Product Information File (PIF) Summary

1. Product Description

Product name

Melovibes Moisturising Cream with 1000mg CBD

Volume

50ml

Intended use of the product

Composition type:	Light Cream
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)
DISTILLED WATER	AQUA	Moisturiser	**77.31**
JOJOBA OIL	SIMMONDSIA CHINENSIS SEED OIL	Emollient / Moisturiser	**7.98**
EMULSIFYING WAX	CETEARYL ALCOHOL, CETEARETH-20	Emulsifier	**4.99**
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	Emollient / Moisturiser	**2.99**
GLYCERIN	GLYCERIN	Emollient / Moisturiser	**2.00**
CBD	CANNABIDIOL	Anti-inflammatory	**2.00**
PRESERVATIVE ECO	BENZYL ALCOHOL, SALICYLIC ACID, GLYCERIN, SORBIC ACID	Preservative	**1.00**
VITAMIN E	TOCOPHEROL, HELIANTHUS ANNUUS SEED OIL	Nutrients	**1.00**
COLLOIDAL OATMEAL	AVENA SATIVA KERNEL FLOUR	Anti-inflammatory	**0.50**
PANTHENOL	PANTHENOL	Preservative / Nutrients	**0.25**

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)

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

	FORMULATI

INGREDIENT NAME	INCI NAME	CONC. BAND
DISTILLED WATER	AQUA	B
JOJOBA OIL	SIMMONDSIA CHINENSIS SEED OIL	E
EMULSIFYING WAX	CETEARYL ALCOHOL, CETEARETH-20	F
MANGO BUTTER	MANGIFERA INDICA SEED BUTTER	F
GLYCERIN	GLYCERIN	F
CBD	CANNABIDIOL	F
PRESERVATIVE ECO	BENZYL ALCOHOL, SALICYLIC ACID, GLYCERIN, SORBIC ACID	G
VITAMIN E	TOCOPHEROL, HELIANTHUS ANNUUS SEED OIL	G
COLLOIDAL OATMEAL	AVENA SATIVA KERNEL FLOUR	G
PANTHENOL	PANTHENOL	G

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

PHYSICAL AND CHEMICAL PROPERTIES:

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

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

The exact pH of the product 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.

3) MICROBIOLOGICAL QUALITY OF THE PRODUCT(S).

The product(s) manufacturer is responsible for ensuring the product meets the microbiological quality standards as outlined in ISO 11930. The manufacturer must ensure the risk to the end-user is deemed to be tolerable by calculation of microbiological quality as laid down in ISO 11930 2013-5-1.

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.

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

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

It is a leave on product.

It is intended to be used by the general population.

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

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

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

5) PRODUCT AND SUBSTANCE EXPOSURE INFORMATION.

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

AREAS OF SPECIFIC EXPOSURE

Inhalation – not relevant for this type of product.

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

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):

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.

	TOXICOLOGICA INGRED
INCI NAME	**TOXICOLOGICAL PROFILE**
AQUA	MOLECULAR FORMULA: H2O CHEMICAL (IUPAC) NAME: Water CAS#: 7732-18-5 EC#: 231-791-2 FUNCTION: Solvent No toxicological significance.

AVENA SATIVA KERNEL FLOUR	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: N/A CAS#: 84012-26-0 EC#: 281-672-4 FUNCTION: Bulking, Soothing No toxicological significance – oat is a widely used food product. Considered safe as a cosmetic ingredient: (https://doi.org/10.1177%2F109158181989890 4)
BENZYL ALCOHOL	Single oral application of gavage doses to rats and observation for 14 days: LD50 = 1620 mg/kg bw (Bayer AG 1978); no indications of toxicity were observed at the lowest dose of 1045 mg/kg bw . Exposure of rats according to OECD TG 403 to single 4-hour aerosol concentrations up to 4178 mg/m³ air (maximum technically achievable conc., Bayer 1990) or at the limit dose of 5400 mg/m³ (Elf Atochem SA, 1993) and observation for 14 days: LC50 > 4178 mg/m³; no mortalities were observed and only minor symptoms. In a study for skin irritation/corrosion with rabbits according to OECD TG 404 benzyl alcohol was evaluated as not irritating to the skin (Bayer AG 1990). Based on the results of two eye irritation studies according to OECD TG 405 it was concluded that benzyl alcohol has an irritant potential to the eye (Bayer 1990, Elf Atochem 1998). Based on acute and repeated inhalation studies (OECD TG 403 and 412, respectively) no potential for respiratory irritation was concluded. In a 13 week dose-finding study male and female rats received daily up to 800 mg/kg bw benzyl alcohol. The NOAEL was considered to be 400 mg/kg bw/daybased on signs of neurotoxicity, reduced body weight development and histopathological effects mainly in the brain at next higher dose (800 mg/kg bw/day)(NTP 1989). This NOAEL was confirmed in a 2 year study (carcinogenicity study). In a 13 week dose-finding study male and female mice received daily up to 800 mg/kg bw benzyl alcohol. The NOEL was considered to be 200 mg/kg bw/day. At 400 mg/kg a slight decreased body weight gain was reported and at 800 mg/kg additionally staggering after dosing during the first and second weeks of the studies was observed. No compound-related histopathological effects were found in the mice study, indicating adaptive response to the compound and no adverse effect at 400 or 800 mg/kg. This NOEL was confirmed in a 2 year study (carcinogenicity study). In a subacute inhalation toxicity study according to OECD TG 412, male and female rats were exposed nose-only to benzyl alcohol at mean analytical exposure concentrations up to 1072 mg/m³ air for 6 hour/day, 5 day/week for 4 weeks. The NOAEL was concluded to be 1072 mg/m³ based based on the fact that the exposure was tolerated without adverse effects up to and including this test substance concentration (Roper 2010).
CANNABIDIOL	Molecular Formula C21H30O2 Molecular Weight 314.5

CBD has a chemical formula of C2lH30O2 and a molecular weight of 314.469 g/mol.

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 (lCAM-l) and tissue inhibitor of matrix metalloproteinases-l (TlMPl) 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.

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.

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.

CBD is not controlled under the Misuse of Drugs Act of 1971.

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.

Mouse study

GWTXl503, l3 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

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

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 (GWTXl413) 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 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.

	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 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. CONSIDERED SAFE FOR USE (FDA, FSA, SCCS) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000PharmR.pdf	
CETEARETH-20	Considered safe as a cosmetic ingredient: https://www.cir-safety.org/sites/default/files/alkyle032013rep.pdf NOAEL (read-across, ethylhexyl laurate) = 1000mg/kg	>100

CETEARYL ALCOHOL	Molecular formula: C16 H34 O IUPAC Name: Alcohols, C16-18 Considered safe as a cosmetic ingredient: https://www.cir-safety.org/sites/default/files/alkyle032013rep.pdf −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. -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 -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 -The acute eye irritation study (Carter, G., Dharmarajan, V., and Weill, H. .1975) indicates that Alcohols, C16-18 was not irritating. 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. −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. Result: non-irritant to skin	>100

	- Respiratory irritation 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. Oral repeated dose toxicity 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. 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. Dermal repeated dose toxicity 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. 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. Inhalation repeated dose toxicity 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/m³ . (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. 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	
GLYCERIN	MOLECULAR FORMULA: C3H8O3 CHEMICAL (IUPAC) NAME: propane-1,2,3-triol (Glycerin / Glycerol) CAS#: 56-81-5 EC#: 200-289-5 FUNCTION: Humectant, Skin Conditioning, Skin controlling (reaction product of NaOH & Fatty acids) Glycerin (Glycerol) is a polyol (polyhydric alcohol) that functions as a humectant, crystallization modifier, and plasticizer. it is a bit- tersweet liquid which has a high solubility of 71 g/100 g of water at 25°c. it is 75% as sweet as sugar. it is a fair oil solvent and has a medium to high hygroscopicity. it is used to maintain a certain moisture content to prevent the drying-out of foods; at 10—15% in raisins, it keeps them from drying out and prevents their moisture from migrating into cereal. it is used in confections to maintain the initial level of crystallization of the soft sugar. in reduced-fat frozen desserts, it helps prevent ice crystal formation. it also functions as a flavor solvent. applications include marshmallows, candy, and baked goods. CAS Number: 56-81-5 Molecular formula: C3H8O3 The acute oral LD50 was determined in three species, rat, mice and guinea pigs. In all three species the oral LD50 was >/= 11,500 mg/kg. The acute dermal toxicity of glycerin was examined in guinea pigs. The dermal LD50 was determined to be 45 ml/kg (56,750 mg/kg) in guinea pigs. In an inhalation study, rats were exposed to aerosol from test material at targeted concentrations of 1.0, 2.0, or 4.0 mg glycerol/L for 6 hours. The 4 h inhalation LC50 was determined to be above 5.85 mg/L in rats.	>100

A round-robin testing program was conducted in 14 laboratories. The dermal irritation potential was examined.

Glycerin was considered to be non irritating to the skin in rabbit irritation studies in 14 testing laboratories. In another study with rabbits, glycerin was considered to be non-irritating also.

Glycerol was applied to the skin of 33 humans for 24 hours on a semi-occluded patch and the response to the test material was observed. Under the conditions of the study, Glycerine USP (25% concentration) exhibited no clinical irritation when tested in humans.

not sensitising, OECD 429: S.I. of 1.1, 0.7 and 0.5 at 25%, 50% and 100% v/v not

sensitising based on human data

In the best available dietary study, groups of 22 rats (Long-Evans)/sex/treatment received 5, 10 and 20% glycerol (natural or synthetic) in their diet (males 2000, 4000 and 8000 mg/kg bw; females 2500, 5000 and 10000 mg/kg bw) for 2 years. Although the results were not described in detail, based on this limited dietary study it can be concluded that no adverse effects were observed at up to 10,000 mg/kg bw.

The effect of glycerine following administration for 90 days in a subchronic toxicity study was examined. Rats fed 5 or 20% glycerine in the diet for 90 days gained weight at a faster rate than control animals. There were no adverse treatment related effects noted in male or female rats fed 5% glycerine in the diet. In the male rats which received 20 percent glycerine, there was an increase in the final liver/body weight ratio and upon microscopic examination generalized cloudy swelling and hypertrophy of the parenchymal cells was observed. The only effect in the female rats on this level was some generalized cloudy selling upon microscopic examination of the liver. A 5% glycerol in the diet corresponded to 4580 and 6450 mg/kg/day for male and female rats, respectively, after 4 weeks and a 20% glycerol in the diet corresponded to 18,750 and 25,800 mg/kg/day for male and female rats, respectively, after 4 weeks.

A number of other studies have been incorporated in the dossier. These studies are considered less reliable indicators of the systemic effects of glycerol following repeated administration, mainly because of limited toxicity assessments and/or deficient experimental design. The effects they do report are consistent with those observed in the key studies and as such they may contribute to the overall assessment of toxicity of glycerol.

The acute oral LD50 was determined in three species, rat, mice and guinea pigs. In all three species the oral LD50 was >/= 11,500 mg/kg.

The acute dermal toxicity of glycerin was examined in guinea pigs.

The dermal LD50 was determined to be 45 ml/kg (56,750 mg/kg) in guinea pigs.

In an inhalation study, rats were exposed to aerosol from test material at targeted concentrations of 1.0, 2.0, or 4.0 mg glycerol/L for 6 hours. The 4 h inhalation LC50 was determined to be above 5.85 mg/L in rats.

A round-robin testing program was conducted in 14 laboratories. The dermal irritation potential was examined.

Glycerin was considered to be non irritating to the skin in rabbit irritation studies in 14 testing laboratories. In another study with rabbits, glycerin was considered to be non-irritating also.

Glycerol was applied to the skin of 33 humans for 24 hours on a semi-occluded patch and the response to the test material was observed. Under the conditions of the study, Glycerine USP (25% concentration) exhibited no clinical irritation when tested in humans.

	not sensitising, OECD 429: S.I. of 1.1, 0.7 and 0.5 at 25%, 50% and 100% v/v not sensitising based on human data A number of other studies have been incorporated in the dossier. These studies are considered less reliable indicators of the systemic effects of glycerol following repeated administration, mainly because of limited toxicity assessments and/or deficient experimental design. The effects they do report are consistent with those observed in the key studies and as such they may contribute to the overall assessment of toxicity of glycerol.	
HELIANTHUS ANNUUS SEED OIL	EC Number: 273-195-5 EC Name: Fatty acids, sunflower-oil, conjugated CAS Number: 68953-27-5 Molecular formula: not applicable for UVCB substance IUPAC Name: Fatty acids, sunflower-oil, conjugated Acute Toxicity: **1)** oral: LD50 >2000 mg/kg bw (OECD 401; Analogy CAS 112-80-1); **2)** inhalative: LC50 >0.152l mg/L (IHT; Analogy CAS 124-07-2); **3)** dermal: LD50 >2000 mg/kg bw (Analogy CAS 57-11-4); Irritation / corrosion: **4)** skin: not irritating (OECD 404, human data; Analogy CAS 67001-08-0); **5)** eyes: irreversible effects (OECD 405; Analogy CAS 143-07-7, CAS 67001-08-0); 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) Subchronic: NOAEL oral = 1000 mg/kg bw/d; CAS# 112-85-6, C22 (Nagao 2002) No data are available for repeated dose toxicity after dermal exposure and inhalation, respectively. Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/sites/default/files/Helianthus%20annuus.pdf) Sunflower oil is the second most used edible oil – there are no toxicological concerns and no toxicological significance. 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.	>100

MANGIFERA INDICA SEED BUTTER	READ ACROSS - COCOA (SIMILAR FATTY ACID PROFILE) A non-guideline study has been carried out to assess the behavioural effects of acute oral treatment with cocoa powder on male mice. In an ambulation study, drug-naïve dd mice were given saline, or cocoa powder by stomach tube at 100, 300, 1000 or 3000 mg/kg bw [it is not clear whether 10-20 mice were tested in total, or whether there were 10-20 per concentration]. Saline was administered to 10-20 control animals. Ambulation was assessed for 3 hours after treatment using a tilting-type ambulometer. Lever-press and shuttle avoidance experiments were conducted on 9 or 10 trained ddY mice, respectively. Mice were treated with 0 (saline), 100, 300 or 1000 mg/kg bw by stomach tube. [It appears that the same mice were treated with each concentration.] Apparently the same mice were later tested with the cocoa components theobromine (at 3-300 mg/kg bw) and caffeine (at 1-100 mg/kg bw). Each "drug testing session" was separated by an	>100
	interval of 3-4 days. [It is not clear whether these "drug testing sessions" comprised all testing with one substance, or each test with an individual concentration.] The minimum observation period after testing with cocoa was therefore 6 days. In each experiment, mortality and clinical observations are not described. Presumably, however, mortality and other overt effects would have been reported, if seen. No significant, dose-related behavioural effects were reported following treatment with cocoa powder. As no deaths were reported, presumably the acute oral LD50 exceeds 3000 mg/kg bw in male mice (3 hr observation period). In the experiment using a more reliable observation time of 6 days, the LD50 presumably exceeds 1000 mg/kg bw. While these values are not sufficient to formally conclude on classification for acute oral toxicity, the LD50 for Cocoa powder probably exceeds 2000mg/Kg bw. On this basis cocoa would not require classification for acute toxicity under current EU guidelines. In the studies documented in CSR, the dietary level(s) of cocoa tested represent amounts far exceeding cocoa consumption by humans. A recent approximation of cocoa powder consumption in 2011 (using cocoa production data from 2011 and EU27 population statistics) approximates European cocoa powder consumption to be 18.5 mg/kg bw day. The above information, as well as the knowledge that a vast majority of the population (including children) regularly consume large quantities of cocoa containing products, clearly indicates that there is no concern regarding the repeated oral toxicity of cocoa. In accordance with the results obtained from the key and supporting studies, cocoa powder is not classified according to CLP i.e. NOEL (or derived/adjusted LOEL) dose/concentration exceeds the guidance value ranges of 10 < C ≤ 100 mg/kg/bw/day, (Regulation (EC) No 1272/2008). Considered safe as a cosmetic ingredient: (https://journals.sagepub.com/doi/pdf/10.1177/1091581817740569) No toxicological significance. Similar plant-derived fatty acid oils are not known to be photosensitising, phototoxic, dermal or ocular irritants or sensitisers.	

PANTHENOL	EC Number: 240-540-6 EC Name: Panthenol , DL-form CAS Number: 16485-10-2 Molecular formula: C9H19NO4 IUPAC Name: 2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide For DL-Panthenol, no acute toxicity studies for oral and dermal toxicity were performed. A read across approach was performed with the structural similar substance DL-Ethyl Panthenol. DL-Ethyl Panthenol showed an acute oral LD50 greater than 2000 mg/KG bw in the rat. The dermal LD50 for DL- Ethyl Panthenol was found to be greater than 2000 mg/kg bw in the rat. Performance of an inhalation toxicity study was waived, as exposure via inhalation is not considered relevant, due to unlikely exposure via inhalation. Skin irritation was derived from read across approach with the supporting substances DL-Ethylpanthenol and D-Panthenol. None of these two substances showed skin irritation when applied to the rabbit skin. Eye Irritation was derived from read across approach with the supporting substances DL-Ethylpanthenol and D-Panthenol. None of these two substances showed eye irritation when applied to the rabbit eye. In the key GLP and guideline study, DL-Panthenol was tested for skin sensitization in the Buehler test according to OECD guideline 406/EU method B.6. In the test group of 20 Pirbright White Dunkin Hartley guinea pigs, the test substance was applied undiluted in the induction and challenge application. A control group of 10 animals was used. Based on the results of this study and applying the evaluation criteria it was concluded that DL-Panthenol does	>100

not have a sensitizing effect on the skin of the guinea pig in the BUEHLER Test under the test conditions chosen.Based on the results of this study and applying the evaluation criteria it was concluded that DL-Panthenol does not have a sensitizing effect on the skin of the guinea pig in the BUEHLER Test under the test conditions chosen.

A read across approach was performed with the supporting substance DL-Ethylpanthenol. For justification of read across please refer to the attachment in IUCLID5 section 13.

In a supporting GLP and guideline study, the skin sensitizating properties of DL-Ethylpanthenol were evaluated in a Maximization test with guinea pigs according to OECD guideline 406/EU method B.6. A test group of 10 albino guinea pigs and a control group of 5 animals were investigated for signs of skin hypersensitivity after intradermal and epidermal exposure. Under the conditions used in this study, exposure of DL-Ethylpanthenol induced no sensitisation.

Migrated from Short description of key information:

DL-Panthenol was tested for its sensitizing effect on the skin of the guinea pig in the BUEHLER Test. It was concluded that DL-Panthenol does not have a sensitizing effect on the skin of the guinea pig in the BUEHLER Test under the test conditions chosen. A read across approach was performed in addition with the supporting substance DL-Ethylpanthenol. DL-Ethylpanthenol showed no sensitization in a maximization test with guinea pigs.

A read across approach was performed with the supporting substance DL-Ethyl Panthenol. In a 90 day subchronic GLP and guideline study in rats, the test item showed a NOAEL of 1000 mg/kg bw/day. In addition oral exposure of rats for 28 days resulted in a NOAEL of 1000 mg/kg bw/day. In a supporting subchronic oral toxicity study with DL- Panthenol the voluntary consumption of the test item by male and female rats in drinking water in the concentrations of 200, 50 and 20 mg/kg bw/day for a 90 day period showed essentially negative results. The no observed adverse effect level (NOAEL) under the conditions of this study was considered to be 200 mg/kg bw/day. In conclusion no adverse effects releated on DL-Panthenol could be observed after oral exposure for 90 days.

Developmental toxicity (read across):

The objective of the study was to determine the potential of DL-Ethyl Panthenol to induce developmental toxicity after maternal exposure from implantation to 1 day prior to expected parturition, to characterize maternal toxicity at the exposure levels tested and to determine a no-observed- adverse-effect level (NOAEL) for maternal and developmental toxicity. The study was conducted in compliance with GLP regulations and in accordance with regulatory guidelines, including OECD 414.

The test item, DL- Ethyl Panthenol, in the vehicle (deionized water), was administered orally by gavage to 3 groups of 25 bred female Crl:CD(SD) rats once daily from gestation days 6 through 19. Dosage levels were 250, 500, and 1000 mg/kg/day administered at a dosage volume of 10 mL/kg.

Dosages were selected following a range-finding study in which systemic exposure was demonstrated in the pregnant rat. A concurrent control group composed of 25 bred females received the vehicle on a comparable regimen. The females were approximately 14 weeks of age at the initiation of dose administration. All animals were observed twice daily for mortality and moribundity. Clinical observations, body weights, and food consumption were recorded at appropriate intervals. On gestation day 20, a laparohysterectomy was performed on each female. The uteri, placentae, and ovaries were examined, and the numbers of fetuses, early and late resorptions, total implantations, and corpora lutea were recorded. Gravid uterine weights were recorded, and net body weights and net body weight changes were calculated. The fetuses were weighed, sexed, and examined for external, visceral, and skeletal malformations and developmental variations.

The analyzed dosing formulations were within the requested limits (85% to 115%), homogeneous, and stable after 10 days of refrigerated storage. All females survived to the scheduled necropsy on gestation day 20. There were no test article-related clinical observations noted at any dosage level.

	Additionally, there were no test article-related maternal macroscopic findings noted at the scheduled necropsy. There were no test article-related effects on body weights, body weight gains, net body weights, net body weight gains, or food consumption at any dosage level tested. Based on the parameters evaluated, including postimplantation loss, litter size, mean fetal body weights, and fetal sex ratios, intrauterine growth and survival were unaffected by test article administration at all dosage levels tested. There were no test article-related external, visceral, or skeletal malformations or developmental variations observed at any dosage level tested. There were no test article-related clinical findings or effects on maternal body weight, body weight gains, or food consumption observed at any dosage level. In addition, there were no test article-related effects on embryo/fetal development at any dosage level. Based on the results of this study, a dosage level of 1000 mg/kg/day, the highest dosage level evaluated, was considered to be the no-observed-adverse-effect level (NOAEL) for maternal toxicity and embryo/fetal development when DL- Ethyl Panthenol was administered orally by gavage to bred Crl:CD(SD) rats. Based on these data it can be concluded that animals fed with DL-Ethyl Panthenol are concurrently exposed to Panthenol. Due to structure similarity and the absence of any effect in the developmental toxicity study with DL-Ethyl Panthenol in rats up to the highest tested dose of 1,000 mg/kg bw/d, it is highly likely that DL- Panthenol shows any developmental toxicity.	
SALICYLIC ACID	Physical state at 20°C and 1013 hPa: solid Melting point is considered to be in the range 157-160 deg C by weight of evidence. Boiling point at 101 325 Pa: 256 °C For acute oral toxicity, a study report (Bio-Fax, 1971; Rel. 2) has been chosen as key study, reporting oral LD50 891 mg/kg in rats. Publications by Hasegawa et al (1989) and Schlede et al. (1995) on NaS (both Rel. 2) were chosen as supporting studies. For acute dermal toxicity, one Rel. 1 study report (Bomhard, 1989) has been chosen as key study. No mortality and no local changes were noted, with dermal LD50 > 2000 mg/kg. For acute inhalation toxicity, only one Klim. 3 on SA itself is available (BioFax, 1971). Salicylic acid was administered as a dust at 0.9 mg/l, at which concentration no mortality occurred, with signs of slight irritation only in one animal during exposure. Since this study alone is not sufficient to fulfil this endpoint, it is used by weight of evidence with a subacute inhalation toxicity study (Gage, 1970) on methyl salicylate vapour, which supports a conclusion of low potential for systemic toxicity by inhalation. For skin irritation, a GLP guideline study (RCC, 2008) has been chosen as key study. Results show that salicylic acid does not elicit any skin reactions at the application site at any of the observation times. A study of lower reliability (Bio-fax, 1971) has been chosen as supporting study. These studies show that salicylic acid is not a primary skin irritant. A human patch test (Berner, 1989) showed slight irritation. For eye irritation, a publication by Sugai et al. (1991) has been chosen as key study. Salicylic acid induced severe irritation not recovering within 21 days of treatment. A similar result was obtained in a supporting study (Bio-Fax, 1971) These studies indicate that salicylic acid is a severe eye irritant. No specific study has been carried out on respiratory irritation. Data from an acute toxicity study and worker experience suggest that high dust levels cause slight irritation. Not sensitising to the skin No valid repeated dose toxicity studies on salicylic acid are available. A read-across approach is therefore proposed from studies on Methyl salicylate (MeS) which is readily metabolised to salicylic acid (See section 7.1.1). A set of studies was conducted on MeS by Webb & Hansen (1963), consisting of oral feeding studies of duration 17 weeks and 2 years in rats, studies in dogs by capsule administration of duration 59 days and 2 years, and a dermal study in rabbits. These studies did not examine all the parameters recommended in the current OECD guidelines 409 and 452, however they were conducted according to good scientific principles by US FDA. The chronic studies in rat and dog are therefore proposed as key studies for this endpoint, with the subchronic studies in rats and dogs as supporting	>100

	study. A second set of subacute oral studies was conducted on MeS by Abbott & Harrisson (1978) to further investigate the effects on bone in rats and liver in dogs, identified in the studies by Webb & Hansen. These are considered to be acceptable as supporting studies.	
SIMMONDSIA CHINENSIS SEED OIL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Simmondsia Chinensis (Jojoba) Seed Oil CAS#: 90045-98-0 EC#: 289-964-3 FUNCTION: Emollient, Skin conditioning Considered safe as a cosmetic ingredient: (https://doi.org/10.3109%2F09758920941992) Read across data for Palmitic Acid (C16): NOAEL: >5000mg/kg/day (150 day oral study in rats https://echa.europa.edu/) Read across data for Oleic Acid (C18:1): NOAEL: >4,500mg/kg/day (16-week oral study in rabbits (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2012.EN-274)	>100
SORBIC ACID	The substance is an organic solid, white odourless powder, which melts at 134°C and decomposes prior to boiling at an atmospheric pressure of 1013 hPa. Its relative density is 1.20 at 20°C (compared to water). It has a vapor pressure of 1.8 x 10 -4hPa at 20°C. The particle sizes L10 and L90 of the test item deduced from the particle size distribution is 16.57 µm and 254.18 µm, respectively. Sorbic acid is soluble in water with a water solubility of 1.34 g/L and a log Po/w of 1.32 (at pH 2.5) and -1.72 (at pH 6.5). No self ignition temperature was observed until the maximum test temperature of 400 °C. Sorbic acid could not be ignited by a flame and no explosive or oxidising properties are expected due to its chemical structure. The pKa of sorbic acid in aqueous solution of 20 °C was determined to be 4.65 +/- 0.04. Acute toxicity testing by any route (oral, inhalation, and dermal) demonstrate no evidence of toxicity. Animal studies suggest that sorbic acid and potassium sorbate are not skin irritants but eye irritants. Animal studies suggest that sorbic acid and potassium sorbate are not skin sensitizers. In short-term to subchronic oral studies, Sorbic Acid and Potassium Sorbate were pratically non-toxic in rats and dogs at concentrations up to 10 and 2% respectively .	>100

TOCOPHEROL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: N/A CAS#: 54-28-4 (gamma)/ 16698-35-4(beta) / 10191-41-0(DL) / 1119-13-1 / 1406-18-4 / 1406-66-2 / 2074-53-5 (DL) / 59-02-9 (D)/7616-22-0 EC#: 200-201-5 / 240-747-1 / 233-466-0 / 204-299-0 /215-798-8 / - / 218-197-9 / 200-412-2 / - FUNCTION: Antioxidant Considered safe as a cosmetic ingredient: (https://journals.sagepub.com/doi/full/10.1177/10915818794455)	>100
	NOAEL (repeat-dose, rat study) = 642mg/kg (Food Chem Toxicol. 2006;44(7):916–932). 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 - *SKIN CREAM*

RESPONSIBLE PERSON DETAILS:

MELOVIBES LTD

Melovibes Ltd

2, Eagle Road, Eglwys Brewis, Barry. Vale of Glamorgan. 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 skin cream**). 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.

VARIANT 1 ALLERGENS: N/A

11) REASONING

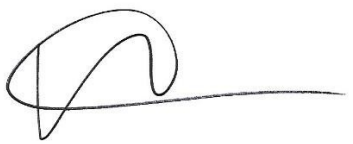
All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

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

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

12) ASSESSORS CREDENTIALS AND APPROVAL OF PART B

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



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

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

DATE: 27/10/2023

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.