

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Refreshing Massage-Horse Balm 500 ml
Revision date : 25.01.2023
Print date : 30.01.2023

Version (Revision) : 3.0.0 (2.0.0)

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1 Product identifier

Refreshing Massage-Horse Balm 500 ml

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Cosmetics, personal care products

1.3 Details of the supplier of the safety data sheet

Supplier

Pharmaka GmbH

Street : Westring 24

Postal code/City : 48356 Nordwalde

Country : Deutschland

Telephone : +49 2573 920900

Telefax : +49 2573 9209050

Information contact : info@pharmakas.de
www.pharmakas.de

1.4 Emergency telephone number

Germany: Poisons Information Centre Berlin
Charité – Universitätsmedizin Berlin
Campus Benjamin Franklin
Haus VIII, UG
Hindenburgdamm 30
D-12203 Berlin
+49(0)30/30686 700, Internat. INFOTRAC +1 3523233500

Austria: Poisons Information Centre (VIZ) Österreich: +43 1 406 43 43

SECTION 2: Hazards identification

This product is a cosmetic product and according to the regulation (EC) No. 1223/2009 it is exempted from classification and labelling pursuant to the regulation (EC) No. 1272/2008 (and its changes). When used properly, the product is safe and tolerable in accordance with the legal provisions. The following information applies to inadvertent misuse or accidents as well as possible commercial uses. Product may be flammable (see under Point 9).

2.1 Classification of the substance or mixture

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH)

Classification according to Regulation (EC) No 1272/2008 [CLP]

None

2.2 Label elements

None

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

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3.2 Mixtures

Hazardous ingredients

ETHANOL ; REACH No. : 01-2119457610-43 ; EC No. : 200-578-6; CAS No. : 64-17-5

Weight fraction : $\geq 40 - < 45$ %

Classification 1272/2008 [CLP] : Flam. Liq. 2 ; H225 Eye Irrit. 2 ; H319

Specific Conc. Limits : Eye Irrit. 2 ; H319: C ≥ 50 %

Eucalyptus globulus, ext. ; REACH No. : 01-2119978250-37--XXXX ; EC No. : 283-406-2; CAS No. : 84625-32-1

Weight fraction : $\geq 0,1 - < 0,5$ %

Classification 1272/2008 [CLP] : Flam. Liq. 3 ; H226 Asp. Tox. 1 ; H304 Skin Irrit. 2 ; H315 Skin Sens. 1B ; H317 Aquatic Chronic 2 ; H411

Additional information

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

Following inhalation

In case of respiratory tract irritation, consult a physician. Provide fresh air.

In case of skin contact

In case of skin reactions, consult a physician.

After eye contact

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. In case of eye irritation consult an ophthalmologist.

Following ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting. Seek medical advice immediately (poison centre).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms

Important or further important known symptoms and effects are described in the GHS labelling of the product (see section 2) and in section 11 (Toxicological information). (Further) symptoms and/or effects are not yet known.

In our experience, no special hazards are to be expected if the product is handled properly and is used as intended.

4.3 Indication of any immediate medical attention and special treatment needed

treatment: Symptoms (decontamination, vital functions), no known specific antidote.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

Suitable extinguishing media

Extinguishing powder , Carbon dioxide (CO₂) , Foam , Sand

5.2 Special hazards arising from the substance or mixture

Thermal decomposition can lead to the escape of irritating gases and vapours.

5.3 Advice for firefighters

Special protective equipment for firefighters

Full protection suit , Use suitable breathing apparatus.

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5.4 Additional information

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

See protective measures under point 7 and 8. Special danger of slipping by leaking/spilling product.

6.2 Environmental precautions

Do not allow to enter into surface water or drains.

6.3 Methods and material for containment and cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Clear contaminated areas thoroughly.

6.4 Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed and in a well-ventilated place.
Protect against UV-radiation/sunlight, Heat.

Requirements for storage rooms and vessels

Floors should be impervious, resistant to liquids and easy to clean. Keep/Store only in original container. Keep container tightly closed.

Hints on joint storage

Storage class (TRGS 510) : 3

7.3 Specific end use(s)

Cosmetics, personal care products Observe instructions for use. see section 1.2

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

ETHANOL ; CAS No. : 64-17-5

Limit value type (country of origin) : TRGS 900 (D)

Limit value : 200 ppm / 380 mg/m³

Peak limitation : 4(II)

Remark : Y

Version : 02.07.2021

DNEL-/PNEC-values

DNEL/DMEL

ETHANOL ; CAS No. : 64-17-5

Limit value type : DNEL/DMEL (Consumer)

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Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 114 mg/m³
Limit value type : DNEL/DMEL (Consumer)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 206 mg/kg
Assessment factor : day(s)
Limit value type : DNEL/DMEL (Consumer)
Exposure route : Oral
Exposure frequency : Long-term
Limit value : 87 mg/kg
Assessment factor : day(s)
Limit value type : DNEL/DMEL (Worker)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 950 mg/m³
Limit value type : DNEL/DMEL (Worker)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 343 mg/kg
Assessment factor : day(s)

PNEC

ETHANOL ; CAS No. : 64-17-5

Limit value type : PNEC (Aquatic, freshwater)
Limit value : 0,96 mg/l
Limit value type : PNEC (Aquatic, marine water)
Limit value : 0,79 mg/l
Limit value type : PNEC (Sediment, freshwater)
Limit value : 3,6 mg/kg
Limit value type : PNEC (Sediment, marine water)
Limit value : 2,9 mg/kg
Limit value type : PNEC (Soil)
Limit value : 0,63 mg/l
Limit value type : PNEC (Secondary poisoning)
Limit value : 0,38 g/kg

8.2 Exposure controls

Personal protection equipment

Use personal protection equipment.

Eye/face protection



Eye glasses with side protection EN 166

Skin protection

Hand protection

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By short-term hand contact : Hand protection is not required.

By long-term hand contact : Check leak tightness/impermeability prior to use.

Suitable material NBR (Nitrile rubber) , Butyl caoutchouc (butyl rubber)

Breakthrough time 480 min

Thickness of the glove material 5 mm

Remark : When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. EN ISO 374

Body protection

Wear anti-static footwear and clothing

Protective clothing. EN 13034 Natural fibres (e.g. cotton) , heat-resistant synthetic fibres

Chemical resistant safety shoes DIN EN 13832-2

Respiratory protection

Usually no personal respirative protection necessary.

General information

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Gel

Colour : light blue

Odour : characteristic

Safety characteristics

Physical state :

Liquid

Melting point/freezing point :

not relevant

Initial boiling point and boiling range : (1013 hPa) >

65 °C

Decomposition temperature :

not determined

Flash point :

26,2 °C

Auto-ignition temperature :

not applicable

Lower explosion limit :

not applicable

Upper explosion limit :

not applicable

Vapour pressure : (50 °C)

No data available

Density : (20 °C)

0,935 - 0,945 g/cm³

Solvent separation test : (20 °C)

0 %

Water solubility : (20 °C) approx.

0 - 100 Weight-%

Fat solubility : (20 °C)

Not determined.

pH :

5,3 - 6,2

log P O/W :

not determined

Flow time : (20 °C) >

100 s DIN-cup 4 mm

Viscosity : (20 °C)

2300 - 3300 mPa*s

Cinematic viscosity : (40 °C)

not relevant

Odour threshold :

not determined

Relative vapour density : (20 °C)

not determined

Vapourisation rate :

not determined

Maximum VOC content (EC) :

43,4 Weight-%

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Flammable solids : Not applicable.
Flammable gases : Not applicable.
Oxidising liquids : Not relevant.
Explosive properties : Not applicable.
Corrosive to metals : Not relevant.

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

See section 7 of the safety data sheet.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

Corrosion

Based on available data, the classification criteria are not met.

Irritation to respiratory tract

Practical experience/human evidence

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List. In rare cases the product can cause temporary erythema of the skin.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

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STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting potential:

The product does not contain any substance above the legal limits that is included in the list established under Article 59(1) of Regulation (EC) No 1907/2006 on the basis of endocrine disrupting properties or that has endocrine disrupting or endocrine damaging properties according to Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Other indications of toxicity

The product has not been tested. The statements on toxicology were derived from the properties of the individual components.

SECTION 12: Ecological information

12.1 Toxicity

The product has not been tested. The statement is derived from the properties of the single components.

Aquatic toxicity

Based on available data, the classification criteria are not met.

12.2 Persistence and degradability

Technically correct releases of minimal concentrations to adapted biological sewage plants, will not disturb the biodegradability of activated sludge.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This product does not contain components in concentrations of 0.1% or higher which are classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Endocrine disrupting properties

The product does not contain any substance above the legal limits that is included in the list established under Article 59(1) of Regulation (EC) No 1907/2006 on the basis of endocrine disrupting properties or that has endocrine disrupting or endocrine damaging properties according to Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7 Other adverse effects

The product does not contain any substances listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

12.8 Additional ecotoxicological information

Additional information

Do not allow uncontrolled discharge of product into the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose according to legislation.

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13.2 Additional information

Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

Land transport (ADR/RID) : UN1993
Sea transport (IMDG) : UN1170
Air transport (ICAO-TI / IATA-DGR) : UN1170

14.2 UN proper shipping name

Land transport (ADR/RID)
FLAMMABLE LIQUID, N.O.S. (ETHANOL)
Sea transport (IMDG)
ETHANOL, SOLUTION
Air transport (ICAO-TI / IATA-DGR)
ETHANOL, SOLUTION

14.3 Transport hazard class(es)

Land transport (ADR/RID)
Class(es) : 3
Classification code : F1
Hazard identification number (Kemler No.) : 30
Tunnel restriction code : D/E
Special provisions : LQ 5 I · E 1 · Transport in containers with max. 450 litres contents are not subject to the regulations of ADR/RID.
Hazard label(s) : 3
Sea transport (IMDG)
Class(es) : 3
EmS-No. : F-E / S-D
Special provisions : LQ 5 I · E 1 · IMDG 2.3.2.5 (<= 450 l)
Hazard label(s) : 3
Air transport (ICAO-TI / IATA-DGR)
Class(es) : 3
Special provisions : E 1
Hazard label(s) : 3

14.4 Packing group

III

14.5 Environmental hazards

Land transport (ADR/RID) : No
Sea transport (IMDG) : No
Air transport (ICAO-TI / IATA-DGR) : No

14.6 Special precautions for user

None

14.7 Maritime transport in bulk according to IMO instruments

No transport as bulk according to IBC Code.

SECTION 15: Regulatory information

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

EU legislation

The Product is subject to the German Cosmetics Ordinance.

Authorisations and/or restrictions on use

Restrictions on use

Regulation (EC) No. 1907/2006 (REACH), Annex XVII (restrictions)

Use restriction according to REACH annex XVII, no. : 40, 75

National regulations

Technische Anleitung Luft (TA-Luft)

Weight fraction (Number 5.2.5. I) : < 5 %

Water hazard class

Classification according to AwSV - Class : 1 (Slightly hazardous to water)

Other regulations, restrictions and prohibition regulations

Switzerland

VOCV-Regulation

See section 9.1

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment has been carried out. For the following substances of this mixture a chemical safety assessment has been carried out :

ETHANOL ; REACH No. : 01-2119457610-43 ; EC No. : 200-578-6; CAS No. : 64-17-5

Eucalyptus globulus, ext. ; REACH No. : 01-2119978250-37--XXXX ; EC No. : 283-406-2; CAS No. : 84625-32-1

SECTION 16: Other information

16.1 Indication of changes

03. Hazardous ingredients · 07. Hints on joint storage - Storage class · 08. Occupational exposure limit values · 11. Acute toxicity · 11. Corrosion · 11. Respiratory or skin sensitisation · 11. Carcinogenicity · 11. Germ cell mutagenicity · 11. Reproductive toxicity · 11. STOT-single exposure · 11. STOT-repeated exposure · 11. Aspiration hazard · 12. Aquatic toxicity · 14. UN proper shipping name - Land transport (ADR/RID) · 14. UN proper shipping name - Sea transport (IMDG) · 14. UN proper shipping name - Air transport (ICAO-TI / IATA-DGR) · 14. Transport hazard class(es) - Land transport (ADR/RID) · 14. Transport hazard class(es) - Sea transport (IMDG) · 14. Transport hazard class(es) - Air transport (ICAO-TI / IATA-DGR) · 15. Restrictions on use · 15. Technische Anleitung Luft (TA-Luft) · 15. Substances WGK

16.2 Abbreviations and acronyms

ADR = European Agreement concerning the carriage of Dangerous goods by Road

ADN = European Agreement concerning the Carriage of Dangerous Goods by Inland Waterways

ATE = Estimated values for acute toxicity

AwSV = Ordinance on Installations for Handling Substances Hazardous to Water

CAS = Chemical Abstract Service Number

CE = European Community

CLP = EC Regulation 1272/2008

CMR = cancerogen mutagen reprotoxic

DIN = German Institute for Standardisation

DNEL = Derived No Effect Level

DMEL = Derived Minimum Effect Level

EC50 = Mean effective concentration that induces a defined effect other than death in a test population

EG = European Community

EN = European standards

IATA = International Air Transport Association Dangerous Goods Regulation

IBC-Code = International Code for the construction and equipment of ships carrying dangerous chemicals in large

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quantities
IMDG = International Maritime Code for dangerous goods
ISO = International Organization for Standardization
LC50 = Lethal Concentration 50%
LD50 = Lethal dose 50%
MAK = Maximum workplace concentration
MARPOL = International Convention for the Protection of the Marine Environment from Ship-generated Litter
NOEC = No Observed Effect Concentration
OECD = Organisation for Economic Cooperation and Development
PBT = Persistent, bioaccumulative and toxic
pH = potential of hydrogen
PNEC = Predicted no effect concentration
PPM = parts per million
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals (EC Regulation 1907/2006)
RID = Regulation concerning the international transport of dangerous goods by train
TRGS = Technical rules for hazardous substances (german rules)
TWA = Time-weighted average exposure limit
UN-Number = UN number for the transport of dangerous goods
vPvB = Very Persistent and very Bioaccumulative as for REACH Regulation
VOC = Volatile organic Compounds

16.3 Key literature references and sources for data

None

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

This product is a cosmetic product and according to the regulation (EC) No. 1223/2009 it is exempted from classification and labelling pursuant to the regulation (EC) No. 1272/2008 (and its changes).

16.5 Relevant H- and EUH-phrases (Number and full text)

H225	Highly flammable liquid and vapour.
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.
H411	Toxic to aquatic life with long lasting effects.

16.6 Training advice

None

16.7 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.