



## Product Information File (PIF) Summary

### 1) Product Description

#### Product name

Melovibes Fractionated Coconut Oil with 600mg CBD

#### Product Volume

30ml

#### Intended use of the product

Composition type:	Oil
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)
Fractionated Coconut Oil	Caprylic/Capric Triglyceride	Emollient, skin conditioning agents, viscosity increasing agent	98
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.

## **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.

[Redacted]		
INGREDIENT NAME	INCI NAME	CONC. BAND
CBD	CANNABIDIOL	A

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

[Redacted] VARIANT		
INGREDIENT NAME	INCI NAME	CONC. BAND
COCONUT OIL	CAPRYLIC/CAPRIC TRIGLYCERIDE	A
CBD	CANNABIDIOL	F

[Redacted] VARIANT		
INGREDIENT NAME	INCI NAME	CONC. BAND
JOJOBA OIL	SIMMONDSIA CHINENSIS SEED OIL	A
CBD	CANNABIDIOL	F

[Redacted]



VARIANT

INGREDIENT NAME	INCI NAME	CONC. BAND
ROSEHIP OIL	ROSA CANINA FRUIT OIL	A
CBD	CANNABIDIOL	F



VARIANT

INGREDIENT NAME	INCI NAME	CONC. BAND
SWEET ALMOND OIL	PRUNUS AMYGDALUS DULCIS OIL	A
CBD	CANNABIDIOL	F



VARIANT

INGREDIENT NAME	INCI NAME	CONC. BAND
ARGAN OIL	ARGANIA SPINOSA KERNEL OIL	A
CBD	CANNABIDIOL	F

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

### **PHYSICAL AND CHEMICAL PROPERTIES:**

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

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

The exact pH of the product 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 x10 <sup>2</sup> CFU per g or ml	≤ 1 x10 <sup>3</sup> CFU per g or ml
<i>Escherichia coli</i>	Absence in lg or lml	Absence in lg or lml
<i>Pseudomonas aeruginosa</i>	Absence in lg or lml	Absence in lg or lml
<i>Staphylococcus aureus</i>	Absence in lg or lml	Absence in lg or lml
<i>Candida albicans</i>	Absence in lg or lml	Absence in lg or lml

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 oil. 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. 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 12<sup>th</sup> 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. Direct contact with the eye is not considered reasonable use.

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

EXPOSURE OF PRODUCT; BODY				
PRODUCT AMOUNT PER APPLICATION <sup>1</sup> (G)	POTENTIAL FREQUENCY OF USE <sup>1</sup> (PER DAY)	MAXIMUM DAILY PRODUCT USE (G)	RETENTION FACTOR <sup>2</sup>	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 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 because of the normal, prescribed use of this product.

Any use other than the prescribed use described in Section 4 & 5 of this report is considered misuse and is outside the scope of this assessment – any undesirable or serious undesirable effects as a result of this misuse is not considered.

## 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):

$$\frac{NOAEL}{D}$$

$$\frac{NOAEL}{D} > 100$$

$$\frac{NOAEL}{D} < 100$$

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
INCI NAME	TOXICOLOGICAL PROFILE

<p>ARGANIA SPINOSA KERNEL OIL</p>	<p>MOLECULAR          FORMULA: N/A          CHEMICAL (IUPAC)          NAME: N/A CAS#: 223747-87-3 ; 299184-75-1          EC#: N/A</p> <p style="text-align: center;">FUNCTION: Skin conditioning, Emollient</p> <p style="text-align: center;">Considered safe as a cosmetic ingredient:  <a href="https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569">https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569</a></p> <p style="text-align: center;">NOAEL (CIR) = &gt;5000mg/kg</p>
<p>CANNABIDIOL</p>	<p>Molecular          Formula  <math>C_{21}H_{30}O_2</math>          Molecular          Weight 314.5</p> <p>CBD has a chemical formula of <math>C_{21}H_{30}O_2</math> and a molecular weight of 314.469 g/mol.</p> <p>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 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.</p> <p>The safety of cosmetic products in the UK is regulated by the EU Cosmetics Regulation 1223/2009 (“the Regulation”) as adopted into UK law. 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.</p> <p>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.</p> <p style="text-align: center;">CBD is not controlled under the Misuse of Drugs Act of 1971.</p> <p>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.</p> <p style="text-align: center;">Mouse study</p> <p style="text-align: center;">GWTX1503, 13 week oral toxicity Mean alanine amino transaminase/alanine aminotransferase (ALT) levels were higher than controls</p>

during Week 7 and 13 in males given  $\geq 150$  mg/kg/day (by approximately 65% and 40%, respectively) and during Week 7 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  $\geq 150$  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 (C<sub>max</sub>) and area under the concentration-time curve calculated to the last observable concentration at time t (AUC(0-t)) values of 9810 ng/mL

and 44300 ng h/mL in males and 5770 ng/mL and 46400 ng h/mL in females.

#### 39-Week Oral

(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,

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 imbalance observed in the studies these effects need to be further substantiated via post-authorisation measure.

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  $\geq 50$  mg/kg/day Doses  $\geq 50$  mg/kg/day

152 No adverse effects were apparent in rats treated with 50 mg/kg bw/day CBD. This would result in a potential HGBV of  $50/10 \times 10 = 0.5$  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.

CONSIDERED SAFE FOR USE (FDA, FSA, SCCS)

[https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2018/210365Orig1s000PharmR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000PharmR.pdf)

CAPRYLIC/CAPRIC TRIGLYCERIDE

MOLECULAR FORMULA: C<sub>24</sub>H<sub>48</sub>O<sub>8</sub>

CHEMICAL (IUPAC) NAME: Decanoic acid, ester with 1,2,3-propanetriol octanoate; Glycerides, mixed decanoyl and octanoyl CAS#: 73398-61-5/ 65381-09-1

EC#: 277-452-2/ 265-724-3

FUNCTION: Emollient, Skin conditioning, Solvent

Considered safe as a cosmetic ingredient:

[https://www.cir-safety.org/sites/default/files/triglycerides\\_0.pdf](https://www.cir-safety.org/sites/default/files/triglycerides_0.pdf)

MW: 387.53076

>100

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	<p>n s i t y : 0 . 9 4 - 0 . 9 6</p> <p>L D 5 0 : 3 3 3 0 0 m g / k g</p>	
	<p>NOAEL (human, repeat-dose, Food Chem Toxicol. 2006;44(9):1530-1538.) = 42000mg/kg</p> <p>Oral/Parenteral Toxicity: Not determined Dermal Toxicity: Not determined Inhalation Toxicity: Not determined</p>	
<p>PRUNUS AMYGDALUS DULCIS OIL</p>	<p>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: &gt;= 5 000 mg/kg bw</p> <p>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</p>	<p>&gt;100</p>

	<p>on the experimental area, have been included in the study. Single application of 25µL of the test item, on the scapular part of the back, maintained for 48 h in contact with the skin, with the help of an occlusive patch (Finn Chambers).</p> <p>11 volunteers have been included and were analyzed. The average irritation index is 0.</p> <p>Under the conditions employed in this study, test item was considered as non-irritant.</p> <p>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.</p> <p>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.</p> <p>No reaction ++ nor +++ was observed, so the product can be considered as non-sensitizing.</p> <p>Under these study conditions, the product can be considered non-irritating and non-sensitizing</p> <p>Considered safe as a cosmetic ingredient: (<a href="https://doi.org/10.1177/1091581817740569">https://doi.org/10.1177/1091581817740569</a>)</p> <p>Similar plant-derived fatty acid oils are not known to be photosensitising, phototoxic, dermal or ocular irritants or sensitisers (MCII &lt;0.25).</p> <p>LD50 = &gt;5000mg/kg (ECHA, unnamed study report, 2014)</p> <p>Prunus amygdalus dulcis oil was not found to be genotoxic (ECHA, unnamed study report, 2014, OECD 471).</p> <p>Considered a non-toxic ingredient - no repeat-dose toxicity data available</p>	
ROSA CANINA FRUIT OIL	<p>MOLECULAR FORMULA: N/A</p> <p>CHEMICAL (IUPAC) NAME: Rosa Canina Fruit Oil is an oil from the Hip Rose, Rosa canina L., Rosaceae. CAS#: 84696-47-9</p> <p>EC#: 283-652-0</p> <p>FUNCTION: Astringent, Skin conditioning</p> <p>Considered safe as a cosmetic ingredient: (<a href="https://www.cir-safety.org/sites/default/files/rosaca042017FR.pdf">https://www.cir-safety.org/sites/default/files/rosaca042017FR.pdf</a>) Not known as a skin or ocular irritant or sensitiser.</p> <p>Not know to be CMR.</p> <p>NOAEL (30 day guinea pig study, CIR, Biosci.Biotechnol Biochem. 2011;75(3):489-495.) = 500mg/kg</p>	>100

SIMMONDSIA CHINENSIS SEED OIL	<p data-bbox="1252 124 1529 145">MOLECULAR FORMULA: N/A</p> <p data-bbox="819 164 1245 209">CHEMICAL (IUPAC) NAME: Simmondsia Chinensis (Jojoba) Seed Oil CAS#: 90045-98-0</p> <p data-bbox="1319 228 1462 248">EC#: 289-964-3</p> <p data-bbox="1214 268 1568 288">FUNCTION: Emollient, Skin conditioning</p> <p data-bbox="795 328 1041 421">Considered safe as a cosmetic ingredient: (<a href="https://doi.org/10.3109%2F10915819209141992">https://doi.org/10.3109%2F10915819209141992</a>)</p> <p data-bbox="1205 456 1581 477">Read across data for Palmitic Acid (C16):</p> <p data-bbox="824 493 1406 537">NOAEL: &gt;5000mg/kg/day (150 day oral study in rats <a href="https://echa.europa.edu/">https://echa.europa.edu/</a>) Read across data for Oleic Acid (C18:1):</p> <p data-bbox="833 553 1951 574">NOAEL: &gt;4,500mg/kg/day (16-week oral study in rabbits (<a href="https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2012.EN-274">https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2012.EN-274</a>))</p>	>100
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**There are no substances contained within the formulation considered to be acutely toxic (either via dermal and/or oral exposure). There are no known dermal or ocular irritants or sensitizers. 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 OIL*

### RESPONSIBLE PERSON DETAILS:

**MELOVIBES LTD**

2, Eagle Road, St Athan. CF62 4NR

### 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 body oil**). 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. The manufacturer is responsible for ensuring the correct allergens are included on the product label – below is some guidance based on the information available at the time this report was prepared. This information must be checked by the manufacturer to ensure it is accurate at the time the product is manufactured.

*There are no declarable allergens in the product(s).*

## 11) REASONING

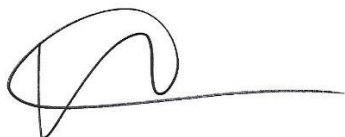
All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

- 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.**

A handwritten signature in black ink, consisting of a large, stylized initial 'D' followed by a horizontal line extending to the right.

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: 08/11/2023

### **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.