# Product Information File (PIF) Summary

## 1. Product Description

### Product name

Melovibes Shea Body Butter with 600mg CBD

### Volume

15ml

### Intended use of the product

| | |
|---|---|
| Composition type: | Butter/Balm |
| General purpose: | Moisturiser and Conditioner |
| Main action: | Moisturisation and Conditioning of skin |
| Target population: | Adults |

**Integral composition of the product**

| Trade Name | INCI | Function | Conc (% w/w) |
|---|---|---|---|
| Shea Butter | Butyrospermum parkii | Emollient, skin conditioning agents, viscosity increasing agent | 97 |
| Vitamin E | α-Tocopherol | Antioxidant and conditioner | 1 |
| CBD | Cannabidiol | Anti-inflammatory | 2 |

## 2. Toxicology Assessment

Local toxicity: Phototoxic materials are not included in this formulation at levels of concern. Nano materials are not included in this formulation.

The toxicological profile and concentration of ingredients in this product do not present a risk to human health when the product is used under normal or reasonably foreseeable conditions of use.

Margins of safety were calculated; the ingredients are considered safe.

# SAFETY REPORT PART A

## A. 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.

| | FORMULATIO |
|---|---|

| INGREDIENT NAME | INCI NAME | CONC. BAND |
|---|---|---|
| MANGO BUTTER | MANGIFERA INDICA SEED BUTTER | A |
| CBD | CANNABIDIOL | F |
| VITAMIN E | TOCOPHEROL, HELIANTHUS ANNUUS SEED OIL | F |

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

| | FORMULATIO |
|---|---|

| INGREDIENT NAME | INCI NAME | CONC. BAND |
|---|---|---|
| MANGO BUTTER | MANGIFERA INDICA SEED BUTTER | A |
| CBD | CANNABIDIOL | F |
| VITAMIN E | TOCOPHEROL, HELIANTHUS ANNUUS SEED OIL | F |

| | FORMULATIO |
|---|---|

| INGREDIENT NAME | INCI NAME | CONC. BAND |
|---|---|---|
| MANGO BUTTER | MANGIFERA INDICA SEED BUTTER | A |
| CBD | CANNABIDIOL | E |
| VITAMIN E | TOCOPHEROL, HELIANTHUS ANNUUS SEED OIL | F |

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

### PHYSICAL AND CHEMICAL PROPERTIES:

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

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

The exact pH of the product has not been empirically determined but based on the understanding of similar products the expected pH is 5.5-6.5.

### STABILITY AND REACTIVITY:

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

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

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

### INGREDIENT PURITY:

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

### PACKAGING MATERIAL:

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

## C. MICROBIOLOGICAL QUALITY OF THE PRODUCT(S).

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

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

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

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

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

It is a leave on product.

It is intended to be used by the general population.

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

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

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

## E. PRODUCT AND SUBSTANCE EXPOSURE INFORMATION.

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

### AREAS OF SPECIFIC EXPOSURE

**Inhalation** – not relevant for this type of product.

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

**Eye** – not relevant for this type of product.

**Ingestion** – not relevant for this type of product.

**EXPOSURE OF PRODUCT; BODY**

| PRODUCT AMOUNT PER APPLICATION[1] (G) | POTENTIAL FREQUENCY OF USE[1] (PER DAY) | MAXIMUM DAILY PRODUCT USE (G) | RETENTION FACTOR[2] | MAXIMUM DAILY PRODUCT EXPOSURE (MG) |
|---|---|---|---|---|
| 5 | 1 | 5 | 1 | 5000 |

**SUBSTANCE EXPOSURE DATA: BODY**

| INGREDIENT CONCENTRATION BAND | MAX. CONCENTRATION (% w/w) | DAILY SUBSTANCE EXPOSURE (mg/day) | SED (mg/kg/day) |
|---|---|---|---|
| A (75-100) | **100** | 5000 | 83.333 |
| B (50-75) | **75** | 3750 | 62.5 |
| C (25-50) | **50** | 2500 | 41.667 |
| D (10-25) | **25** | 1250 | 20.833 |
| E (5-10) | **10** | 500 | 8.3333 |
| F (1-5) | **5** | 250 | 4.1667 |

| | | | |
|---|---|---|---|
| G (0.1-1) | 1 | 50 | 0.8333 |
| < 0.1% | **0.1** | 5 | 0.0833 |

***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***

## F. 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.

## G. 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):

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.

## H. 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.

| INCI NAME | TOXICOLOGICAL PROFILE |
|---|---|

| | |
|---|---|
| CANNABIDIOL | Molecular Formula C2lH30O2 Molecular Weight 314.5<br><br>CBD has a chemical formula of C2lH30O2 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 l (CB1), CB2, or vanilloid receptor l. 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 l (ICAM-l) and tissue inhibitor of matrix metalloproteinases-l (TIMPl) and decreases the expression of inhibitor of DNA binding l (ID-l). 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, l972) 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><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><br>GWTXl503, l3 week oral toxicity Mean alanine amino transaminase/alanine aminotransferase (ALT) levels were higher than controls during Week 7<br><br>and 13 in males given ≥ 150 mg/kg/day (by approximately 65% and 40%, respectively) and during Week 7<br>for females given l50 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<br><br>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 (GWTXl4l3) Beagle dogs (4/sex/main groups) received CBD-OS at 0 (vehicle), l0, 50, or l00 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<br><br>groups). In dogs, the target organ for toxicity was liver with hepatocyte hypertrophy, |

| | | |
|---|---|---|
| | 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><br>https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000PharmR.pdf | |
| HELIANTHUS ANNUUS SEED OIL | EC Number: 273-195-5<br>EC Name: Fatty acids, sunflower-oil, conjugated CAS Number: 68953-27-5<br>Molecular formula: not applicable for UVCB substance IUPAC Name: Fatty acids, sunflower-oil, conjugated<br><br>Acute Toxicity:<br>– oral: LD50 >2000 mg/kg bw (OECD 401; Analogy CAS 112-80-1);<br>– inhalative: LC50 >0.152 mg/L (IHT; Analogy CAS 124-07-2);<br>– dermal: LD50 >2000 mg/kg bw (Analogy CAS 57-11-4);<br><br>Irritation / corrosion:<br>– skin: not irritating (OECD 404, human data; Analogy CAS 67001-08-0);<br>– eyes: irreversible effects (OECD 405; Analogy CAS 143-07-7, CAS 67001-08-0);<br><br>Reliable studies on oral repeated dose toxicity are available for the following category members: Subchronic: NOAEL oral = ca. 5000 mg/kg bw/d; CAS# 143-07-7, C12 (Fitzhugh 1960)<br><br>Subchronic: NOAEL oral = 1000 mg/kg bw/d; CAS# 112-85-6, C22 (Nagao 2002)<br><br>No data are available for repeated dose toxicity after dermal exposure and inhalation, respectively.<br><br>Considered safe as a cosmetic ingredient:<br><br>(https://www.cir-safety.org/sites/default/files/Helianthus%20annuus.pdf)<br><br>Sunflower oil is the second most used edible oil – there are no toxicological concerns and no toxicological significance. | >100 |

| | | |
|---|---|---|
| | Sunflower oil is not know to be a dermal irritant, an ocular irritant, a skin or ocular sensitiser and it is not a know phototoxic ingredient. | |

| | | |
|---|---|---|
| MANGIFERA INDICA SEED BUTTER | READ ACROSS - COCOA (SIMILAR FATTY ACID PROFILE)<br><br>A non-guideline study has been carried out to assess the behavioural effects of acute oral treatment with cocoa powder on male mice.<br><br>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.<br><br>Ambulation was assessed for 3 hours after treatment using a tilting-type ambulometer.<br><br>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.<br><br>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.<br><br>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.<br><br>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.<br>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.<br><br>In accordance with the results obtained from the key and supporting studies, cocoa powder is not classified according to CLP i.e. NOEL (or<br><br>derived/adjusted LOEL) dose/concentration exceeds the guidance value ranges of 10 < C ≤ 100 mg/kg/bw/day, (Regulation (EC) No 1272/2008).<br><br>Considered safe as a cosmetic ingredient:<br>(https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569)<br><br>No toxicological significance.<br><br>Similar plant-derived fatty acid oils are not known to be photosensitising, phototoxic, dermal or ocular irritants or sensitisers. | >100 |
| TOCOPHEROL | MOLECULAR FORMULA: N/A<br>CHEMICAL (IUPAC) NAME: N/A<br><br>CAS#: 54-28-4 (gamma)/ 16698-35-4(beta) / 10191-41-0(DL) / 119-13-1 / 1406-18-4 / 1406-66-2 / 2074-53-5 (DL) / 59-02-9 (D)/7616-22-0<br><br>EC#: 200-201-5 / 240-747-1 / 233-466-0 / 204-299-0 /215-798-8 / - / 218-197-9 / 200-412-2 / -<br><br>FUNCTION: Antioxidant<br><br>Considered safe as a cosmetic ingredient:<br>(https://journals.sagepub.com/doi/full/10.1177/1091581818794455) | >100 |

| | | |
|---|---|---|
| | NOAEL (repeat-dose, rat study) = 642mg/kg (Food Chem Toxicol. 2006;44(7):916–932).<br><br>Not know to be a dermal or ocular irritant or sensitiser. Not phototoxic. Not known to be genotoxic, no know reproductive toxicity and not mutagenic. | |

**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 – *BODY BUTTER*

**RESPONSIBLE PERSON DETAILS:**

**MELOVIBES LTD**

**Melovibes Ltd**

2, Eagle Road, Eglwys Brewis, Barry. Vale of Glamorgan. CF62 4NR

## I. ASSESSMENT CONCLUSIONS

Each of the products assessed by this report (specified in Part A) have been deemed safe for the prescribed use (**as a body butter**). 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.

## J. 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.

**VARIANT 1 ALLERGENS:** N/A

**VARIANT 2 ALLERGENS:** N/A

## K. REASONING

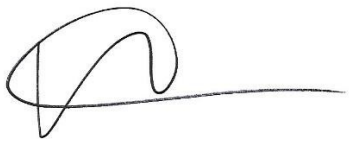
All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

- 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.

## L. ASSESSORS CREDENTIALS AND APPROVAL OF PART B

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



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

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

DATE: 17/10/2023

## 3. Method of manufacture

Mixing machine. Hand blended and poured.

## 4. Evidence of compliance with Good Manufacturing Practices (GMP)

All ingredients are sourced from reputable UK suppliers with relevant MSDS and lab reports.

Best practice is followed in terms of hygiene, storage, and working environment.

## 5. Proof of the effect claimed

No claims made.

## 6. Data on Animal Testing

No testing on animals

## 7. Responsibility/Traceability

**Responsible person**

Melovibes Ltd

### Manufacturer

Melovibes Ltd

### Person responsible for packaging

Melovibes Ltd

## Technical assessor

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

## 8. Labeling

Compliant with EU guidelines.

Warnings: For external use only. Avoid contact with eyes. Keep out of the reach of children. Do not store in direct sunlight.

## 9. Data on serious undesirable effects

None declared at the time of preparation of this document.

## APPENDIX

**1) Handling and Storage**
No special handling techniques required.
Keep out of reach of children. Store in a cool dry place. Keep from extreme heat, cold & sunlight.

**2) Exposure controls and personal protection**
No special personal protective equipment required.

**3) Stability & Reactivity**
The product is stable non-reactive. Avoid strong oxidising agents.

**4) Toxicological Information**
No acute or chronic toxic effects when used as directed.

**5) Ecological information**
No ecological hazards are associated with this product. It is biodegradable.

**6) Disposal considerations**
Dispose of product according to local and national regulations.

**7) Transport information**
Non Hazardous / Non-flammable. No shipping restrictions

**8) Declaration of Allergens**
The customer should satisfy themselves that the product is suitable for the intended purpose, and that a suitable and sufficient assessment of any risks created by any activity using this product is undertaken before use. This information is based upon our knowledge of the product at the time of publication. The data is given in good faith and should be viewed as guidance only. This product sheet cannot cover all possible situations which the user may experience. We do not assume any responsibility and expressly disclaim any liability for any use of this product.

**9) Other Information**

This PIF Summary does not constitute a legal document. Customers who retail Melovibes products under their own label are responsible for ensuring that their packaging and labels are compliant with the relevant legislation in the jurisdiction of sale.
Any customers who modify or add to our standard products are responsible for ensuring their product complies with legislation requirements in their jurisdiction of sale and Melovibes Ltd accept no liability. Any product marketed under private label must be registered with the OPSS and have a responsible person and registered address assigned to the brand that the product is being traded under.
To the best of our knowledge, the information contained in this document is correct.