

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



Trade name : Pharmaka Equiskin Balance
Revision date : 19.01.2023
Print date : 30.01.2023

Version (Revision) : 2.0.0 (1.0.1)

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

1.1 Product identifier

Pharmaka Equiskin Balance

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

Products for animals

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

2.1 Classification of the substance or mixture

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

None

2.2 Label elements

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

Precautionary statements

P102 Keep out of the reach of children.

Special rules for supplemental label elements for certain mixtures

EUH208 Contains alpha-Bisabolol. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

Safety Data Sheet

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Trade name : Pharmaka Equiskin Balance
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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 : $\geq 1 - < 5 \%$

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

Specific Conc. Limits : Eye Irrit. 2 ; H319: C $\geq 50 \%$

alpha-Bisabolol ; REACH No. : 01-2120738997-32-0001 ; EC No. : 208-205-9; CAS No. : 72691-24-8

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

Classification 1272/2008 [CLP] : 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

Remove casualty to fresh air and keep warm and at rest. In case of respiratory tract irritation, consult a physician.

In case of skin contact

In case of skin reactions, consult a physician. Wash immediately with: Water and soap

After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

Following ingestion

Rinse mouth immediately and drink plenty of water. 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

Foam , Carbon dioxide (CO₂) , Dry extinguishing powder , Sand

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

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.

5.4 Additional information

Safety Data Sheet

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Trade name : Pharmaka Equiskin Balance
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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

Provide adequate ventilation. 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

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Clear contaminated areas thoroughly. Treat the recovered material as prescribed in the section on waste disposal.

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
Use only in well-ventilated areas.

Protective measures

Measures to prevent fire

Usual measures for fire prevention.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.
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) : 12

7.3 Specific end use(s)

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

GLYCEROL ; CAS No. : 56-81-5

Safety Data Sheet

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



Trade name : Pharmaka Equiskin Balance
Revision date : 19.01.2023
Print date : 30.01.2023

Version (Revision) : 2.0.0 (1.0.1)

Limit value type (country of origin) : TRGS 900 (D)
Parameter : E: inhalable fraction
Limit value : 200 mg/m³
Peak limitation : 2(I)
Version : 27.10.2020
PYRIDINE-2-THIOL 1-OXIDE, SODIUM SALT ; CAS No. : 3811-73-2
Limit value type (country of origin) : TRGS 900 (D)
Parameter : E: inhalable fraction
Limit value : 0,2 mg/m³
Peak limitation : 2(II)
Remark : H, Y
Version : 02.07.2021

DNEL-/PNEC-values

DNEL/DMEL

ETHANOL ; CAS No. : 64-17-5
Limit value type : DNEL/DMEL (Consumer)
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)
alpha-Bisabolol ; CAS No. : 72691-24-8
Limit value type : DNEL worker (systemic)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 9,8 mg/m³
Limit value type : DNEL worker (systemic)
Exposure route : Dermal
Exposure frequency : KURZZEITIG-LOKAL
Limit value : 2,8 mg/kg bw/day

PNEC

ETHANOL ; CAS No. : 64-17-5
Limit value type : PNEC (Aquatic, freshwater)
Limit value : 0,96 mg/l

Safety Data Sheet

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



Trade name : Pharmaka Equiskin Balance
Revision date : 19.01.2023
Print date : 30.01.2023

Version (Revision) : 2.0.0 (1.0.1)

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
alpha-Bisabolol ; CAS No. : 72691-24-8	
Limit value type :	PNEC (Aquatic, freshwater)
Limit value :	0,0013 mg/l
Limit value type :	PNEC (Aquatic, marine water)
Limit value :	0,00013 mg/l
Limit value type :	PNEC (Sediment, freshwater)
Limit value :	0,268 mg/kg dry weight
Limit value type :	PNEC (Sediment, marine water)
Limit value :	0,027 mg/kg dry weight
Limit value type :	PNEC (Soil)
Limit value :	0,11 mg/kg dry weight
Limit value type :	PNEC (Sewage treatment plant)
Limit value :	10 mg/l

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



By short-term hand contact : Suitable gloves type Disposable gloves. NBR (Nitrile rubber)

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

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

Safety Data Sheet

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



Trade name : Pharmaka Equiskin Balance
Revision date : 19.01.2023
Print date : 30.01.2023

Version (Revision) : 2.0.0 (1.0.1)

Usually no personal respiratory 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 : emulsion

Colour : light yellow

Odour : characteristic

Safety characteristics

Melting point/freezing point :			not relevant
Initial boiling point and boiling range :	(1013 hPa)	approx.	100 °C
Decomposition temperature :			not determined
Flash point :			not applicable
Auto-ignition temperature :			not applicable
Lower explosion limit :			not applicable
Upper explosion limit :			not applicable
Vapour pressure :	(50 °C)		not applicable
Density :	(20 °C)		0,998 - 1,004 g/cm ³
Water solubility :	(20 °C)		not determined
Fat solubility :	(20 °C)		Not determined.
pH :			4,5 - 5,5
log P O/W :			not determined
Viscosity :	(20 °C)		4000 - 5000 mPa*s
Odour threshold :			not determined
Relative vapour density :	(20 °C)		not determined
Vapourisation rate :			not determined
Maximum VOC content (EC) :			4,9 Weight-%
Flammable solids :		Not applicable.	
Flammable gases :		Not applicable.	
Oxidising liquids :		Not relevant.	
Explosive properties :		Not applicable.	

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.

Safety Data Sheet

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



Trade name : Pharmaka Equiskin Balance
Revision date : 19.01.2023
Print date : 30.01.2023

Version (Revision) : 2.0.0 (1.0.1)

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

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.

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.

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.

Safety Data Sheet

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



Trade name : Pharmaka Equiskin Balance
Revision date : 19.01.2023
Print date : 30.01.2023

Version (Revision) : 2.0.0 (1.0.1)

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.

13.2 Additional information

Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

14.4 Packing group

No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

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

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

Safety Data Sheet

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



Trade name : Pharmaka Equiskin Balance
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EU legislation

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)

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out for this preparation. 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

alpha-Bisabolol ; REACH No. : 01-2120738997-32-0001 ; EC No. : 208-205-9; CAS No. : 72691-24-8

SECTION 16: Other information

16.1 Indication of changes

03. Hazardous ingredients · 15. Restrictions on use · 15. Sum 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 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

Safety Data Sheet

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



Trade name : Pharmaka Equiskin Balance
Revision date : 19.01.2023
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Version (Revision) : 2.0.0 (1.0.1)

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]

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

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

H225	Highly flammable liquid and vapour.
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.
