

BERGAMOT OIL MELITO

Ref. 16275

Version 2RME13 (Revision Number: 2 - Revision Date: November 22, 2023)

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1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/UNDERTAKING

1.1 Product identification

product (trade name): Bergamot Oil Melito - Ref. 16275
 EC name/registration name: Bergamot, ext.
 EC number: 289-612-9
 CAS number (EC inventory): 89957-91-5
 REACH registration number: 01-2120117613-65-0000

1.2 Relevant identified uses of the substance and uses advised against

relevant uses: odour agent / flavouring agent - ingredient for industrial manufacturing.
 uses advised against: not for personal use in this form or concentration.

1.3 Details of the supplier of the safety data sheet

company: CAPUA 1880 s.r.l. - Zona Industriale, 89052 Campo Calabro (RC) - ITALY • www.webcapua.com
 telephone number: phone: +390965793901 • fax: +390965797111/757792
 responsible person: Dr. Gianfranco Capua (CEO) • phone: +3909657939236 • mail: sales@webcapua.com
 manufacturing plant: Zona Industriale, 89052 Campo Calabro (RC) - ITALY
 competent person SDS: mail: legis@webcapua.com

1.4 Emergency telephone number

supplier: available on office hours: 9:30÷17:03 (GMT+1) phone: +390965793901
 (languages: IT, EN, FR, DE, ES) - other time: +393483852033 (languages: IT, EN, FR).
 poison control center: Azienda Ospedaliera Niguarda Ca' Granda (MILANO - ITALY) +390266101029
 (languages: IT, EN).

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance

Reg. (EC) No 1272/2008:	Flam. Liq. 3	Asp. Tox. 1	Skin Irrit. 2	Skin Sens. 1	Eye Irrit. 2	Aquatic Chronic 3
hazard categories:	FL3	AH1	SCI2	SS1	EDI2A	EHC3
hazard statements:	H226	H304	H315	H317	H319	H412
hazard pictograms:	GHS02	GHS08	GHS07		-	

2.2 Label elements

hazard pictograms:



signal word: danger
 hazard statements: H226, H304, H315, H317, H319, H412
 precautionary statement: P210, P280, P331, P301/310, P302/352, P305/351/338, P273

2.3 Other hazards

Ecological information:
 according to Annex XIII of REACH Regulation, the substance contains no constituent considered either Persistent, Bioaccumulative and Toxic (PBT), or very Persistent and very Bioaccumulative (vPvB) at a concentration equal to or greater than 0.1%.
 The substance contains no constituent identified as having endocrine disrupting properties according to REACH Article 59(1) or in accordance with the criteria set out in Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1%.

Toxicological information:
 the substance contains no constituent identified as having endocrine disrupting properties according to REACH Article 59(1) or Commission Delegated regulation (EU) 2017/2100 at a concentration equal to or greater than 0.1%.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

botanical origin: *Citrus bergamia*, RISSO et POITEAU
 production process: obtained by physical means from the outer part of fresh bergamot fruits peel.
 status: 100% Natural Complex Substance
 EU name: Bergamot, ext.
 EC number: 289-612-9
 CAS number (EC inventory): 89957-91-5
 other CAS number: 8007-75-8

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3.1.1 Substance: main constituents & typical values

common name	EINECS	CAS	Hazards classification	range (%)
D-limonene	227-813-5	5989-27-5	AH1, EHC3, FL3, SCI2, SS1B	20÷55
linalool	201-134-4	78-70-6	ATO5, EDI2A, FL4, SCI2	3÷45
linalyl acetate	204-116-4	115-95-7	EDI2A, FL4, SCI2	15÷40
β-pinene	204-872-5	127-91-3	AH1, FL3, SCI2, SS1B	3÷12
γ-terpinene	202-794-6	99-85-4	AH1, FL3, SCI3	2÷12
α-pinene	201-291-9	80-56-8	AH1, FL3, SCI2, SS1B, ATO5	0.5÷4
β-myrcene	204-622-5	123-35-3	AH1, EDI2A, FL3, SCI2	0.5÷2.5

4. FIRST AID MEASURES

4.1 Description of first aid measures

inhalation:	move outdoor and breath fresh air for at least 15 minutes - in case of complaints seek medical attention.
contact with the skin:	remove contaminated clothing and wash with water and soap the contaminated part - make sure you have eliminated the contamination - in case of complaints seek medical attention.
contact with the eyes:	abundant eye-wash for several minutes with pure water, make sure you have eliminated the contamination - in case of persistent eye irritation seek medical attention.
ingestion:	ask immediately medical assistance - mouth washing with water and do not provoke vomiting .

4.2 Most important symptoms and effects, both acute and delayed

symptoms:	inhalation: can cause slight headache - contact: can cause eye irritation - can cause slight skin rash.
acute and delayed effects:	no post-disorder effects are reported.

4.3 Indication of any immediate medical attention and special treatment needed

immediate medical assistance:	see point 4.1.
immediate/special treatment:	see point 4.1.
first aid specific means:	eye wash fountain / safety shower should be available in the work area.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

suitable extinguishing media:	SMALL FIRE: use CO ₂ , foam, dry powder - LARGE FIRE: use water spray or fog - cool containing vessels with water jet in order to prevent pressure build-up, autoignition or explosion.
unsuitable extinguishing media:	pressurized water jet.

5.2 Special hazards arising from the substance

vapours may form explosive mixture with air - in case of fire, the following can be released: carbon monoxide (CO), carbon dioxide (CO₂), smoke, soot.

5.3 Advice for firefighters

standard procedure for chemical fires - spray extinguishing media to base of flames - use adequate protections for respiratory apparatus and protection bodysuits.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

for non emergency personnel:	in case of unintentional important release of the product in enclosed space use respiratory protection (Gas filter A, Colour code brown: consider the maximum duration for wear) must be worn. Use insulating device for respiratory protection with an independent air supply in circumstances which are unclear - use adequate protections solvent resistant: security shoes, bodysuit, gloves and protective goggles solvent-resistant (see section 8).
for emergency responders:	as per non-emergency personnel.
emergency procedures:	remove any ignition source and ensure adequate ventilation in working areas following accidental releases.

6.2 Environmental precautions

keep away from drains - keep away from surface and ground water.

6.3 Methods and material for containment and cleaning up

keep away from heat and use non-combustible absorbing sawdust (sand, specific binder) - using suitable pumping systems for inflammable materials. Refer to section 13 for the appropriate methods of waste treatment.

6.4 Reference to other sections

section 4, 8 & 13

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

safe handling:	during handling keep original container closed - avoid contact with skin and eyes - wear adequate protective gloves and eye/face protection - avoid to place or handle near any sources of ignition - avoid exposing to high temperature during processing - maintain adequate local and general ventilation where product is handled.
hygiene at work:	do not ingest or apply to the skin as such - no smoking - remove contaminated clothing - good personal washing routines should be followed - if at risk of contamination, foods, beverages and other articles of consumption must not be stored or consumed at the work areas.

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7.2 Conditions for safe handling, including any incompatibilities

container: to be stored in stainless steel drums, preferably under inert atmosphere (nitrogen) with minimum head space, protected from day-light. • **take note:** the container used during transportation must be considered only as a temporary container and it must not be considered in any case adequate for medium or long term warehousing.

conditions: stored in a dry, aerated place, away from any heat source and ignition source.

temperature: from 5 °C to 21 °C.

7.3 Specific end uses

use as odour agent / flavouring agent - the information of this section are not related to the use of the product in combination with any other material or any other process altering its characteristics.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Control parameters

occupational exposure limit: Component with limit values that require monitoring at the workplace:

CAS 5989-27-5, (R)-p-mentha-1,8-diene

AGW (Germany): 110 mg/m³, 20 ppm, 2(II); DFG, Sh, Y

8.2 Exposure control

refer to the Exposure Scenario document in Annex I.

8.2.1 Appropriate engineering controls

where appropriate, use closed system to transfer and/or process this material - if appropriate, isolate mixing rooms and other areas where this material is used or openly handled - maintain these areas under negative air pressure relative to the rest of the plant.

8.2.2 Individual protection measures, such as personal protective equipment



eye/face protection: protective goggles with built-in-frame tested to EN166 (should be checked regularly).

skin protection - hand: suitable gloves tested to EN374 (should be checked regularly) - always use with clean, dry hands.

skin protection - other: protective work clothing solvent resistant (should be checked regularly).



respiratory protection: not necessary in adequate local with general ventilation - avoid breathing vapors.

thermal hazards: none.

8.2.3 Environmental exposure controls

the usual precautions for safe handling have to be observed.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

physical form: liquid

color: yellow to green-yellowish

odour: citrusy

odour threshold: N/D

pH: N/A

initial boiling point (& range): N/A

melting point/freezing point: < -30°C at 101.3 kPa

flash point: 58 °C

evaporation rate: N/D

upper/lower explosive limits: N/D

vapour pressure: 123.1 Pa at 25 °C

vapour density: N/D

relative density d_4^{20} : 0.8720÷0.8820

solubility: in alcohol & other oils • 87% of the substance have solubility > 40 mg/L into H₂O

partition coefficient n-octanol/H₂O: 4.38 at 25°C for the component D-Limonene; 3.38 at 25°C for the component Linalool; 4.39 at 25°C for the component Linalyl acetate.

auto-ignition temperature: 235°C at 101.89 kPa.

decomposition temperature: N/D

viscosity: N/D

explosive properties: none

oxidizing properties: none

9.2 Other information

9.2.1. Information with regard to physical hazard classes

none

9.2.2. Other safety characteristics

none

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10. STABILITY AND REACTIVITY

10.1 Reactivity

This substance does not react with water - the substance is unreactive if it is stored according to the recommendations in point 7 and in accordance with the identified uses (see subsection 1.2).

10.2 Chemical stability

stable substance when stored according to recommendations in Section 7 and in accordance with the identified uses (see subsection 1.2). • **shelf life:** 18 months from the date of production, in the recommended storage conditions (see Section 7).

10.3 Possibility of hazardous reactions

none if used according to storage & handling conditions (see Section 7) & identified uses (see subsection 1.2).

10.4 Conditions to avoid

avoid exposure to any heat source.

10.5 Incompatible materials

avoid exposure to highly oxidizing agents.

10.6 Hazardous decomposition products

no known hazardous decomposition products under recommended storage & handling conditions - in case of combustion: carbon monoxide (CO), carbon dioxide (CO₂).

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

acute toxicity (oral):	LD50: > 10000 mg/kg bw (male) (method: rat (albino) gavage – equivalent Guideline 401 OECD).
acute toxicity (dermal):	LD50: > 20000 mg/kg bw (method: rabbit (albino) – OECD Guideline 402).
acute toxicity (other routes):	no data available.
severe eyes damages/irritations:	no data available.
respiratory sensitization:	no data available.
dermal sensitization:	no data available.
mutagenicity:	no adverse effect observed (negative).
carcinogenicity:	no data available.
toxicity for reproduction:	oral route: adverse effect observed NOAEL: 365 mg/kg bw/day (rat) (read across with coriander oil study - Owner company: Lorillard, Inc. - Report date: 1989-04-12) . oral route: adverse effect observed NOAEL: 365 mg/kg bw/day (rat) (read across with coriander oil study - Owner company: Lorillard, Inc. - Report date: 1989-04-12)
developmental toxicity:	oral route: target organs: urogenital: kidneys; digestive: stomach NOAEL: 117 mg/kg bw/day (subacute; rat)
STOT-exp. repeated :	no data available
STOT-exp. single :	no data available
aspiration hazard:	no data available.

Based on available information on Bergamot oil and its constituents, Bergamot oil is expected to be readily and fully absorbed by the oral route (approximately 100%). Dermal absorption is expected to be lower. However, as no specific information is available on the extent of dermal and inhalation absorption, this is assumed to be comparable to oral absorption as a worst case. For risk assessment purposes, the absorption after oral, dermal and inhalation exposure are therefore assumed to be identical and route-to-route extrapolation from the oral to inhalation and dermal route is not required.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

the substance contains no constituent identified as having endocrine disrupting properties according to REACh Article 59(1) or Commission Delegated regulation (EU) 2017/2100 at a concentration equal to or greater than 0.1%.

11.2.2 Other information

no data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

aquatic environment:	Harmful to aquatic life with long lasting effects.
acute - fish	
(semi-static freshwater):	LL50 (24 h): 57 mg/L test mat. (nominal) - <i>Oncorhynchus mykiss</i> - metodo OECD Guideline 203 (Fish, Acute Toxicity Test) LL50 (48 h): 18 mg/L test mat. (nominal) - <i>Oncorhynchus mykiss</i> - metodo OECD Guideline 203 (Fish, Acute Toxicity Test) LL50 (72 h): 18 mg/L test mat. (nominal) - <i>Oncorhynchus mykiss</i> - metodo OECD Guideline 203 (Fish, Acute Toxicity Test) LL50 (96 h): 18 mg/L test mat. (nominal) - <i>Oncorhynchus mykiss</i> - metodo OECD Guideline 203 (Fish, Acute Toxicity Test)
acute - aquatic invertebrates	
(static freshwater):	EL50 (24 h): 60 mg/L test mat. - OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

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EL50 (48 h): 33 mg/L test mat. - OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)
 NOEL (48 h): 18 mg/L test mat. (nominal) - OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

acute - algae & aquatic plants (static freshwater): EL50 (72 h): 11 mg/L test mat. (Tested as WAF) (nominal) OECD Guideline 201 (Alga, Growth Inhibition Test)

acute - other organisms: not tested.
 chronic: not tested.

12.2 Persistence and degradability

this substance is considered as a NCS readily biodegradable and therefore is not persistent.

12.3 Bioaccumulative potential

as the constituents are readily biodegradable.

12.4 Mobility in soil

this substance is considered as a readily biodegradable NCS. Based on the ready biodegradability of the NCS, simulation tests in surface water, sediment and soil are not required.

12.5 Results of PBT and vPvB assessment

according to Annex XIII of REACH Regulation, the substance contains no constituent considered either Persistent, Bioaccumulative and Toxic (PBT), or very Persistent and very Bioaccumulative (vPvB) at a concentration equal to or greater than 0.1%.

12.6 Endocrine disrupting properties

the substance contains no constituent considered to have endocrine disrupting properties according to REACH Article 59(1) or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1%.

12.7 Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

the containers used for this product must completely empty before disposal - dispose product and packaging in accordance with federal, state and local environmental control regulations - dispose of this product in the environment is illegal.

14. TRANSPORT INFORMATION

14.1 UN Number

1197

14.2 UN proper shipping name

extracts, liquid, for flavour or aroma

14.3 Transport hazard class

Class 3

14.3.1 Transport hazard symbols

for IMDG-ADR/RID: flame
 for ICAO/IATA: flame



14.4 Packing group

III

14.5 Environmental hazards

marine pollutant

14.6 Special precautions for user

this product contains constituents flammables & dangerous for the environment - in case of pouring out, make sure to label new package accordingly, reproducing original label with relevant symbols.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

N/A

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

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15.2 Chemical Safety Assessment

A study for the chemical safety assessment of the substance was conducted during the preparation of registration for REACH.

16. OTHER INFORMATION

a Revision

Version 1RME13 (Revision Number: 1 - Revision Date: April 2010) – FIRST ISSUE OF THE DOCUMENT			
Edited Section	Description	from	to
N/A	N/A		N/A
Version 2RME13 (Revision Number: 2 - Revision Date: November 22, 2023)			
Edited Section	Description	from	to
Updates to Sections: 2, 8, 9, 11, 12, 14, 15 according to Reg. (EU) No 2020/878			

b Legend

CLP: Regulation (EC) No 1272/2008 / **CSR:** Chemical Safety Report / **Asp. Tox.:** aspiration hazard / **Aquatic Chronic:** aquatic hazard / **Skin Irrit.:** skin irritation hazard / **Skin Sens.:** skin sensitization hazard / **Flam. Liq.:** flammable liquid hazard / **WAF:** Water Accommodated Fractions / **LD50:** Lethal Dose 50 / **LL50:** Lethal Loading 50 / **EL50:** Effective Loading 50 / **NOAEL:** No-Observed Adverse Effect Level / **NOEL:** No-Observed Effect Level / **LOEL:** Lowest Observed Effect Level / **OECD:** Organisation for Economic Co-operation and Development

c Literature references and source of data

CSR - RIFM - FEMA database

d List of relevant hazard and precautionary statements

H226 flammable liquid and vapour
H304 may be fatal if swallowed and enters airways
H315 causes skin irritation
H317 may cause an allergic skin reaction
H319 causes serious eye irritation
H412 Harmful to aquatic life with long lasting effects
P210 keep away from heat/sparks/open flames/hot surfaces – no smoking
P280 wear protective gloves/eye protection/face protection
P331 do not induce vomiting
P301/310 if swallowed: immediately call a poison center or doctor/physician
P302+352: IF ON SKIN: Wash with plenty of water/...
P305/351/338 if in eyes: rinse cautiously with water for several minutes. remove contact lenses if present and easy to do. continue rinsing
P273: Avoid release to the environment.

e Inventories & other

	CAS	ID	NOTE
EINECS	89957-91-5	289-612-9	
TSCA	8007-75-8	-	
IECSC	8007-75-8	-	
KECI	8007-75-8	KE-26829	
DSL	8007-75-8	-	
AICS	8007-75-8	-	
ENCS - ISHL	8007-75-8	11-(1)-575	
NZIOC	8007-75-8	-	
PICCS	8007-75-8	-	
FDA	-	21CFR182.20	
CoE	-	137	
FEMA	8007-75-8	2153	
HS Code	-	3301192000	EU TARIC

f Further information

the information on this SDS is correct to the best of our knowledge, covering the involved product at the date of its publication. They apply to the product as such as per the described specifications. The information are not related to the use of the product in combination with any other material or any other process altering its characteristics. The end user should apply to the existing normative and laws covering the use of the product, the hygiene and security at work. The container used during transportation must be considered only as a temporary container and it must not be considered in any case adequate for medium or long term warehousing. Upon receipt, our product must be stored as soon as possible in compliance with section 7 of this SDS. The information given in this SDS is in accordance with the Reg. (EU) No 2020/878.

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ANNEX I

Exposure Scenarios

Exposure Scenarios -> 