SAFETY DATA SHEET

in accordance with Regulation (EC) No 1907/2006 (REACH), Annex II, as amended by Regulation (EU) 2020/878
Version 1.0 (DRAFT)

BIORUŽA s.r.o.
Laborecká 1, 010 01 Žilina,
Slovakia
Company ID: 52234070
+421 905 864 140 ·
info@emerosa.sk

DRAFT – subject to review by the responsible person. The classification was calculated from the safety data sheets of the individual essential oils (calculation method according to Annex I of the CLP Regulation). The flash point of the blend has not been measured.

SECTION 1: Identification of the mixture and of the company

1.1 Product identifier	**Aromatherapy Essential Oil Blend Immunity Venoc 10 ml**
Product code	4276
Product type	blend of essential oils (100 % essential oils, no carrier oil)
UFI	*to be added after notification of the mixture (PCN, Annex VIII CLP)*
1.2 Relevant identified uses	aromatherapy – aroma diffuser, inhalation; after dilution with a carrier oil, cosmetic and massage use. Uses advised against: internal use, application of the undiluted blend to the skin.
1.3 Supplier	BIORUŽA s.r.o., Laborecká 1, 010 01 Žilina, Slovakia tel.: +421 905 864 140, e-mail: info@emerosa.sk Brand: Venoc
Contact for the SDS	info@emerosa.sk
1.4 Emergency telephone number	National Toxicological Information Centre (NTIC), Limbová 5, 833 05 Bratislava, Slovakia, tel.: +421 2 5477 4166 (24 hours)

SECTION 2: Hazards identification

2.1 Classification of the mixture according to Regulation (EC) No 1272/2008 (CLP)

Hazard class and category	Hazard statement
Flam. Liq. 3	H226 – Flammable liquid and vapour.
Asp. Tox. 1	H304 – May be fatal if swallowed and enters airways.
Skin Irrit. 2	H315 – Causes skin irritation.
Eye Irrit. 2	H319 – Causes serious eye irritation.
Skin Sens. 1	H317 – May cause an allergic skin reaction.
Aquatic Chronic 2	H411 – Toxic to aquatic life with long lasting effects.

2.2 Label elements



GHS02 GHS08 GHS07 GHS09

Signal word: **Danger**

Contains: Boswellia carterii (Frankincense) Oil, Boswellia serrata (Frankincense) Oil, Citrus limon (Lemon) Peel Oil, Lavandula angustifolia (Lavender) Flower Oil, Melaleuca alternifolia (Tea Tree) Oil

Hazard statements:

- H226 Flammable liquid and vapour.
- H304 May be fatal if swallowed and enters airways.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.

- H317 May cause an allergic skin reaction.
- H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
- P331 Do NOT induce vomiting.
- P405 Store locked up.
- P261 Avoid breathing vapours.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves/eye protection.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P264 Wash hands thoroughly after handling.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P273 Avoid release to the environment.
- P391 Collect spillage.
- P370+P378 In case of fire: Use foam, dry powder or CO_2 to extinguish.
- P403+P235 Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local/national regulations.

Packaging supplied to the general public must have a child-resistant fastening and a tactile warning of danger (CLP, Annex II, Part 3).

2.3 Other hazards

Based on the available data on the components, the mixture does not contain PBT or vPvB substances or substances with endocrine disrupting properties at a concentration of 0.1 % or more. Essential oils may irritate the skin and eyes on direct contact; some citrus oils may increase the sensitivity of the skin to sunlight.

SECTION 3: Composition / information on ingredients

3.2 Mixtures

Component (INCI)	CAS	EC	%	Classification (CLP)
Citrus limon (Lemon) Peel Oil Venoc 4102	138-86-3	205-341-0	20.0	Flam. Liq. 3 (H226); Asp. Tox. 1 (H304); Skin Irrit. 2 (H315); Skin Sens. 1 (H317); Eye Irrit. 2 (H319); Aquatic Chronic 1 (H410)
Melaleuca ericifolia (Rosalina) Leaf Oil Venoc 4217	8022-72-8 / 85085-48-9	285-377-1	20.0	not classified
Boswellia serrata (Frankincense) Oil Venoc 4220	97952-72-2	308-366-6	20.0	Skin Sens. 1 (H317); Aquatic Chronic 4 (H413)
Melaleuca alternifolia (Tea Tree) Oil Venoc 4101	85085-48-9/68647-73-4	285-377-1	20.0	Flam. Liq. 3 (H226); Acute Tox. 4 (oral) 4 (H302); Acute Tox. 4 (inhal) 4 (H332); Asp. Tox. 1 (H304); Skin Irrit. 2 (H315); Aquatic Chronic 2 (H411)
Lavandula angustifolia (Lavender) Flower Oil Venoc 4099	8000-28-0	289-995-2	10.0	Asp. Tox. 1 (H304); Skin Irrit. 2 (H315); Skin Sens. 1 (H317); Eye Irrit. 2 (H319); Aquatic Chronic 3 (H412)
Boswellia carterii (Frankincense) Oil Venoc 4170	8016-36-2 ; 89957-98-2	289-620-2	10.0	Skin Sens. 1 (H317); Aquatic Chronic 4 (H413)

Shares according to the manufacturer's formulation (parts by volume); used as % by weight for the classification.

Selected constituents of the essential oils (allergens, calculated)

Substance	Estimated content in the blend (% w/w)
Alpha-Pinene	18.44
Linalool	12.46
Terpinolene	4.12
Linalyl Acetate	2.95
Alpha-Terpinene	2.07
Limonene	1.97
Terpineol	0.85
Beta-Caryophyllene	0.48
Beta-Pinene	0.42
Citral	0.20

Calculated from the certificates of analysis (COA) or safety data sheets of the individual oils and the component shares.

SECTION 4: First aid measures

After inhalation	Move the person to fresh air. Seek medical advice if symptoms occur.
After skin contact	Remove contaminated clothing. Wash the skin with soap and plenty of water, then apply vegetable oil. If irritation or rash occurs, seek medical advice.
After eye contact	Remove contact lenses. Rinse the open eyes with clean water for at least 15 minutes. If irritation persists, seek medical advice.
After ingestion	Do NOT induce vomiting (risk of aspiration into the lungs). Rinse the mouth with water. Immediately call a poison centre or doctor and show the container or this sheet.
4.2 Symptoms	skin and eye irritation, redness; repeated contact may cause an allergic skin reaction; inhalation of high vapour concentrations may cause headache or dizziness. If swallowed and aspirated, chemical pneumonitis may occur.
4.3 Medical attention	Treat symptomatically. Do not induce vomiting if swallowed.

SECTION 5: Firefighting measures

5.1 Suitable extinguishing media	alcohol-resistant foam, dry powder, carbon dioxide (CO_2), water mist
Unsuitable extinguishing media	full water jet
5.2 Special hazards	Flammable liquid. Combustion produces carbon monoxide, carbon dioxide and smoke. Vapours may form explosive mixtures with air.
5.3 Advice for firefighters	Self-contained breathing apparatus and protective clothing. Cool containers exposed to fire with water.

SECTION 6: Accidental release measures

6.1 Personal precautions	Ensure ventilation, remove ignition sources, avoid contact with eyes and skin (gloves, goggles). Beware of slippery surfaces.
6.2 Environmental precautions	Prevent release into drains, surface water, groundwater and soil.
6.3 Methods for cleaning up	Absorb with non-combustible absorbent material (sand, vermiculite, diatomaceous earth), place in a closable container and dispose of according to Section 13. Wash the area with water and detergent.
6.4 Reference to other sections	Sections 8 and 13

SECTION 7: Handling and storage

7.1 Safe handling	Avoid contact with eyes and skin; do not apply undiluted to the skin. Do not eat, drink or smoke during use. Wash hands after handling. Keep away from ignition sources.
7.2 Storage	In tightly closed (dark) glass containers, in a cool, dry and well-ventilated place, protected from light and heat, out of reach of children. Do not store together with strong oxidising agents. Recommended temperature 5–25 °C.
7.3 Specific end use	aromatherapy (diffuser, inhalation); cosmetic and massage use after dilution

SECTION 8: Exposure controls / personal protection

8.1 Control parameters	No occupational exposure limits have been established for the mixture or its components.
8.2 Engineering controls	adequate ventilation of the workplace
Eye protection	safety glasses with side shields (EN 166) where there is a risk of splashing
Hand protection	nitrile protective gloves (EN ISO 374) for prolonged contact
Body protection	work clothing
Respiratory protection	not required under normal use
Environmental exposure controls	prevent release into drains and water

SECTION 9: Physical and chemical properties

Physical state	liquid
Colour	depends on the batch; colours of the components: Colorless to Pale yellow - Conforms; Colorless to pale yellow (Conforms); Colorless to pale yellow - Conforms; Light yellow to pale amber; colourless to pale yellow (complies); yellowish to yellow
Odour	characteristic, of the component essential oils
Melting / freezing point	not determined
Boiling point	not determined (components typically > 150 °C)
Flammability	combustible liquid
Flash point	not measured; lowest flash point of a component: 53 °C (Lemon essential oil). *Measurement (closed cup) is recommended.*
Auto-ignition temperature	not determined
pH	not applicable (non-aqueous mixture)
Kinematic viscosity	low, < 20.5 mm^2/s at 40 °C (essential oils)
Solubility	insoluble in water; soluble in ethanol and vegetable oils
Partition coefficient n-octanol/water	not determined
Vapour pressure	not determined
Density (20 °C)	approx. 0.879 g/cm^3 (calculated from the component COAs)
Relative vapour density	not determined
Particle characteristics	not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity	not reactive under normal conditions
10.2 Chemical stability	stable under recommended storage conditions; may oxidise on exposure to air and light (especially terpenes)

10.3 Possibility of hazardous reactions	with strong oxidising agents
10.4 Conditions to avoid	heat, direct sunlight, open flames, sparks
10.5 Incompatible materials	strong oxidising agents, strong acids and bases, some plastics (polystyrene)
10.6 Hazardous decomposition products	CO and CO_2 on combustion; terpene peroxides on oxidation

SECTION 11: Toxicological information

- Acute toxicity: based on available data, the classification criteria are not met.
- Skin corrosion/irritation: causes skin irritation (Skin Irrit. 2).
- Serious eye damage/irritation: causes serious eye irritation (Eye Irrit. 2).
- Skin sensitisation: may cause an allergic skin reaction (Skin Sens. 1).
- Germ cell mutagenicity, carcinogenicity, reproductive toxicity: criteria not met.
- STOT – single and repeated exposure: criteria not met.
- Aspiration hazard: may be fatal if swallowed and enters airways (Asp. Tox. 1).

Data on the components (from the suppliers' safety data sheets)

Component	Acute toxicity
Lemon essential oil	Pin-2(10)-ene: LD50 oral (rat) > 5,000 mg/kg bw; LD50 dermal (rabbit) > 5,000 mg/kg bw. Citral: LD50 oral (rat) approx. 6,800 mg/kg bw; LD50 dermal (rat) > 2,000 mg/kg bw. Product: does not meet the criteria for acute toxicity classification.
Rosalina	Oral [rat]: >2500 mg/Kg; Dermal [rat]: >5000 mg/Kg
Frankincense Serrata (Indian Olibanum) Essential Oil	Not available.
Tea Tree Essential Oil	LD50 oral 2.6 mL/kg bw and 1.9 mL/kg bw (rat); LD50 dermal > 2,000 mg/kg bw (rabbit, OECD 402); inhalation (aerosol, rat, OECD 403) 4.78 / 5.23 / 4.29 mg/L air.
Lavender, Bulgaria	LD50 Oral (rat) >2000mg/Kg; LD50 Dermal (rabbit) > 2000mg/Kg
Frankincense Essential Oil	Not available.

11.2 Endocrine disrupting properties: none known.

SECTION 12: Ecological information

12.1 Toxicity: Aquatic Chronic 2 (H411 – Toxic to aquatic life with long lasting effects.) The classification was calculated by the summation method from the classification of the components.

12.2 Persistence and degradability: the constituents of essential oils are predominantly biodegradable.
12.3 Bioaccumulative potential: not determined.
12.4 Mobility in soil: insoluble in water, volatile.
12.5 Results of PBT and vPvB assessment: the mixture does not contain PBT or vPvB substances.
12.6 Endocrine disrupting properties: none known.
12.7 Other adverse effects: none known.

SECTION 13: Disposal considerations

13.1 Disposal of the mixture	Do not empty into drains. Dispose of as hazardous waste through an authorised waste company in accordance with local and national regulations. Suggested European Waste Catalogue code: 16 03 05* – organic wastes containing hazardous substances.
Packaging	Hand in completely emptied glass containers for glass recycling (15 01 07); contaminated packaging 15 01 10*.
Consumers	small quantities and empty bottles can be taken to a municipal collection point

SECTION 14: Transport information (ADR/RID, IMDG, IATA)

14.1 UN number	UN 1169
14.2 UN proper shipping name	EXTRACTS, AROMATIC, LIQUID
14.3 Transport hazard class	3
14.4 Packing group	III
14.5 Environmental hazards	yes (marine pollutant)
14.6 Special precautions for user	10 ml packages may be transported as limited quantities (LQ, ADR chapter 3.4).
14.7 Maritime transport in bulk	not applicable

SECTION 15: Regulatory information

- Regulation (EC) No 1907/2006 (REACH) and Commission Regulation (EU) 2020/878
- Regulation (EC) No 1272/2008 (CLP), as amended
- Slovak Act No. 67/2010 Coll. on conditions for placing chemical substances and mixtures on the market (Chemical Act)
- Slovak Act No. 79/2015 Coll. on waste
- Regulation (EC) No 1223/2009 on cosmetic products and Regulation (EU) 2023/1545 (fragrance allergens) – for cosmetic use

15.2 Chemical safety assessment: not carried out.

SECTION 16: Other information

Classification method: calculation method according to Article 9 and Annex I of the CLP Regulation, based on the classification of the components stated in their safety data sheets. Flammability is an estimate based on the flash points of the components.

Data sources (SDS and COA of the components):

- Lemon essential oil (Venoc 4102): SDS "4102_olej_Citron_KBU_BIORUZA.pdf"
- Rosalina (Venoc 4217): SDS "4217_SDS_Rosalina.pdf"
- Frankincense Serrata (Indian Olibanum) Essential Oil (Venoc 4220): SDS "4220_FRANKINCENSE SERRATA - MSDS.pdf"
- Tea Tree Essential Oil (Venoc 4101): SDS "4101_Olej_TeaT ree_KBU BIORUZA.pdf"
- Lavender, Bulgaria (Venoc 4099): SDS "4099_Lavender Oil Bulgaria SDS.pdf"
- Frankincense Essential Oil (Venoc 4170): SDS "4170_MSDS_FRANKINCENSE ESSENTIAL OIL.pdf"

Full text of the H statements referred to in Sections 2 and 3:

- H226 Flammable liquid and vapour.
- H302 Harmful if swallowed.
- 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.
- H332 Harmful if inhaled.
- H410 Very toxic to aquatic life with long lasting effects.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.
- H413 May cause long lasting harmful effects to aquatic life.

Abbreviations: CLP – Regulation (EC) No 1272/2008; SDS – safety data sheet; COA – certificate of analysis; ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road; PBT/vPvB – persistent, bioaccumulative and toxic / very persistent and very bioaccumulative; UFI – unique formula identifier.

The information in this safety data sheet is based on our current knowledge and on data provided by the suppliers of the components. It describes the product with regard to safety and does not constitute a guarantee of product properties.

Reviewed and approved by (responsible person), signature