-irritant substance (Clement, 1988). No relevant respiratory tract irritation data were identified. No in vitro skin sensitisation studies or in vivo murine LLNA were identified, or are required, as a reliable in vivo guinea pig study is already available. The skin sensitisation potential of Anthemis nobilis, ext., (Chamomile oil) was assessed in guinea pigs in an in vivo open epicutaneous test. 0.1 mL of the test material (as a 4% solution) was applied to clipped skin on one flank of each of 6 guinea pigs, daily for 21 days. A challenge application was made on the contralateral flank on days 21 and 25. Anthemis nobilis, ext., (Chamomile oil) was not sensitising to the skin of guinea pigs in this study (Klecak, 1985). No respiratory tract sensitisation data are available.	
CITRUS AURANTIUM BERGAMIA FRUIT OIL	Acute oral toxicity: LD50>5000 mg/kg bw (standard acute method, limit test) Acute dermal toxicity: LD50>5000 mg/kg bw (standard acute method, limit test) Skin irritation: not irritating (OECD404), although some effects were noted. Eye irritation: not irritating (OECD405) Read across based on d-limonene content: sensitising Repeated dose toxicity: oral Weight of evidence approach 6-month repeated dose toxicity study in dogs: LOAEL 1000 mg/kg bw/day 90-day repeated dose toxicity study in mice: LOAEL 1000 mg/kg bw/day 90-day repeated dose toxicity study in rats: LOAEL 1200 mg/kg bw/day supporting 6-month repeated dose toxicity study in dogs: LOAEL 1000 mg/kg bw/day - Gene mutation in bacteria: (Bacterial Reverse Mutation Assay/Ames) (according to OECD 471): not mutagenic. - In vitro Mammalian chromosome aberration test (equivalent or similar to OECD 473): not clastogenic without metabolic activation. - In vitro Mammalian cell gene mutation test (according to OECD 476): negative. Developmental toxicity study in rats: not teratogenic, NOAELmaternal and developmental 591 mg/kg bw/day	>100

	Developmental toxicity study in rabbits: not teratogenic, NOAELmaternal 250 mg/kg bw/day, NOEAL developmental 1000 mg/kg bw/day Developmental toxicity study in mice: not teratogenic, NOAELmaternal and developmental 591 mg/kg bw/day	
CITRUS RETICULATA PEEL OIL	Acute oral toxicity: LD50>5000 mg/kg bw (standard acute method, limit test) Acute dermal toxicity: LD50>5000 mg/kg bw (standard acute method, limit test) Skin irritation: not irritating (OECD404), although some effects were noted. Eye irritation: not irritating (OECD405) Read across based on d-limonene content: sensitising Repeated dose toxicity: oral Weight of evidence approach 6-month repeated dose toxicity study in dogs: LOAEL 1000 mg/kg bw/day 90-day repeated dose toxicity study in mice: LOAEL 1000 mg/kg bw/day 90-day repeated dose toxicity study in rats: LOAEL 1200 mg/kg bw/day supporting 6-month repeated dose toxicity study in dogs: LOAEL 1000 mg/kg bw/day - Gene mutation in bacteria: (Bacterial Reverse Mutation Assay/Ames) (according to OECD 471): not mutagenic. - In vitro Mammalian chromosome aberration test (equivalent or similar to OECD 473): not clastogenic without metabolic activation. - In vitro Mammalian cell gene mutation test (according to OECD 476): negative. Developmental toxicity study in rats: not teratogenic, NOAELmaternal and developmental 591 mg/kg bw/day Developmental toxicity study in rabbits: not teratogenic, NOAELmaternal 250 mg/kg bw/day, NOEAL developmental 1000 mg/kg bw/day Developmental toxicity study in mice: not teratogenic, NOAELmaternal and developmental 591 mg/kg bw/day	>100
COCOS NUCIFERA OIL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Coconut Oil CAS#: 8001-31-8 EC#: 232-282-8 FUNCTION: Skin conditioning, Emollient 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	>100

	Oral/Parenteral Toxicity: Not determined Dermal Toxicity: Not determined Inhalation Toxicity: Not determined	
LAVANDULA ANGUSTIFOLIA OIL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Lavender, Lavandula hbrida, ext. CAS#: 90063-37-9 EC#: 289-995-2 FUNCTION: Perfuming Lavandula Angustifolia Oil is the volatile oil obtained from the flowers of the Lavender, Lavandula angustifolia, Labiatae. ISO 8902:2009 Physical Properties: Appearance: colorless to pale yellow clear liquid (est) Food Chemicals Codex Listed: No Specific Gravity: 0.87700 to 0.89200 @ 25.00 °C. Pounds per Gallon - (est).: 7.298 to 7.422 Refractive Index: 1.45700 to 1.46400 @ 20.00 °C. Boiling Point: 204.00 °C. @ 760.00 mm Hg Flash Point: 182.00 °F. TCC (83.33 °C.) Soluble in: alcohol Insoluble in: water Organoleptic Properties: Odor Type: floral Odor Strength:medium Substantivity:12 hour(s) at 100.00 % herbal lavender Odor Description:at 100.00 %. herbal lavender Flavor Type: herbal lavender Taste Description: lavender Odor and/or flavor descriptions from others (if found). Organ-specific effects Adverse skin reactions: Undiluted lavender absolute was slightly irritating to rabbits; tested at 10% on 25 volunteers it was neither irritating nor ensitizing (Opdyke 1976 p. 449). Tested at 2, 5 and 10% on 25 volunteers with a previous history of reaction to fragrance materials, lavender absolute produced allergic reactions in 7, 11 and 13 individuals, respectively. In this high-risk group, 0.12% was the concentration at which any observable reaction disappears (Bouhlal et al 1988b). The cause of facial dermatitis in a physiotherapist was due to a pharmaceutical gel she often used on patients. She also reacted to 2% lavender absolute, which was present in the gel (Rademaker 1995). Two cases of facial dermatitis are reported following the nightly application of a few drops of undiluted lavender oil to the bed pillow as a sedative; both tested positive to 2% lavender absolute (Coulson and Khan 1999). An eczema patient using an aromatherapy lavender gel tested positive to 10% lavender absolute, but not to 2% (Varma et	>100

	al 2000). Carcinogenic/anticarcinogenic potential: No information found. Coumarin is carcinogenic in rodents, but is anticarcinogenic in umans (Felter et al 2006). Systemic effects Acute toxicity: Lavender absolute acute oral LD50 in rats 4.25 g/ kg; acute dermal LD50 in guinea pigs >5 g/kg (Opdyke 1976 p. 449). Safety in Use Information: Category: flavor and fragrance agents IFRA Code of Practice Notification of the 49th Amendment to the IFRA Code of Practice IFRA fragrance material specification: Linalool and natural products known to be rich in linalool, such as bois de rose, coriander or ho wood oil, should only be used when the level of peroxides is kept to the lowest practical level. It is recommended to add antioxidants at the time of production of the raw material. The addition of 0.1% BHT or alpha-tocopherol for example has shown great efficiency. The maximum peroxide level for products in use should be 20 mmol/l. contains the following IFRA (Annex) restricted components: (non-analysis max. level reference only) 7-methoxycoumarin Max. Found: <0.02 % and Reason: Sentitization / Photo Sensitization geraniol Max. Found: trace to <0.10 % and Reason: Sensitization Recommendation for lavender oil CO2 extract usage levels up to: 16.0000 % in the fragrance concentrate.	
MANGIFERA INDICA SEED BUTTER	READ ACROSS - COCOA (SIMILAR FATTY ACID PROFILE) A non-guideline study has been carried out to assess the behavioural effects of acute oral treatment with cocoa powder on male mice. In an ambulation study, drug-naïve dd mice were given saline, or cocoa powder by stomach tube at 100, 300, 1000 or 3000 mg/kg bw [it is not clear whether 10-20 mice were tested in total, or whether there were 10-20 per concentration]. Saline was administered to 10-20 control animals. Ambulation was assessed for 3 hours after treatment using a tilting-type ambulometer. Lever-press and shuttle avoidance experiments were conducted on 9 or 10 trained ddY mice, respectively. Mice were treated with 0 (saline), 100, 300 or 1000 mg/kg bw by stomach tube. [It appears that the same mice were treated with each concentration.] Apparently the same mice were later tested with the cocoa components theobromine (at 3-300 mg/kg bw) and caffeine (at 1-100 mg/kg bw). Each “drug testing session” was separated by an interval of 3-4 days. [It is not clear whether these “drug testing sessions” comprised all testing with one substance, or each test with an individual concentration.] The minimum observation period after testing with cocoa was therefore 6 days. In each experiment, mortality and clinical observations are not described. Presumably, however, mortality and other overt effects would have been reported, if seen. No significant, dose-related behavioural effects were reported following treatment with cocoa powder. As no deaths were reported, presumably the acute oral LD50 exceeds 3000 mg/kg bw in male mice (3 hr observation period). In the experiment using a more reliable observation time of 6 days, the LD50 presumably exceeds 1000 mg/kg bw. While these values are not sufficient to formally conclude on classification for acute oral toxicity, the LD50 for Cocoa powder probably exceeds 2000mg/Kg bw. On this basis cocoa would not require classification for acute toxicity under current EU guidelines. In the studies documented in CSR, the dietary level(s) of cocoa tested represent amounts far exceeding cocoa consumption by humans. A recent approximation of cocoa powder consumption in 2011 (using cocoa production data from 2011 and EU27 population statistics) approximates European cocoa powder consumption to be 18.5 mg/kg bw day.	>100

	The above information, as well as the knowledge that a vast majority of the population (including children) regularly consume large quantities of cocoa containing products, clearly indicates that there is no concern regarding the repeated oral toxicity of cocoa. In accordance with the results obtained from the key and supporting studies, cocoa powder is not classified according to CLP i.e. NOEL (or derived/adjusted LOEL) dose/concentration exceeds the guidance value ranges of 10 < C ≤ 100 mg/kg/bw/day, (Regulation (EC) No 1272/2008). Considered safe as a cosmetic ingredient: (https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569) No toxicological significance. Similar plant-derived fatty acid oils are not known to be photosensitising, phototoxic, dermal or ocular irritants or sensitisers.	
MENTHA PIPERITA LEAF	EC Number: 282-015-4 EC Name: Peppermint, ext. CAS Number: 84082-70-2 Molecular formula: Not applicable (UVCB substance) Acute toxicity oral: - Standard acute method (Rat): LD50 = 2650 mg/kg (95% CI >= 2300 - <= 3000) (similar to OECD guideline 401) Acute toxicity dermal: - Standard actue method (Rabbit): LD50 > 5000 mg/kg bw (similar to OECD guideline 402) Skin irritation: - in vivo (rabbit): slightly/moderately irritating Eye irritation: - WoE: not irritating Several studies on the skin sensitising potential of Cornmint oil were available for the dossier, which are read across to peppermint oil. Because of the comparable reliability between the studies and the differing outcomes, a Weight of Evidence approach was used to describe the endpoint of skin sensitisation. Four guinea pig maximisation tests were available with different forms of cornmint oil, one using Peppermint Arvensis (65% Peppermint Brazilian and 35% Peppermint Chinese), one using Peppermint Chinese, and two using Peppermint Brazilian. In all tests three challenges with the test substance were performed. The first two challenges with Peppermint Arvensis indicated no skin sensitisation, only after three challenges sensitisation was indicated. The first challenge with Peppermint Chinese indicated skins sensitisation. However, the second and third challenge did not indicate skin sensitisation. In both studies conducted with Peppermint Brazilian, the first and third challenge indicated skin sensitisation. Additionally tot the guinea pig maximisation tests, a human repeated occluded patch test was available which indicated allergic contact sensitisation in 2 out of 22 male subjects. Based on the above information, it was concluded that peppermint oil is a substance that possesses the ability to induce skin sensitisation. Three of the four animal studies indicated sensitisation and the human study indicated skin sensitisation in two subjects. Migrated from Short description of key information:	>100

	Skin sensitisation (Weight of Evidence, read across from cornmint oil): - GPMT (5% Peppermint Arvensis): not sensitising (method similar to OECD 406) - GPMT (5% Peppermint Chinese): sensitising (method similar to OECD 406) - GPMT (5% Peppermint Brazilian): sensitising (method similar to OECD 406) - GPMT (5% Peppermint Brazilian): sensitising (method similar to OECD 406) - Maximization test (humans): sensitising Justification for selection of skin sensitisation endpoint: No selection is made as a Weight of Evidence approach was followed which is described below. 28-d oral repeated dose toxicity study with peppermint oil: NOAEL 400 mg/kg bw/day based on absence of effects at the highest dose tested (Serota, 1990)	
MENTHA PIPERITA OIL	EC Number: 282-015-4 EC Name: Peppermint, ext. CAS Number: 84082-70-2 Molecular formula: Not applicable (UVCB substance) Acute toxicity oral: - Standard acute method (Rat): LD50 = 2650 mg/kg (95% CI >= 2300 - <= 3000) (similar to OECD guideline 401) Acute toxicity dermal: - Standard actue method (Rabbit): LD50 > 5000 mg/kg bw (similar to OECD guideline 402) Skin irritation: - in vivo (rabbit): slightly/moderately irritating Eye irritation: - WoE: not irritating Several studies on the skin sensitising potential of Cornmint oil were available for the dossier, which are read across to peppermint oil. Because of the comparable reliability between the studies and the differing outcomes, a Weight of Evidence approach was used to describe the endpoint of skin sensitisation. Four guinea pig maximisation tests were available with different forms of cornmint oil, one using Peppermint Arvensis (65% Peppermint Brazilian and 35% Peppermint Chinese), one using Peppermint Chinese, and two using Peppermint Brazilian. In all tests three challenges with the test substance were performed. The first two challenges with Peppermint Arvensis indicated no skin sensitisation, only after three challenges sensitisation was indicated. The first challenge with Peppermint Chinese indicated skins sensitisation. However, the second and third challenge did not indicate skin sensitisation. In both studies conducted with Peppermint Brazilian, the first and third challenge indicated skin sensitisation. Additionally tot the guinea pig maximisation tests, a human repeated occluded patch test was available which indicated allergic contact sensitisation in 2 out of 22 male subjects. Based on the above information, it was concluded that peppermint oil is a substance that possesses the ability to induce skin sensitisation. Three of the four animal studies indicated sensitisation and the human study indicated skin sensitisation in two subjects.	>100

	Migrated from Short description of key information: Skin sensitisation (Weight of Evidence, read across from cornmint oil): - GPMT (5% Peppermint Arvensis): not sensitising (method similar to OECD 406) - GPMT (5% Peppermint Chinese): sensitising (method similar to OECD 406) - GPMT (5% Peppermint Brazilian): sensitising (method similar to OECD 406) - GPMT (5% Peppermint Brazilian): sensitising (method similar to OECD 406) - Maximization test (humans): sensitising Justification for selection of skin sensitisation endpoint: No selection is made as a Weight of Evidence approach was followed which is described below. 28-d oral repeated dose toxicity study with peppermint oil: NOAEL 400 mg/kg bw/day based on absence of effects at the highest dose tested (Serota, 1990)	
PRUNUS AMYGDALUS DULCIS OIL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Almond Oil CAS#: 8007-69-0 / 90320-37-9 EC#: - / 291-063-5 FUNCTION: Emollient, Skin conditioning Dose descriptor: LD50 Effect level: >= 5 000 mg/kg bw In a single patch test, 11 volunteers (men and women) from 20 to 65 years of age, with a normal skin, without any dermatological lesion on the experimental area, have been included in the study. Single application of 25µL of the test item, on the sacapular part of the back, maintained for 48 h in contact with the skin, with the help of an occlusive patch (Finn Chambers). 11 volunteers have been included and were analyzed. The average irritation index is 0. Under the conditions employed in this study, test item was considered as non-irritant. A panel of 110 male and female human volunteers participated in a repeat insult patch test in which a test product applied to the back of the subjects under occlusive patches. 107 subjects completed the study. During the induction or challenge phase, no skin reactions were observed. The test item showed a score of 0.01. It can thus be considered as non-irritating. No reaction ++ nor +++ was observed, so the product can be considered as non-sensitizing. Under these study conditions, the product can be considered non-irritating and non-sensitizing Considered safe as a cosmetic ingredient: (https://doi.org/10.1177/1091581817740569)	>100

	Similar plant-derived fatty acid oils are not known to be photosensitising, phototoxic, dermal or ocular irritants or sensitisers (MCII <0.25). LD50 = >5000mg/kg (ECHA, unnamed study report, 2014) Prunus amygdalus dulcis oil was not found to be genotoxic (ECHA, unnamed study report, 2014, OECD 471). Considered a non-toxic ingredient - no repeat-dose toxicity data available	
THEOBROMA CACAO SEED BUTTER	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Cocoa (Theobroma cacao) extract, kernel, partially fat reduced CAS#: 84649-99-0 / 8002-31-1 EC#: 283-480-6 / - FUNCTION: Emollient 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
URTICA DIOICA LEAF	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: N/A CAS#: N/A EC#: N/A FUNCTION: Abrasive, colourant. No toxicological significance.	>100
VETIVERIA ZIZANOIDES ROOT OIL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Vetiver oil: khas khas oil CAS#: 8016-96-4 / 84238-29-9 EC#: 282-490-8 FUNCTION: Perfuming Acute oral toxicity (equivalent to OECD 401, pre-GLP)): LD50>5000 mg/kg bw (limit test) Acute dermal toxicity (equivalent to OECD 402, pre-GLP): LD50>5000 mg/kg bw (limit test) Skin irritation: irritating (based on results of eye iritation test) Eye irritation: irritating (procedure by Draize, 1959, under GLP conditions) Based on the available data and the Weight of Evidence approach, Vetiver Oil needs to be classified as sensitising when taking into account the criteria outlined in Annex I of 1272/2008/EC and Annex VI of 67/548/EEC. In vitro gene mutation in bacteria (Ames): negative with and without metabolic activation (OECD 471, GLP)	>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 – *APPROVAL OF 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 beard / hair / body 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.

11. REASONING

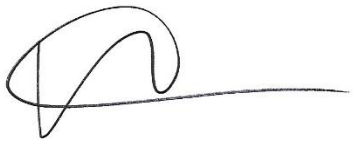
All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

- 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**

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QUALIFICATIONS:	BSc (Hons) Biochemistry, MRes Biochemistry, AMRSB
ADDRESS:	5 Market Arcade, Newport, NP20 1FS
DATE:	08/12/2023

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

05391641-01-DEUG

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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

62739650-01-A6DF

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