

SAFETY DATA SHEET**Section 1. Identification of Substance/Mixture and of the company undertaking****1.1 Product Identifier**

- **Substance Name/Trade Name:** Asonor®
- **CE-marked in conformity with the EEC Directive 93/42/EEC**
- **Basic UDI-DI number:** 05703562001007
- **US FDA CDER listing:** Labeler code 024804, NDC 24804*001
- **Reg. #** 3005919226,
- **FEI #** 3005919226
- **ARTG No.:** 219685
- **GMDN No.:** 59281
- **NPN:** 80042277
- **Product label**

**1.2 Relevant identified uses of the substance and uses advised against**

- **Relevant identified uses:** Asonor® is intended to act in the prevention of snoring.
- **Uses advised against:** The product has no effect on patients with sleep apnea (OSA).
- **Reasons why uses advised against:** Asonor® has no healing power for OSA patients; the use of the product does not eliminate the recommendations given by doctors to reduce snoring such as: weight loss, quitting smoking, avoiding alcoholic beverages and physical exercise.

1.3 Details of the supplier of the Safety Data Sheet

- **Supplier:** Tanner Medico A/S
- **Street/P.O Box:** DTU Science Park - Agern Alle 1
- **Post Code/City:** 2970 – Horsholm
- **Country:** Denmark
- **Phone:** +45 70204093
- **E-mail competent person:** info@tannermedico.com
- **Emergency Information:** info@tannermedico.com

1.4 Emergency telephone number

- **Please contact:** Rene Arnfeldt Moller
- Opening hours: 8 am to 5 pm (Monday to Friday).
- Phone: +45 40822090
- ram@tannermedico.com
- Language: Danish, English

Section 2. Hazards Identification

2.1 Classification of the mixture

- Classification according to regulation EC 1272/2008
 - **Skin:** do not cause any skin irritation.
 - **Ingestion:** non-toxic if ingested.
 - **Inhalation:** non-toxic if inhaled.
 - **Eyes:** may cause mild irritation.

2.2 Label elements

- Labeling according to regulation EC 1272/2009 (CLP).
- **Hazard pictogram:** not classified as hazardous according to GHS
- **Signal word:** non signal required.
- **Hazard statements:** non-toxic. Not classified as hazardous according to GHS
- **Precautionary Statements:**
 - **P273:** avoid release to the environment.
 - **Skin contact:** first aid not normally required.

- **Eye contact:** flush eyes with plenty of water for at least 2 minutes.
- **Ingestion:** first aid not normally required.
- **Inhalation:** first aid not normally required.
- **Supplemental hazard information (EU):** Not applicable

2.3 Other hazards

- Not applicable

Section 3. Composition/Information on Ingredients

3.1 Substances

CAS Number	EC No	REACH No	Substance Name	Range/Weight %	Classification according to regulation EC (No 1278/2008 CLP)
9005-65-6	500-019-9	-x-	Polysorbate 80 ; Sorbitan monooleate, ethoxylated	0,003 to 0,3%	<ul style="list-style-type: none"> • Skin Irrit. 2 - H315 • Eye Irrit. 2 - H319
56-81-5	200-289-5	-x-	Glycerol; 1,2,3-Propanetriol	0,1 to 10%	This substance does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC
7647-14-5	231-598-3	-x-	Sodium Chloride	0,1 to 3,0%	This substance is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008
139-33-3	205-358-3	-x-	Dissodium Edetate; Disodium dihydrogen ethylenediaminetetraacetate	0,05 to 0,09%	<ul style="list-style-type: none"> • Acute Tox. 4 H332 • Skin Irrit. 2 H315 • Eye Irrit. 2 H319
24634-61-5	246-376-1	-x-	Potassium Sorbate Potassium (E,E)-hexa-2,4-dienoate	0,1 to 0,5%	<ul style="list-style-type: none"> • Eye Irrit. 2 H319

3.2 Additional Information

- This mixture does not require registration according to Regulation (EC) No 1907/2006 [REACH].
- This mixture is exempted from registration according to the provisions of the Annex IV of REACH (Article 2(7)(a)).

- The Annex IV of REACH (Article 2(7)(a)) identifies substances that are exempted from the registration, evaluation and downstream user provisions of REACH on the basis that sufficient information is known about the mixture so that it is considered to cause minimum risk because of its intrinsic properties.

Section 4. First aids and measures

4.1 Description of First Aids Measures

4.1.1 General Information

This product and its ingredients are not hazardous according to the RMP (risk management plan).

4.1.2 Following Inhalation

First aid not normally required.

4.1.3 Following skin contact

First aid not normally required.

4.1.4 Following eye contact

Immediately flush eyes with plenty of water for at least 2 minutes.

4.1.5 Following ingestion

First aid not normally required.

4.1.6 Self-protection of the first aider

Not required.

4.2 Most important symptoms and effects both acute and delayed

- Health effects - Eyes May cause mild irritation.
- Health effects - Skin Do not cause any skin irritation
- Health effects - Ingestion Practically non-toxic if ingested.
- Health effects - Inhalation Practically non-toxic if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes for the doctor: treat symptomatically.

Section 5. Firefighting measures

5.1 Extinguishing media

No extinguishing media is required.

5.2 Special hazards arising from the mixture

This mixture is stable under normal conditions.

5.3 Advice for fire fighters

- Respiratory protection: Not required.
- Hand protection: Not required.
- Eye protection: Not required.

5.4 Additional information

- None.

Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Not required.

6.1.2 For emergency responders

Not required.

6.2 Environmental precautions

Make sure spills can be contained. Do not allow to enter into surface water or drains. Do not allow enter in soil or subsoil.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material, disposal as special waste in compliance with local and national regulations.

6.3.1 For containment

Collect in closed and suitable containers for disposal.

6.3.2 For cleaning up

Clean up the area observing environmental regulations.

6.3.3 Other information

None.

6.4 Reference to other sections

Materials to avoid strong acids, strong oxidizing agents and strong bases.

Section 7. Handling and storage

7.1 Precaution for safe handling

7.1.1 Protective measures

No special handling is required.

7.1.2 Measures to prevent fire

This product is not flammable; no special fire protection measures are required.

7.1.3 Measures to prevent aerosol and dust generation

No special measures are required.

7.1.4 Measures to protect the environment

Shaft and sewers must be protected from entry of the product.

7.1.5 Advice on general occupational hygiene

The occupational hygiene should follow the good manufacturing process.

7.2 Condition for safe storage including any incompatibilities

7.2.1 Technical measures and storage conditions

Store in the temperature range of 5° to 25°C (41° to 77°F).

7.2.2 Requirements for storage rooms and vessels

Keep store only in the original container.

7.2.3 Further information on storage conditions.

None.

7.3 Specific and use(s)

Recommendation: read and follow instruction of use.

Section 8. Exposure controls/personal protection

8.1 Control Parameters

DNEL Values		Oral Exposures		Dermal Exposures		Inhalative Exposures	
		Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)
Consumer	Local	No data	No data	No data	No data	No data	No data
	Systemic	No data	No data	No data	No data	No data	No data
Worker	Local	No data	No data	No data	No data	No data	No data
	Systemic	No data	No data	No data	No data	No data	No data

PNEC Values		
Environment Protection Target	Values	Notes
Freshwater	No data	No notes
Marine water	No data	No notes
Freshwater sediment	No data	No notes
Marine water sediment	No data	No notes
Sewage treatment plant (STP)	No data	No notes
Intermittent release	No data	No notes
Secondary poisoning	No data	No notes
Soil	No data	No notes

8.2 Exposures Controls

8.2.1 Appropriate engineering controls:

- Mixture related measures to prevent exposure during identified uses: no specific measures.
- Structural measures to prevent exposures: no specific measures.
- Organizational measures to prevent exposures: handle in accordance with good manufacturing practices.
- Technical measures to prevent exposures: handle in accordance with good manufacturing practices.

8.2.2 Personal protective equipment

8.2.2.1 Eye and face protection

Not required.

8.2.2.2 Skin protection

Not required.

8.2.2.3 Respiratory protection

Not required.

8.2.2.4 Thermal hazards

No specific measures.

8.2.3 Environmental exposures controls:

- Mixture related measures to prevent exposures: no specific measures.
- Instruction measures to prevent exposures: no specific measures.
- Organizational measures to prevent exposures: no specific measures.
- Technical measures to prevent exposures: no specific measures.

Section 9. Physical & Chemical Properties

9.1 Information on basic Physical and Chemical properties

- a. Appearance: Clear liquid, free from visible particles.
- b. pH range: 4 to 6.
- c. Odor: Slightly fatty.
- d. Boiling Point: 100 °C
- e. Melting Point: no data available
- f. Flash point: no data available
- g. Flammability: no data available
- h. Explosive properties: no data available
- i. Vapor pressure: 17.53
- j. Solubility: no data available

- k. Vapor Density: no data available
- l. Viscosity: no data available
- m. Relative vapor density: no data available
- n. Evaporation Rate: no data available
- o. Partition coefficient n-octanol/water: no data available
- p. Auto ignition temperature: no data available
- q. Decomposition temperature: no data available
- r. Density: 1.005 gr./ml (abs. density)
- s. Explosive properties: not applicable
- t. Oxidizing properties: avoid strong oxidizing agents.

9.2 Other information

No additional information relevant to safe use of the substance.

Section 10. Stability & Reactivity

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical Stability

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

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

No specific conditions to avoid.

10.5 Incompatible materials

Strong acids, strong oxidizing agents and strong bases.

Section 11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

- Practical experience / human evidence / animal evidence: no toxicity if swallowed
- Symptoms delayed effects: no side effects observed.
- Other information: none
- Assessment/classification: nontoxic.

Skin corrosion/irritation

- Practical experience / human evidence / animal evidence: no skin irritation.

Specie	Method	Observation time	Skin primary irritation	Skin cumulative irritation	Skin Sensitization
Human	Patch test	2 weeks	Negative	Negative	Negative

- Other information: none
- Assessment/classification: nonirritant.

Serious eye damage:

- Practical experience / human evidence / animal evidence: not tested.
- Other information: none.
- Assessment/classification: can cause eye irritation.

Sensitization to the respiratory tract:

- Practical experience / human evidence / animal evidence: no data available.
- Other information: none.
- Assessment/classification: not classified.

Skin corrosion/irritation

- Practical experience / human evidence / animal evidence: no skin sensitization

Specie	Method	Observation time	Skin primary irritation	Skin cumulative irritation	Skin Sensitization
Human	Patch test	2 weeks	Negative	Negative	Negative

- Other information: none
- Assessment/classification: non sensitizer.

Germ cell Mutagenicity

- In vitro mutagenicity/genotoxicity: no experimental indication of in vitro mutagenicity exists.
- Other information: none
- Assessment/classification: not expected.

Carcinogenicity

- Practical experience / human evidence / animal evidence: no indication of human carcinogenicity.
- Animal data: data lacking.
- Other information: there is no suspicion of carcinogenicity.
- Assessment/classification: non carcinogenic.

Reproductive toxicity

- Practical experience / human evidence / animal evidence: no indication of human reproductive toxicity exists.

- Animal data: no evidence for reproductive toxicity in experimental animals.
- Effects on or via lactation: data lacking
- Other information: none.
- Assessment/Classification:
 - Fertility: no evidence, not expected.
 - Developmental toxicity: data lacking.
- Overall assessment on CMR properties:

This product does not meet the criteria for classification as CMR category 1A to CLP.
- Specific target organ toxicity (single exposure):
 - Practical experience / human evidence: not expected.
 - Animal data: no data.
 - Other information: none.
 - Assessment/ classification: not expected.
- Specific target organ toxicity (repeated exposure):
 - Practical experience / human evidence: not expected.
 - Animal data: no data.
 - Other information: none.
 - Assessment/ classification: not expected.
- Aspiration hazard
 - Practical experience / human evidence: not expected.
 - Experimental data: no data.
 - Assessment/ classification: not expected.

Section 12. Ecological Information

12.1 Toxicity

- Acute (short term) fish toxicity: no data available.
- Chronic (long term) fish toxicity: no data available.
- Acute (short term) toxicity to crustaceans: no data available.
- Chronic (long term) toxicity to crustaceans: no data available.
- Acute (short term) toxicity to algae and cyanobacteria: no data available.
- Chronic (long term) toxicity to algae and cyanobacteria: no data available.
- Toxicity to other aquatic plant and organism: no data available.
- Toxicity to microorganisms: no data available.

12.1 Persistence and degradability

- Persistence and degradability: no information found.
- Biodegradation: no information found.
 - Assessment/ classification: not readily biodegradable.

12.2 Bio cumulative potential

- Bio concentration factor (BCF): no information found.

12.3 Mobility in soil

- No information found.
- Surface tension: no information found.
- Assessment/Classification: no information found.

12.4 Results of PBT and vPvB assessment

This product does not meet the PBT/vPvB criteria REACH.

12.5 Other adverse effects

None.

Section 13. Disposal consideration

13.1 Waste treatment methods

Dispose of the product according to local requirements.

13.1.1 Product/Packing disposal

Dispose of the product according to local requirements.

13.1.2 Waste treatment relevant information

Can be incinerated in compliance with applicable local technical regulations, following consultation with approved waste disposal management companies and authorities in charge.

13.1.3 Sewage disposal-relevant information

Release to environment or sewage system is prohibited. Must be treated as hazardous waste.

13.1.4 Other disposal recommendation

Handle contaminated package in the same way as the substance itself.

Section 14. Transport information

14.1 UN number

- ADR/RID: Void
- IMDG: Void
- ICAO/TI/IATA-DGR: Void

- AND: Void

14.2 UN proper shipping name

- ADR/RID: Void
- IMDG: Void
- ICAO/TI/IATA-DGR: Void
- AND: Void

14.3 Transport hazard class

- ADR/RID: Void
- IMDG: Void
- ICAO/TI/IATA-DGR: Void
- AND: Void

14.4 Packing group

- ADR/RID: Void
- IMDG: Void
- ICAO/TI/IATA-DGR: Void
- AND: Void

14.5 Environmental hazards

- ADR/RID: Not applicable.
- IMDG: Not applicable.
- ICAO/TI/IATA-DGR: Not applicable.
- AND: Not applicable.

14.6 Special precaution for users

Transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk

Transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

- Transport/additional information: Not dangerous according to the above specifications.

Section 15. Regulatory information

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

EU Regulations:

Authorizations and/or restrictions on use: none

Other EU legislations:

- Commission regulation (EU) N° 474/2014 of 8 May 2014 amending Annex XVII to regulation EC n° 1907/2006

- Commission regulation (EU) N° 944/2013 of 2 October 2013 (5th ATP) amending regulation EC n° 1272/2008 on classification, labeling and packaging of substances and mixtures.
- Waste framework directive 2008/98/EC.

National regulations (UK)

Management of health and safety at work regulations (1999)

Control of Substances hazardous to health regulations (COSHH 2002)

Personal Protective Equipment Regulations (2002)

15.2 Chemical Safety Assessment

For this product a safety assessment has been carried out.

Section 16. Other information

Abbreviations and acronyms:

- ATP: adaptation to technical progress
- Bw: body weight
- CAS N° : chemical abstracts service number
- CLP: classification labeling and packaging regulation
- EC: European commission
- EC N°: European chemical number: EINECS, ELINCS or NLP
- ECHA: European chemical agency
- EEC: European economic community
- EINECS: European inventory of existing commercial chemical substances
- ELINCS: European list of notified chemical substances
- ERC: Environmental release category
- EU: European Union
- GLP: Good Laboratory Practice
- GMP: Good Manufacturing Practice
- PBT: Persistence, Bio cumulative and Toxic
- PC: Product category
- REACH: Registration Evaluation, Authorization and Restriction of Chemicals
- SDS: Safety Data Sheet
- SU: Sector of Use
- vPvB: Very Persistent and Very Bio cumulative

- WEL: Workplace exposure limits.

Additional Information

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 safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In case of mixing the product with other product, the information on this safety data sheet is not necessarily valid for the new made up material.