

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

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

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

1.1 Product identifier

ENSBONA Anti Itch Gel

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

Medical device

1.3 Details of the supplier of the safety data sheet

Supplier

Ferdinand Eimermacher GmbH & Co. KG

Street : Westring 24

Postal code/City : 48356 Nordwalde

Country : Deutschland

Telephone : +49 2573/9390-0

Telefax : +49 2573/2053

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

This product is a medical product and according to the regulation (EC) No. 2017/745 it is exempted from classification and labelling pursuant to the regulation (EC) No. 1272/2008 (and its changes).

None

2.2 Label elements

None

2.3 Other hazards

Adverse human health effects and symptoms

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Adverse environmental effects

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

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

SECTION 3: Composition/information on ingredients

Safety Data Sheet

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

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

3.2 Mixtures

Hazardous ingredients

PROPAN-2-OL ; REACH No. : 01-2119457558-25-0000 ; EC No. : 200-661-7; CAS No. : 67-63-0

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

Classification 1272/2008 [CLP] : Flam. Liq. 2 ; H225 Eye Irrit. 2 ; H319 STOT SE 3 ; H336

L-Menthol ; REACH No. : 01-2119458866-21-XXXX ; EC No. : 218-690-9; CAS No. : 2216-51-5

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

Classification 1272/2008 [CLP] : Skin Irrit. 2 ; H315 Eye Irrit. 2 ; H319

Specific Conc. Limits : Eye Irrit. 2 ; H319: C ≥ 25 % • Skin Irrit. 2 ; H315: C ≥ 25 %

3-P-MENTHANON ; REACH No. : 01-2119983789-09-XXXX ; EC No. : 237-926-1; CAS No. : 14073-97-3

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

Classification 1272/2008 [CLP] : Skin Irrit. 2 ; H315 Skin Sens. 1B ; H317

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

Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours.

Following inhalation

Provide fresh air. If unconscious but breathing normally, place in recovery position and seek medical advice.

In case of skin contact

After contact with skin, wash immediately with plenty of water and soap.

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.

Following ingestion

If swallowed, immediately drink: Water

Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Headache , Nausea , Dizziness

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

Suitable extinguishing media

Carbon dioxide (CO₂) , Extinguishing powder , Water mist , alcohol resistant foam

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

Unsuitable extinguishing media

Full water jet Strong water jet

Safety Data Sheet
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Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

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

Use water spray jet to protect personnel and to cool endangered containers. 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). 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

Handle and open container with care. Use only in well-ventilated areas.

Avoid: generation/formation of aerosols

Protective measures

Measures to prevent fire

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges. Always close containers tightly after the removal of product.

Specific requirements or handling rules

Take precautionary measures against static discharges.

7.2 Conditions for safe storage, including any incompatibilities

Avoid: UV-radiation/sunlight

Do not expose to temperatures above 50 °C. Keep container tightly closed and in a well-ventilated place.

Requirements for storage rooms and vessels

Floors should be impervious, resistant to liquids and easy to clean. Ensure adequate ventilation of the storage area. Keep/Store only in original container. Keep container tightly closed.

Hints on joint storage

Storage class (TRGS 510) : 10

7.3 Specific end use(s)

Observe instructions for use. see section 1.2

SECTION 8: Exposure controls/personal protection

Safety Data Sheet
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1907/2006 (REACH)

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

8.1 Control parameters

Occupational exposure limit values

PROPAN-2-OL ; CAS No. : 67-63-0

Limit value type (country of origin) : TRGS 900 (D)
Limit value : 200 ppm / 500 mg/m³
Peak limitation : 2(II)
Remark : Y
Version : 23.06.2022

2,2',2''-NITRILOTRIETHANOL ; CAS No. : 102-71-6

Limit value type (country of origin) : TRGS 900 (D)
Parameter : E: inhalable fraction
Limit value : 1 mg/m³
Peak limitation : 1(I)
Remark : Y
Version : 23.06.2022

Biological limit values

PROPAN-2-OL ; CAS No. : 67-63-0

Limit value type (country of origin) : TRGS 903 (D)
Parameter : Acetone / Whole blood (B) / End of exposure or end of shift
Limit value : 25 mg/l
Version : 25.02.2022

Limit value type (country of origin) : TRGS 903 (D)
Parameter : Acetone / Urine (U) / End of exposure or end of shift
Limit value : 25 mg/l
Version : 25.02.2022

DNEL-/PNEC-values

DNEL/DMEL

PROPAN-2-OL ; CAS No. : 67-63-0

Limit value type : DNEL/DMEL (Consumer)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 89 mg/m³
Limit value type : DNEL/DMEL (Consumer)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 319 mg/kg
Assessment factor : day(s)
Limit value type : DNEL/DMEL (Consumer)
Exposure route : Oral
Exposure frequency : Long-term
Limit value : 26 mg/kg
Assessment factor : day(s)
Limit value type : DNEL/DMEL (Worker)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 500 mg/m³
Limit value type : DNEL/DMEL (Worker)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 888 mg/kg
Assessment factor : day(s)

PNEC

Safety Data Sheet

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

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

PROPAN-2-OL ; CAS No. : 67-63-0

Limit value type :	PNEC (Aquatic, freshwater)
Exposure route :	Water (Including sewage plant)
Limit value :	140,9 mg/l
Limit value type :	PNEC (Aquatic, marine water)
Exposure route :	Water (Including sewage plant)
Limit value :	140,9 mg/l
Limit value type :	PNEC (Sediment, freshwater)
Limit value :	552 mg/kg
Limit value type :	PNEC (Sediment, marine water)
Limit value :	552 mg/kg
Limit value type :	PNEC (Soil)
Exposure route :	Soil
Limit value :	28 mg/kg
Limit value type :	PNEC (Secondary poisoning)
Limit value :	160 mg/kg
Limit value type :	PNEC (Sewage treatment plant)
Exposure route :	Water (Including sewage plant)
Limit value :	2251 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 CR (polychloroprene, chloroprene 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

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

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

9.1 Information on basic physical and chemical properties

Appearance : Gel
Colour : colourless
Odour : characteristic

Safety characteristics

Physical state :			Liquid
Melting point/freezing point :			not determined
Decomposition temperature :			not determined
Flash point :			25,9 - 26,9 °C
Auto-ignition temperature :			not applicable
Lower explosion limit :			not applicable
Upper explosion limit :			not applicable
Density :	(20 °C)	approx.	0,93 g/cm ³
Water solubility :	(20 °C)		100 Weight-%
Fat solubility :	(20 °C)		Not determined.
pH :		approx.	7
log P O/W :			not determined
Viscosity :	(20 °C)		3500 - 4750 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) :			40,3 Weight-%
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

Oxidising agent, strong.

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

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

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

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.

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

Safety Data Sheet

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

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

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. The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

13.2 Additional information

Dispose of contents / partially emptied container to hazardous waste. Dispose of empty container to municipal waste after proper use of the product.

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

Observe technical data sheet or other information on the label.

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

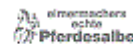
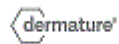
Water hazard class

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

Safety Data Sheet

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

eimermacher since 1910



Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
Print date : 04.12.2024

Version (Revision) : 1.0.1 (1.0.0)

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out for this preparation. For the following substances of this mixture/preparation a chemical safety assessment has been carried out :

PROPAN-2-OL ; REACH No. : 01-2119457558-25-0000 ; EC No. : 200-661-7; CAS No. : 67-63-0

L-Menthol ; REACH No. : 01-2119458866-21-XXXX ; EC No. : 218-690-9; CAS No. : 2216-51-5

3-P-MENTHANON ; REACH No. : 01-2119983789-09-XXXX ; EC No. : 237-926-1; CAS No. : 14073-97-3

SECTION 16: Other information

16.1 Indication of changes

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

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

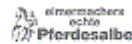
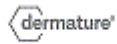
None

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] This product is a medical product and according to the regulation (EC) No. 2017/745 it is exempted from classification and labelling

Safety Data Sheet
according to Regulation (EC) No.
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Trade name : ENSBONA Anti Itch Gel
Revision date : 25.11.2024
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Version (Revision) : 1.0.1 (1.0.0)

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.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

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.