# MOISTURISING BATH BOMB – FORMULATION GUIDE

## *SUGGESTED RECIPE*

| **INGREDIENTS** | **AMOUNT (*to make 100g of product)*** |
|---|---|
| SODIUM BICARBONATE | 56g |
| CITRIC ACID | 29g |
| BUTTER | 4g |
| EMULSIFYING WAX | 3g |
| SLSa OR Epsom Salts | 2g |
| OIL | 2g |
| FRAGRANCE / ESSENTIAL OIL* | 3g |
| DRIED MILK* | 1g |

*** OPTIONAL / FLEXIBLE INGREDIENTS (your assessment will specify if you can use these)**

**MILKS:** You can use one, or a combination of one or more of the dried milks listed in your assessment: Cow Milk, Sheep/Ewe Milk, Goat Milk or Coconut Milk. *If you use 1% milk, you will need to remove 1% of another dry ingredient.*

**SALT:** You can use up to 1% Himalayan salt, sea salt, or rock salt as decoration on the bath bombs.

**BOTANICALS:** These are great to make the product look more "high-end" and add a touch of luxury. However, be cautious with how much you use, too much will result in a tricky rinse off after the bath (and you might end up with wet flowers stuck in your hair!). The following may be used: Mallow, Cornflower, Calendula, Rose Petals, Lavender, Rosemary, Seaweed

**CBD Isolate –** you can add up to 1% CBD isolate. This is a powdered product that can be mixed with your salts.

**Essential / Fragrance Oils (if shown on assessment) –** you can add up to 3%.

**MICA / COLOURANT:** Several CI numbers are listed in your assessment. You are permitted to use either the pigment (unmixed with any other pigment) or a commercially blended mica colourant made up of one or more of the pigments listed below. If you choose a commercially blended mica, ALL of the CI numbers listed in the SDS / on the supplier website, must be one of the CI numbers listed below.

E.g., Clementine Pop Mica (Naturally Balmy) contains CI 77019, CI 77891 and CI 77492. You may use this mica as all of the CI numbers are listed in your assessment.

**CI numbers included in your assessment:**

| | |
|---|---|
| MICA | **CI 77019** |
| TITANIUM DIOXIDE | **CI 77891** |
| IRON OXIDE | **CI 77491 & CI 77499** |
| ULTRAMARINE BLUE | **CI 77007** |
| TIN OXIDE | **CI 77861** |
| CHROMIUM OXIDE GREEN | **CI 77288** |
| MANGANESE VIOLET | **CI 77742** |
| CARBON BLACK | **CI 77266** |
| ACID BLUE 9 | **CI 42090** |
| ACID RED 92 | **CI 45410** |
| ACID YELLOW 23 | **CI 19140** |
| YELLOW 6 | **CI 15985** |

## METHOD

- Weigh your butter and emulsifying wax into a heatproof container and melt.
- Weigh your dry ingredients and add to a bowl, breaking up any chunks or clumps of powder (for a super-fine powder, you could push it through a sieve).
- Mix your colour (if using) and essential / fragrance oils with the melted butter / emulsifier.
- Slowly add your liquid ingredients to the dry mixture and mix well by hand.
- Test the mixture by grabbing a clump and squeezing hard; if it sticks together it is ready to mould. If it doesn't hold together, spritz with some binder (witch hazel or alcohol) and repeat.
- Pack the mixture in the mould very tightly, press in as much as you can ensuring the mould is completely full.
- Leave a while, de-mould and leave the bombs to harden before packaging.

## USE

- Add to running bath water and ensure the product is fully dissolved.

# 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-PA-1122-01 MOBBO**

**RESPONSIBLE INDIVIDUAL:**

**STACEY CHARLES**

MILL FARM

CHEPSTOW,

NP166QN UNITED

KINGDOM

**PRODUCT BEING ASSESSED:** Moisturising Bath Bomb

**CATEGORY OF PRODUCT & INTENDED USE:** Bathwater additive – bath water additive with exposure to the skin of the whole body. Rinse off 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 tables detail the base formulation of the product.

| BASE FORMULATION | | | | |
|---|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CAS NUMBER** | **CONCENTRATION BAND** | **MAX. CONCENTRATION (% w/w)** |
| **SODIUM BICARBONATE** | SODIUM BICARBONATE | 144-55-8 | B | **57.00** |
| **CITRIC ACID** | CITRIC ACID | 77-92-9 | C | **29.00** |
| **BUTTER** | SEE OPTION TABLE | N/A | F | **4.00** |
| **EMULSIFYING WAX** | SEE OPTION TABLE | N/A | F | **3.00** |
| **ESSENTIAL OIL / FRAGRANCE OIL** | SEE OPTION TABLE | N/A | F | **3.00** |
| **SLSa OR Epsom Salts** | SODIUM LAURYL SULFOACETATE / EPSOM SALTS | 1847-58-1 / 10034-99-8 | F | **2.00** |
| **OIL** | SEE OPTION TABLE | N/A | F | **2.00** |

**BUTTER & OIL OPTIONS:** The following tables detail the butters and oils that may be used in the formulation of the product. You may use any one, or combination of one or more of the following butter and oils. Any combination / ratio is acceptable, but the maximum concentration is shown in the table.

| BUTTER OPTIONS | | | | |
|---|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CAS NUMBER** | **CONCENTRATION BAND** | **MAX. CONCENTRATION (% w/w)** |
| **COCOA BUTTER** | THEOBROMA CACAO SEED BUTTER | 84649-99-0 | F | **4.00** |
| **SHEA BUTTER** | BUTYROSPERMUM PARKII BUTTER | 194043-92-0 | F | **4.00** |
| **MANGO BUTTER** | MANGIFERA INDICA SEED BUTTER | 90063-86-8 | F | **4.00** |

| OIL OPTIONS | | | | |
|---|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CAS NUMBER** | **CONCENTRATION BAND** | **MAX. CONCENTRATION (% w/w)** |
| **OLIVE OIL** | OLEA EUROPAEA FRUIT OIL | 8001-25-0 | F | **2.00** |
| **SWEET ALMOND OIL** | PRUNUS AMYGDALUS DULCIS OIL | 8007-69-0 | F | **2.00** |
| **GRAPESEED OIL** | VITIS VINIFERA SEED OIL | 85594-37-2 | F | **2.00** |
| **AVOCADO OIL** | PERSEA GRATISSIMA OIL | 8024-32-6 | F | **2.00** |
| **HEMPSEED OIL** | CANNABIS SATIVA SEED OIL | 89958-21-4 | F | **2.00** |
| **FRACTIONATED COCONUT** | CAPRYLIC/CAPRIC TRIGLYCERIDE | 73398-61-5 | F | **2.00** |

**EMULSIFIER OPTIONS:** The following tables detail the emulsifier that may be used in the formulation of the product.

| EMULSIFIER OPTIONS | | | | |
|---|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CAS NUMBER** | **CONCENTRATION BAND** | **MAX. CONCENTRATION (% w/w)** |
| **EMULSIFYING WAX** | CETEARYL ALCOHOL, CETEARETH-20 | N/A | F | **3.00** |
| **OLIVEM 1000** | CETEARYL OLIVATE, SORBITAN OLIVATE | N/A | F | **3.00** |
| **BTMS 25** | CETEARYL ALCOHOL, BEHENTRIMONIUM METHOSULFATE | N/A | F | **3.00** |

**PRODUCT FORMULATION – OPTIONAL INGREDIENTS:** The following table details the optional ingredients that may be used in the formulation of the product. One, or a combination of one or more of these may be used.

| ADDITIONAL - OPTIONAL INGREDIENTS | | | | |
|---|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CAS NUMBER** | **CONCENTRATION BAND** | **MAX. CONCENTRATION (% w/w)** |
| **BOTANICALS** | SEE OPTION TABLE | N/A | F | **5.00** |
| **COLOUR / MICA** | SEE OPTION TABLE | N/A | F | **5.00** |
| **SALT** | SODIUM CHLORIDE, MARIS SAL | N/A | F | **4.00** |
| **FRAGRANCE OIL / ESSENTIAL OIL** | SEE OPTION TABLE | N/A | F | **3.00** |
| **MILK** | SEE OPTION TABLE | N/A | G | **1.00** |
| **CBD ISOLATE** | CANNABIDIOL | N/A | G | **1.00** |

**OPTIONAL INGREDIENTS – BOTANICAL OPTIONS:** The following table details the botanicals that may be used in the formulation of the product. One or more may be used in any ratio.

| BOTANICAL OPTIONS | | | | |
|---|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CAS / CI NUMBER** | **CONCENTRATION BAND** | **MAX CONCENTRATION (W/W%)** |
| **LAVENDER BUDS** | LAVANDULA ANGUSTIFOLIA FLOWER | 90063-37-9 | F | **5.00** |
| **CALENDULA** | CALENDULA OFFICINALIS FLOWER | 84776-23-8 | F | **5.00** |
| **ROSE FLOWER / PETALS** | ROSA GALLICA / DAMASCENA / CENTIFOLIA FLOWER | 84604-12-6 / 90106-38-0 | F | **5.00** |
| **CORNFLOWER** | CENTAUREA CYANUS FLOWER | 84012-18-0 | F | **5.00** |
| **MALLOW FLOWER** | MALVA SYLVESTRIS FLOWER | N/A | F | **5.00** |
| **PEPPERCORNS** | PIPER NIGRUM FRUIT | 84929-41-9 | F | **5.00** |
| **MINT LEAF** | MENTHA PIPERITA LEAF | 84082-70-2 | F | **5.00** |
| **ROSEMARY HERB LEAF** | ROSMARINUS OFFICINALIS LEAF | 84604-14-8 | F | **5.00** |
| **DRIED SEAWEED** | ASCOPHYLLUM NODOSUM POWDER | 84775-78-0 | F | **5.00** |

**OPTIONAL INGREDIENTS – MILK OPTIONS:** The following table details the dried milks that may be used in the formulation of the product. One or more may be used in any ratio.

| MILK OPTIONS | | | | |
|---|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CAS / CI NUMBER** | **CONCENTRATION BAND** | **MAX CONCENTRATION (W/W%)** |
| **COCONUT MILK (DIRED)** | COCOS NUCIFERA FRUIT EXTRACT | 8001-31-8 | C | **50.00** |
| **SHEEP/EWE MILK (DIRED)** | SHEEP MILK | N/A | C | **50.00** |
| **COW MILK (DRIED)** | LAC POWDER | N/A | C | **50.00** |
| **GOAT MILK (DRIED)** | CAPRAE LAC | N/A | C | **50.00** |

**PRODUCT COLOURANT OPTIONS:** The following table details the substances that may be used to colour the product(s). Any one, or combination of one or more of the following substances may be used to colour the product. The maximum concentration of colourant permitted for use in this product is 5% (w/w).

A commercially manufactured blend containing one, or any combination of one or more of the substances shown in the following tables may be used to colour the product.

Each of the following substances (with CI numbers) are listed in Annex IV of Regulation 1223/2009 and Annex IV of Regulation (EC) No 1223/2009 on Cosmetic Products as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

These substances are considered safe for use in cosmetic products, without restriction and when used in the manner described in this assessment they do not alter the toxicology of the product and have no impact on the safety of the product.

| SUBSTANCE NAME | CI NUMBER |
|---|---|
| ACID RED 18, CI 11710, CI 15985, CURRY RED, ACID RED 33, ACID YELLOW 23, SOLVENT RED 23, FOOD BLACK 2, CI 28440, CI 40215, BETA CAROTENE, ACID BLUE 1, ACID BLUE 3, FAST GREEN FCF, ACID BLUE 9, ACID BLUE 9 ALUMINIUM LAKE, CI 42170, BASIC VIOLET 2, CI 44090, ACID RED 52, BASIC RED 1, BASIC VIOLET 11:1, ACID YELLOW 73, ACID RED 92, NIGROSINE, CI 71105, ACID BLUE 74, ACID BLUE 74 ALUMINIUM LAKE, CI 73360, CI 73385, PIGMENT VIOLET 19, CI 74260, ANNATTO, PIGMENT BLUE 27, CI 75125, CI FOOD ORANGE 5, CARMINES, ALUMINIUM, CI 77002, KAOLIN / BENTONITE / ILLITE / MONTMORILLONITE, ULTRAMARINES, CI 77015, MICA, CARBON BLACK, CHARCOAL, CHROMIUM (III) OXIDE, CHROMIUM (III) HYDROXIDE, COPPER, GOLD, IRON OXIDE, IRON OXIDE RED, IRON OXIDE YELLOW, IRON OXIDE BLACK, MANGANESE VIOLET, MAGNESIUM CARBONATE, SILVER, TIN OXIDE, TITANIUM DIOXIDE, COKE BLACK | **16255, 11710, 15985, 16035, 17200, 19140, 26100, 27755, 28440, 40215, 40800, 42045, 42051, 42053, 42090, 42090:1, 42170, 42520, 44090, 45100, 45160, 45174, 45350, 45410, 50420, 71105, 73015, 73015:1, 73360, 73385, 73900, 74260, 75120, 77510, 75125, 75130, 75470, 77000, 77002, 77004, 77007, 77015, 77019, 77266, 77267, 77288, 77289, 77400, 77480, 77489, 77491, 77492, 77499, 77742, 77713, 77820, 77861, 77891, 77268:1.** |

| SUBSTANCE NAME | INCI NAME | CAS NUMBER |
|---|---|---|
| SYNTHETIC MICA | SYNTHETIC FLUORPHLOGOPITE | 12003-38-2 |
| STYRENE/ACRYLATE COPOLYMER | STYRENE/ACRYLATE COPOLYMER | 9010-92-8 |
| POLYURETHANE-11 | POLYURETHANE-11 | N/A |
| RAYON | RAYON | 270-493-7 |
| RAYON (CELLULOSE REGENERATED) | RAYON (CELLULOSE REGENERATED) | 270-493-7 |
| GLYCERIN | GLYCERIN | 56-81-5 |
| AQUA | AQUA | 7732-18-5 |
| UREA | UREA | 57-13-6 |
| SHELLAC | SHELLAC | 9000-59-3 |

**PRODUCT FRAGRANCE VARIANTS:** The following table details the essential oils that may be used in the formulation of the product(s). These essential oils may be blended in any ratio, but the overall concentration of essential oils may not exceed 3% (3g in 100g of product).

| ESSENTIAL OIL OPTIONS | | | |
|---|---|---|---|
| **INGREDIENT NAME** | **INCI NAME** | **CONCENTRATION BAND** | **MAX CONCENTRATION (W/W%)** |
| **BLACK PEPPER ESSENTIAL OIL** | PIPER NIGRUM FRUIT OIL | F | **3.00** |
| **CHAMOMILE ESSENTIAL OIL** | CHAMOMILLA RECUTITA FLOWER OIL | F | **3.00** |
| **LAVENDER ESSENTIAL OIL** | LAVANDULA ANGUSTIFOLIA OIL | F | **3.00** |
| **LEMONGRASS ESSENTIAL OIL** | CYMBOPOGON FLEXUOSUS OIL | F | **1.00** |
| **ROSEMARY ESSENTIAL OIL** | ROSMARINUS OFFICINALIS LEAF OIL | F | **3.00** |
| **SANDALWOOD ESSENTIAL OIL** | AMYRIS BALSAMIFERA BARK OIL | F | **3.00** |
| **SPEARMINT ESSENTIAL OIL** | MENTHA SPICATA HERB OIL | F | **3.00** |
| **SWEET ORANGE ESSENTIAL OIL** | CITRUS AURANTIUM DULCIS PEEL OIL | F | **3.00** |
| **UNSCENTED** | N/A | N/A | N/A |

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

**PHYSICAL AND CHEMICAL PROPERTIES:** Product is a solid, or may be sold as bath dust / fizz / rocks.

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 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 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).

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 bathwater additive. It is intended to be dissolved in bath water.

It is a rinse off 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 1% 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 skin of the 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; WHOLE 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) |
| 25 | 0.28 | 7.00 | 0.01 | 70 | **1.147540984** |

| SUBSTANCE EXPOSURE DATA: WHOLE BODY | | | | |
|---|---|---|---|---|
| INGREDIENT CONCENTRATION BAND | MAX. CONCENTRATION (% w/w) | DAILY SUBSTANCE EXPOSURE (mg/day) | SED (mg/kg/day) | LED (mgkg/day) |
| A (75-100) | **100** | 70 | 1.1667 | **7.44522E-05** |
| B (50-75) | **75** | 52.5 | 0.8750 | **5.58392E-05** |
| C (25-50) | **50** | 35 | 0.5833 | **3.72261E-05** |
| D (10-25) | **25** | 17.5 | 0.2917 | **1.86131E-05** |
| E (5-10) | **10** | 7 | 0.1167 | **7.44522E-06** |
| F (1-5) | **5** | 3.5 | 0.0583 | **3.72261E-06** |
| G (0.1-1) | **1** | 0.7 | 0.0117 | **7.44522E-07** |
| < 0.1% | **0.1** | 0.07 | 0.0012 | **7.44522E-08** |

***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 0.01% 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** |
| AVENA SATIVA KERNEL MEAL, AVENA SATIVE KERNEL FLOUR | No toxicological significance. | >100 |
| CALENDULA OFFICINALIS FLOWER | No toxicological significance. | >100 |
| CANNABIDIOL | Molecular Formula C21H30O2<br>Molecular Weight 314.5<br><br>CBD has a chemical formula of C21H30O2 and a molecular weight of 314.469 g/mol.<br><br>Cannabidiol is a phytocannabinoid derived from Cannabis species, which is devoid of psychoactive activity, with analgesic, anti-inflammatory, antineoplastic and chemopreventive activities. Upon administration, cannabidiol (CBD) exerts its anti-proliferative, anti-angiogenic and pro-apoptotic activity through various mechanisms, which likely do not involve signaling by cannabinoid receptor 1 (CB1), CB2, or vanilloid receptor 1. CBD stimulates endoplasmic reticulum (ER) stress and inhibits AKT/mTOR signaling, thereby activating autophagy and promoting apoptosis. In addition, CBD enhances the generation of reactive oxygen species (ROS), which further enhances apoptosis. This agent also upregulates the expression of intercellular adhesion molecule 1 (ICAM-1) and tissue inhibitor of matrix metalloproteinases-1 (TIMP1) and decreases the expression of inhibitor of DNA binding 1 (ID-1). This inhibits cancer cell invasiveness and metastasis. CBD may also activate the transient receptor potential vanilloid type 2 (TRPV2), which may increase the uptake of various cytotoxic agents in cancer cells. The analgesic effect of CBD is mediated through the binding of this agent to and activation of CB1.<br><br>The safety of cosmetic products in the UK is regulated by the EU Cosmetics Regulation 1223/2009 (“the Regulation”) as adopted into UK law2. Narcotic substances, as listed in Tables I and II of the Single Convention on Narcotic Drugs (UN Drug Control Conventions, 1972) are prohibited in cosmetic products via entry 306 of Annex II to the Regulation.<br><br>Cannabis and cannabis resin, cannabinol and cannabinol derivatives are Class B drugs under the Misuse of Drugs Act 1971. Any preparations or product containing the above substances are also controlled as Class B drugs.<br>CBD is not controlled under the Misuse of Drugs Act of 1971.<br><br>Once specific criteria are met (see Annex A), plant-derived and synthetic CBD are not controlled under the Single Convention on Narcotic Drugs and may therefore be used in finished cosmetic products.<br><br>Mouse study<br>GWTX1503, 13 week oral toxicity Mean alanine amino transaminase/alanine aminotransferase (ALT) levels were higher than controls during Week 7 and 13 in males given ≥ 150 mg/kg/day (by approximately 65% and 40%, respectively) and during Week 7<br>for females given 150 or 300 mg/kg/day (by 259% or 83%, respectively). Microscopic centrilobular hepatocyte hypertrophy in all animals given 300 mg/kg/day and in some animals given 100 or 150 mg/kg/day was associated with increased liver weight in all groups and macroscopic enlargement at ≥ 150 mg/kg/day. No observed adverse effect level (NOAEL) was 300 mg/kg/day CBD-OS, corresponding to the respective Week 13 maximum measured plasma concentration (Cmax) and area under the concentration-time curve calculated to the last observable concentration at time t (AUC(0-t)) values of 9810 ng/mL | >100 |

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| | and 44300 ng h/mL in males and 5770 ng/mL and 46400 ng h/mL in females.<br><br>39-Week Oral<br>(Gavage) Toxicity with 4-Week Recovery in Dogs (GWTX1413) Beagle dogs (4/sex/main groups) received CBD-OS at 0 (vehicle), 10, 50, or 100 mg/kg/day once daily for 39 weeks. Reversibility of changes was evaluated following a 4-week recovery phase (2/sex/control and high dose groups). In dogs, the target organ for toxicity was liver with hepatocyte hypertrophy,<br>macroscopic enlargement and increased liver weight. No increase in bilirubin, necrosis or significant inflammation and/or proliferation suggests that effects observed in rats and dogs might be reflections of adaptive changes due to microsomal hepatic induction. However, due to absence of hormonal examinations and some other effects of hormonal misbalance observed in the studies these effects need to be further substantiated via post-authorisation measure.<br><br>BioA not GLP CD-1 mice/12 NOAEL (mg/kg/ day): 300 mg/kg Liver centrilobular hypertrophy in some animals given 100 or 150 mg/kg/day and all animals given 300 mg/kg/day Liver centrilobular hyper-trophy at ≥ 50 mg/kg/day Doses ≥ 50 mg/kg/day<br><br>152 No adverse effects were apparent in rats treated with 50 mg/kg bw/day CBD. This would result in a potential HGBV of 50/10x10 = 0.5 mg/kg/bw per day which is equivalent to 35 mg/day in a 70 kg adult. 153 Very little data from this study is publicly available and it is was not conducted to Good Laboratory Practice (GLP) and so it is unclear what conclusions can be drawn. The FDA86 considered the study to be inadequate, stating that "…only the CBD Botanical Drug Substance (BDS) was administered in the diet, resulting in uncertain exposures, potential interactions with impurities, and excessive BW effects in the single species tested is also an important deficiency. This may at least partially be addressed by the mouse study that is currently underway. The toxicity evaluation of the parent compound can otherwise be considered adequate". No Special Protocol Assessment87 (SPA) was submitted for this study.<br><br>cONSIDERED SAFE FOR USE (FDA, FSA, SCCS)<br>https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000PharmR.pdf | |
| CAPRAE LAC | No toxicological significance. | >100 |
| CENTAUREA CYANUS FLOWER | No toxicological significance. | >100 |
| COCOS NUCIFERA FRUIT EXTRACT | No toxicological significance. | >100 |
| LAC POWDER | No toxicological significance. | >100 |
| LAVANDULA ANGUSTIFOLIA FLOWER | No toxicological significance. | >100 |
| MALVA SYLVESTRIS FLOWER | No toxicological significance. | >100 |
| MARIS SAL | No toxicological significance. | >100 |
| MENTHA PIPERITA LEAF | No toxicological significance. | >100 |
| PIPER NIGRUM FRUIT | No toxicological significance. | >100 |
| POLYSORBATE 80 | Considered safe as a cosmetic ingredient:<br>(https://www.cir-safety.org/sites/default/files/polysorbates_0.pdf) | >100 |

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| | NOAEL (28 day rat study) = 2500mg/kg<br>(https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4152) | |
| ROSA GALLICA / DAMASCENA / CENTIFOLIA FLOWER | No toxicological significance. | >100 |
| ROSMARINUS OFFICINALIS LEAF | No toxicological significance. | >100 |
| SHEEP MILK | No toxicological significance. | >100 |
| SODIUM CHLORIDE | No toxicological significance. | >100 |
| OLEA EUROPAEA FRUIT OIL | Considered safe as a cosmetic ingredient:<br>https://www.cir-safety.org/sites/default/files/117_draft_oils.pdf<br><br>CIR have concluded that olive oil (plant-derived edible oil) is safe and there are no toxicological concerns. | >100 |
| PRUNUS AMYGDALUS DULCIS OIL | Density: 0.91 g/mL at room temp.<br>Refractive Index: n20/D1.471<br>Insoluble in water, slightly soluble in ethanol.<br>Clear, colourless or pale yellow coloured oil with a nutty fragrance and aroma.<br><br>Considered safe as a cosmetic ingredient:<br>(https://doi.org/10.1177/1091581817740569)<br><br>Similar plant-derived fatty acid oils are not known to be photosensitising, phototoxic, dermal or ocular irritants or sensitisers (MCII <0.25).<br><br>LD50 = >5000mg/kg (ECHA, unnamed study report, 2014)<br>Prunus amygdalus dulcis oil was not found to be genotoxic (ECHA, unnamed study report, 2014, OECD 471).<br><br>Considered a non-toxic ingredient - no repeat-dose toxicity data available | >100 |
| VITIS VINIFERA SEED OIL | Considered safe as a cosmetic ingredient:<br>https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569<br><br>NOAEL (CIR) = >5000mg/kg | >100 |
| PERSEA GRATISSIMA OIL | Considered safe as a cosmetic ingredient:<br>https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569<br><br>NOAEL (CIR) = >5000mg/kg | >100 |
| CANNABIS SATIVA SEED OIL | Considered safe as a cosmetic ingredient:<br>https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569 | >100 |

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| | NOAEL (CIR) = >5000mg/kg | |
| CAPRYLIC/CAPRIC TRIGLYCERIDE | Considered safe as a cosmetic ingredient:<br>https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569<br><br>NOAEL (CIR) = >5000mg/kg | >100 |
| SODIUM BICARBONATE | Considered safe as a cosmetic ingredient:<br>(https://doi.org/10.3109/10915818709095491)<br><br>Slight irritating to the skin when used in isolation.<br>Not an ocular irritant.<br>NOAEL (repeat dose, 28 day in mouse. Developmental toxicity, no other data available) = 580mg/kg (OECD SIDS) | >100 |
| CITRIC ACID | An acute oral LD50 value of 5400 mg/kg bw in mouse is reported in a reliability 2 study which is broadly equivalent to the OECD test guideline 401 (Roche 1981).<br><br>An acute dermal LD50 value of >2000mg/kg bw in rat was determined in a reliable study conducted according to OECD 402 and in compliance with GLP (Safepharm, 2006; rel 1).<br><br>A reliability 1 key study on skin irritation, which was conducted according to OECD 404, reports that citric acid was not irritating to skin (Haarmaan & Reimer, 1990). The proposal for harmonised classification and labelling has been considered and it is concluded that there is not sufficient evidence for classification of citric acid as irritating to the skin.<br><br>The key eye irritation study (Roche, 1984) found the test substance to be an eye irritant within a 14 day observation period and classification as Eye Irritant, Cat 2 has been proposed.<br><br>Citric acid is used to induce the cough response in human volunteers in studies to evaluate the use of citric acid as a positive control in the efficacy testing of anti-tussive agents (Bickerman et al., 1954; Winther, 1969; Barros et.al., 1990), and has been shown to cause cough and bronchoconstriction in the guinea pig (Zelenak 1982, Forsberg and Karlsson, 1986), and classification for Specific Target Organ Toxicity, Cat 3 respiratory irritation has been proposed.<br><br>In a skin sensitisation study with limited details which was not conducted according to a guideline or in compliance with GLP, the test substance citric acid was concluded to not be a skin irritant or a sensitiser when tested to human volunteers (Clinical Research Laboratories, 2007 as cited in Cosmetic Ingredient Review, 2012).<br><br>In a skin prick test which was not conducted according to any guideline or in compliance to GLP, it was observed that the test substance, citric acid, caused positive results in 3 out of 91 patients. Very limited details were given in the study source (Malanin & Kalimo, 1989 as cited in Cosmetic Ingredient Review, 2012). | >100 |

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| | There are no reliable 28-day or 90-day studies available, so this endpoint is waived. Numerous studies have been reported in the literature and are discussed below. The most reliable studies are 10-day studies in rats and mice, with the following results:<br><br>NOAEL (10 d) 4000 mg/kg bw/day rats (unidentified gender)<br><br>LD50 (10 d) 5660 (+/- 0.44) mg/kg bw/day rats (unidentified gender). | |
| SODIUM LAURYL SULFOACETATE | Considered safe as a cosmetic ingredient:<br>(https://doi.org/10.3109/10915818709098561)<br><br>Not phototoxic.<br>Not a skin or ocular irritant. (Journal of the American College of Toxicology (JACT), vol. 6(3), 1987, pp. 261-277)<br><br>NOAEL (reproductive and developmental, rat 39 day study) = 1000mg/kg (Stepan Study No. 04-015A)<br>NOAEL (28 day oral) = No data – no observed adverse effects at max. treatment dose. | >100 |
| CETEARYL ALCOHOL | Molecular formula: C16 H34 O<br>IUPAC Name: Alcohols, C16-18<br><br>Considered safe as a cosmetic ingredient:<br>https://www.cir-safety.org/sites/default/files/alkyle032013rep.pdf<br><br>- Acute oral toxicity: The acute oral LD50 in male/female rats is >10000 mg/kg bw . No significant gross abnormalities were seen at autopsy. )). This show that Alcohols, C16-18 is practically nontoxic for acute oral toxicity. Alcohols, C16-18 was not classified according to EU or GHS criteria.<br>-Acute Dermal Toxicity: The rabbit dermal LD50 (24 hour occluded) for Alcohols, C16-18 was >8000 mg/kg applied as a 50% solution in peanut oil. There were no deaths or reports of toxicity. This show that Alcohols, C16-18 is not toxic for acute Dermal toxicity . Alcohols, C16-18 was not classified according to EU or GHS criteria<br><br>-Acute inhalation toxicity : Inhalation of vapours of Alcohols, C16-18 at levels up to the saturated vapour pressure is unlikely to be associated with significant toxicity. The LC50 values exceeded the maximum achievable vapour concentrations and showed no evidence of toxicity after a single exposure for 6 hours . Results indicate that Alcohols, C16-18 is not toxic for acute inhalation toxicity. Alcohols, C16-18 was not classified according to EU or GHS criteria<br><br>-The acute eye irritation study (Carter, G., Dharmarajan, V., and Weill, H. .1975) indicates that Alcohols, C16-18 was not irritating.<br>Result: not irritating to eye. Based on the Draize scores reported it is considered that Alcohols, C16-18 is not not an eye irritant according to either EU or GHS criteria.The alcohols with chain lengths of C16-18 are non-irritant to eye.<br>- The results of the study (Carter, G., Dharmarajan, V., and Weill, H. 1975) indicate that Alcohols, C16-18 is non-irritant to skin. Following a 24 hour semi-occlusive exposure to rabbit skin Alcohols, C16-18 is classified as non-irritant based on either EU or GHS criteria. The alcohols with chain lengths of C16-18 are non-irritant to skin.<br>Result: non-irritant to skin | >100 |

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| | - Respiratory irritation<br>There is no information available from single or repeated inhalation exposures in laboratory animals or from human experience allowing a conclusion on potential respiratory tract irritation of the aliphatic alcohols.<br><br>Oral repeated dose toxicity<br>The NOAEL for 13 week dietary feeding study in rats is ca 750 mg/kg/day (males 723, females 875) based on reduced weight gain and food consumption. The toxicological significance of observed changes in organ weights, all in the absence of histopathological change, is questionable. Increased liver weights at higher dose levels may be indicative of a mild adaptive effect on the liver.<br>In view of the structural and chemical similarities, it is considereed that the results of the study can be used for read-across to Alcohols, C16-18.<br>Dermal repeated dose toxicity<br>A 90-day dermal toxicity study in rats with fatty alcohol blend (56.7% decanol, 42.7% octanol) at dose levels of 0, 100, 300, or 1,000 mg/kg resulted in severe irritation at the application site. Severe irritation including fissuring of the skin occurred in 40% of the animals at 100 mg/kg/day and 80% of the animals at the limit dose. Slight changes in hematology, clinical chemistry, and organ weights were noted at the limit dose of 1,000 mg/kg/day.<br>NOAEL has been based on a local irritation effect rather than a systemic effect. Therefore it is proposed (by the author of the EPSR) that on the basis of a lack of systemic effects reported in the study, the NOAEL following dermal administration of fatty alcohol blend for a minimum of 90 days is greater than 1000 mg/kg/day.<br>Inhalation repeated dose toxicity<br>Under the conditions of the test no treatment-related toxic effects were found in male and female Wistar rats which were exposed to 2-ethylhexanol vapor up to 120 ppm ie. 638.4 mg/$m^3$ . (Klimisch HJ; Deckardt K; Gembardt C; Hildebrand B,1998).The substance Alcohols, C16-18, the subject of this dossier) is expected to exhibit very similar toxicity due to its close structural similarity to 2-ethylhexanol.Comparable metabolism would occur.<br>Correcting for molecular weight, a conservative NOAEC of 1188.79 mg/m3 can be derived (638.4 x 242.45) / 130.2 =1188.79 mg/m3 | |
| CETEARETH-20 | Considered safe as a cosmetic ingredient:<br>(https://journals.sagepub.com/doi/pdf/10.3109/10915818809023137)<br><br>Not a skin or ocular sensitiser.<br>Not phototoxic in the concentration used (<3%)<br>Not a skin or ocular irritant.<br>NOAEL (repeat dose study, rats) = 750mg/kg (ECHA). | >100 |
| SORBITAN OLIVATE | Considered safe as a cosmetic ingredient:<br>(https://www.cir-safety.org/sites/default/files/alkyle032013rep.pdf)<br>Minimally orally toxic – structurally similar compounds have a significant LD50 (>5g/kg).<br><br>No toxicological significance. | >100 |
| CETEARYL OLIVATE | Considered safe as a cosmetic ingredient:<br>(https://www.cir-safety.org/sites/default/files/alkyle032013rep.pdf)<br>Minimally orally toxic – structurally similar compounds have a significant LD50 (>5g/kg). | >100 |

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| | No toxicological significance. | |
| BEHENTRIMONIUM METHOSULFATE | Acute oral toxicity: The LD50 in female Wistar rats after a single oral application of the similar supporting substance C20-22-alkyltrimethylammonium chloride was 3190 mg/kg bw.<br>Acute dermal toxicity: In a weight-of-evidence approach data on acute dermal toxicity of similar substances were used together with information on dermal absorption and taking into consideration the low acute oral toxicity of the substance. From this combined evidence it can be concluded that the acute dermal toxicity is >2000 mg/kg bw.<br><br>Skin irritation: The submission substance is rated as a skin irritant according to test results from a similar supporting substance:<br>In a guideline-compliant primary skin irritation/corrosion test in rabbits, a supporting substance caused moderate-to-severe or severe erythema and very slight or slight oedema. No evidence of full thickness destruction of the skin or scar tissue was observed during the observation period, indicating that no corrosion of the skin had occurred by dermal application of the test substance to the intact rabbit skin. The supporting substance was irritating to rabbit skin.<br>Eye irritation: The submission substance is rated as an eye irritant according to test results from a similar supporting substance:<br>In a guideline-compliant acute eye irritation/corrosion study in rabbits, a supporting substance caused corneal opacity (maximum grade 2) with epithelial damage of 100% of the corneal area, iridial irritation grade 1, and irritation of the conjunctivae consisting of redness (grade 3), chemosis (grade 4) and discharge (grade 3) 24 hours after treatment. Signs of necrosis of the eyelids and nictating membrane were observed as grey/white discoloration. Based on the severity of the ocular lesions observed during the study, the animal was sacrificed for ethical reasons after 24 hours. The supporting substance caused irreversible effects on the rabbit eye.<br><br>Repeated oral toxicity:<br>A similar supporting substance was tested in a 28-day oral gavage study in rats that received daily doses of 0, 10, 50 and 150 mg/kg/day. One male of the high dose group died and two females of the high dose group had to be humanely killed during the treatment period. In a dose dependent fashion, animals at 50 and 150 mg/kg/day showed various effects on body weight, hematology, clinical chemistry, organ weights, macroscopic and microscopic examination. In animals at 10 mg/kg/day, mesenteric lymph nodes were affected to a minimal or mild degree only and no further treatment-related changes were noted in these animals. Therefore, a No Observed Adverse Effect Level (NOAEL) for the test substance of 10 mg/kg/day was established.<br>The 28-day study results are supported by an OECD 421 study with the same substance that reported a parental NOAEL of 30 mg/kg/day.<br>Additional data on similar supporting substances was also considered.<br><br>A structural analogue substance was not mutagenic in a guideline-compliant Salmonella typhimurium reverse mutation assay using strains TA 100, TA 1535, TA 1537 and TA 98 in either the absence or presence of rat liver S9 metabolic activation. This supporting substance was not genotoxic in a guideline-compliant mammalian cell gene (HPRT) mutation test in V79 Chinese Hamster cells and did not induce micronuclei in V79 cells (Chinese hamster cell line) in vitro in the absence and the presence of metabolic activation in a guideline-compliant study. | >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 BATH BOMB*

**RESPONSIBLE PERSON DETAILS:**

**STACEY CHARLES**

MILL FARM CHEPSTOW,

NP166QN 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 bathwater additive**). 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 rinse off product (as is the case for these products) in a concentration of 0.01% or greater, then they must be specified on the product label.

## 11. REASONING

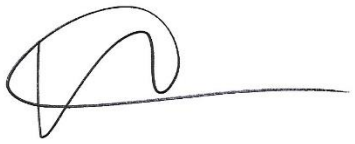
All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

- 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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|---|---|
| NAME: | Michael Ford, MAF Cosmetic Consultants |
| QUALIFICATIONS: | BSc (Hons) Biochemistry, MRes Biochemistry, AMRSB |
| ADDRESS: | 5 Market Arcade, Newport, NP20 1FS |
| DATE: | 20/07/2024 |

# 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

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

# 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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