

Oxygen 4 Pharma

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

1.1. Product identifier

| | |
|------------------------|---|
| Product form | : Substance |
| Trade name | : Oxygen 4 Pharma Oxygen 4 Pharma 5.0 |
| SDS code | : 097A_PHARMA |
| Internal reference no. | : 000380 |
| Chemical description | : Oxygen |
| CAS-No. | : 7782-44-7 |
| EC-No. | : 231-956-9 |
| EC Index-No. | : 008-001-00-8 |
| Registration-No. | : Listed in Annex IV / V REACH, exempted from registration. |
| Chemical formula | : O ₂ |

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

| | |
|--------------------------|--|
| Relevant identified uses | : Industrial and professional. Perform risk assessment prior to use. Pharmaceutical industry. Contact supplier for more information on uses. |
| Uses advised against | : Consumer use. |

1.3. Details of the supplier of the safety data sheet

| | |
|------------------------|---|
| Company identification | : Sapio Produzione Idrogeno Ossigeno Srl Via S. Pellico, 48 20900 Monza - ITALIA +39 039 83981 +39 039 836068 http://www.sapio.it/ sds@sapio.it |
|------------------------|---|

1.4. Emergency telephone number

| | |
|----------------------------|-------------------------|
| Emergency telephone number | : +39 0295705444 (24/7) |
|----------------------------|-------------------------|

SECTION 2: Hazards identification



2.1. Classification of the substance or mixture

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

| | | |
|------------------|--------------------------------------|------|
| Physical hazards | Oxidising Gases, Category 1 | H270 |
| | Gases under pressure: Compressed gas | H280 |

2.2. Label elements

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

| | |
|--------------------------------|--|
| Hazard pictograms (CLP) | :   |
| | : GHS03 GHS04 |
| Signal word (CLP) | : Danger |
| Hazard statements (CLP) | : H270 - May cause or intensify fire; oxidiser. H280 - Contains gas under pressure; may explode if heated. |
| Precautionary statements (CLP) | : - Prevention : P220 - Keep away from clothing and other combustible materials. P244 - Keep valves and fittings free from oil and grease. - Response : P370+P376 - In case of fire: stop leak if safe to do so. - Storage : P403 - Store in a well-ventilated place. |

2.3. Other hazards

| | |
|--|---------|
| Other hazards not contributing to the classification | : None. |
|--|---------|

SECTION 3: Composition/information on ingredients

3.1. Substances

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| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|--------|---|-----|---|
| Oxygen | CAS-No.: 7782-44-7 EC-No.: 231-956-9 EC Index-No.: 008-001-00-8 Registration-No.: *1 | 100 | Ox. Gas 1, H270 Press. Gas (Comp.), H280 |

Contains no other components or impurities which will influence the classification of the product.

*1: Listed in Annex IV / V REACH, exempted from registration.

*2: Registration deadline not expired.

*3: Registration not required: Substance manufactured or imported < 1t/y.

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- Inhalation : Remove victim to uncontaminated area.
- Skin contact : Adverse effects not expected from this product.
- Eye contact : Adverse effects not expected from this product.
- Ingestion : Ingestion is not considered a potential route of exposure.

4.2. Most important symptoms and effects, both acute and delayed

Continuous inhalation of concentrations higher than 75% may cause nausea, dizziness, respiratory difficulty and convulsion.

Refer to section 11.

4.3. Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray or fog.
- Unsuitable extinguishing media : Do not use water jet to extinguish.

5.2. Special hazards arising from the substance or mixture

- Specific hazards : Supports combustion.
Exposure to fire may cause containers to rupture/explode.
- Hazardous combustion products : None.

5.3. Advice for firefighters

- Specific methods : Use fire control measures appropriate for the surrounding fire. Exposure to fire and heat radiation may cause gas receptacles to rupture. Cool endangered receptacles with water spray jet from a protected position. Prevent water used in emergency cases from entering sewers and drainage systems.
If possible, stop flow of product.
Use water spray or fog to knock down fire fumes if possible.
Move containers away from the fire area if this can be done without risk.
- Special protective equipment for fire fighters : Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters.
Standard EN 469 - Protective clothing for firefighters. Standard - EN 659: Protective gloves for firefighters.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- Try to stop release.
- Evacuate area.
- Monitor concentration of released product.
- Wear self-contained breathing apparatus when entering area unless atmosphere is proved to be safe.
- Eliminate ignition sources.
- Ensure adequate air ventilation.
- Act in accordance with local emergency plan.
- Stay upwind.

6.2. Environmental precautions

- Try to stop release.

6.3. Methods and material for containment and cleaning up

- Ventilate area.

6.4. Reference to other sections

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See also sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Safe use of the product

- : The product must be handled in accordance with good industrial hygiene and safety procedures. Only experienced and properly instructed persons should handle gases under pressure. Consider pressure relief device(s) in gas installations. Ensure the complete gas system was (or is regularly) checked for leaks before use. Do not smoke while handling product. Keep equipment free from oil and grease. Use no oil or grease. Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt. Use only oxygen approved lubricants and oxygen approved sealings. Use only with equipment cleaned for oxygen service and rated for cylinder pressure. Avoid suck back of water, acid and alkalis. Do not breathe gas.

Safe handling of the gas receptacle

- : Do not allow backfeed into the container. Protect receptacles from physical damage; do not drag, roll, slide or drop. When moving receptacles, even for short distances, use a cart (trolley, hand truck, etc.) designed to transport receptacles. Leave valve protection caps in place until the container has been secured against either a wall or bench or placed in a container stand and is ready for use. If user experiences any difficulty operating receptacle valve discontinue use and contact supplier. Never attempt to repair or modify container valves or safety relief devices. Damaged valves should be reported immediately to the supplier. Keep container valve outlets clean and free from contaminants particularly oil and water. Replace valve outlet caps or plugs and container caps where supplied as soon as container is disconnected from equipment. Close container valve after each use and when empty, even if still connected to equipment. Never attempt to transfer gases from one container to another. Never use direct flame or electrical heating devices to raise the pressure of a container. Do not remove or deface labels provided by the supplier for the identification of the receptacle contents. Suck back of water into the container must be prevented. Open valve slowly to avoid pressure shock.

7.2. Conditions for safe storage, including any incompatibilities

- Observe all regulations and local requirements regarding storage of containers. Containers should not be stored in conditions likely to encourage corrosion. Container valve guards or caps should be in place. Containers should be stored in the vertical position and properly secured to prevent them from falling over. Stored containers should be periodically checked for general condition and leakage. Keep container below 50°C in a well ventilated place. Segregate from flammable gases and other flammable materials in store. Store containers in location free from fire risk and away from sources of heat and ignition. Keep away from combustible materials.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- OEL (Occupational Exposure Limits) : None available.
- DNEL (Derived-No Effect Level) : None available.
- PNEC (Predicted No-Effect Concentration) : None available.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

- Provide adequate general and local exhaust ventilation. Systems under pressure should be regularly checked for leakages. Avoid oxygen rich (>23,5%) atmospheres. Gas detectors should be used when oxidising gases may be released. Consider the use of a work permit system e.g. for maintenance activities.

8.2.2. Individual protection measures, e.g. personal protective equipment

- A risk assessment should be conducted and documented in each work area to assess the risks related to the use of the product and to select the PPE that matches the relevant risk. The following recommendations should be considered:

PPE compliant to the recommended EN/ISO standards should be selected.

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- Eye/face protection : Wear safety glasses with side shields.
Standard EN 166 - Personal eye-protection - specifications.
- Skin protection
 - Hand protection : Wear working gloves when handling gas containers.
Standard EN 388 - Protective gloves against mechanical risk.
 - Other : Consider the use of flame resistant safety clothing.
Standard EN ISO 14116 - Limited flame spread materials.
Wear safety shoes while handling containers.
Standard EN ISO 20345 - Personal protective equipment - Safety footwear.
- Respiratory protection : None necessary.
- Thermal hazards : None in addition to the above sections.

8.2.3. Environmental exposure controls

Refer to local regulations for restriction of emissions to the atmosphere. See section 13 for specific methods for waste gas treatment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|--|
| Appearance | |
| <ul style="list-style-type: none"> • Physical state at 20°C / 101.3kPa • Colour | <ul style="list-style-type: none"> : Gas : Colourless. |
| Odour | : No odour warning properties. |
| Odour threshold | : Odour threshold is subjective and inadequate to warn of overexposure. |
| pH | : Not applicable for gases and gas mixtures. |
| Melting point / Freezing point | : -219 °C |
| Boiling point | : -183 °C |
| Flash point | : Not applicable for gases and gas mixtures. |
| Evaporation rate | : Not applicable for gases and gas mixtures. |
| Flammability (solid, gas) | : Non flammable. |
| Explosive limits | : Non flammable. |
| Vapour pressure [20°C] | : Not applicable. |
| Vapour pressure [50°C] | : Not applicable. |
| Vapour density | : Not applicable. |
| Relative density, liquid (water=1) | : 1,1 |
| Relative density, gas (air=1) | : 1,1 |
| Water solubility | : 39 mg/l |
| Partition coefficient n-octanol/water (Log Kow) | : Not applicable for inorganic gases. |
| Auto-ignition temperature | : Non flammable. |
| Decomposition temperature | : Not applicable. |
| Viscosity | : No reliable data available. |
| Explosive properties | : Not applicable. |
| Oxidising properties | : Oxidiser. |

9.2. Other information

| | |
|--|------------|
| Molar mass | : 32 g/mol |
| Critical temperature | : -118 °C |
| - Coefficient of oxygen equivalency (Ci) | : 1 |

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazard other than the effects described in sub-sections below.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Violently oxidises organic material.

10.4. Conditions to avoid

Avoid moisture in installation systems.

10.5. Incompatible materials

May react violently with combustible materials.
May react violently with reducing agents.

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Keep equipment free from oil and grease.

Consider the potential toxicity hazard due to the presence of chlorinated or fluorinated polymers in high pressure (> 30 bar) oxygen lines in case of combustion.

For additional information on compatibility refer to ISO 11114.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|---------------------------------------|---|
| Acute toxicity | : No known toxicological effects from this product. |
| Skin corrosion/irritation | : No known effects from this product. |
| Serious eye damage/irritation | : No known effects from this product. |
| Respiratory or skin sensitisation | : No known effects from this product. |
| Germ cell mutagenicity | : No known effects from this product. |
| Carcinogenicity | : No known effects from this product. |
| Toxic for reproduction : Fertility | : No known effects from this product. |
| Toxic for reproduction : unborn child | : No known effects from this product. |
| STOT-single exposure | : No known effects from this product. |
| STOT-repeated exposure | : No known effects from this product. |
| Aspiration hazard | : Not applicable for gases and gas mixtures. |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|--------------------------|--|
| Assessment | : No ecological damage caused by this product. |
| EC50 48h - Daphnia magna | : No data available. |
| EC50 72h - Algae | : No data available. |
| LC50 96 h - Fish | : No data available. |

12.2. Persistence and degradability

| | |
|------------|--|
| Assessment | : No ecological damage caused by this product. |
|------------|--|

12.3. Bioaccumulative potential

| | |
|------------|----------------------|
| Assessment | : No data available. |
|------------|----------------------|

12.4. Mobility in soil

| | |
|------------|---|
| Assessment | : Because of its high volatility, the product is unlikely to cause ground or water pollution. Partition into soil is unlikely. |
|------------|---|

12.5. Results of PBT and vPvB assessment

| | |
|------------|----------------------|
| Assessment | : No data available. |
|------------|----------------------|

12.6. Other adverse effects

| | |
|---------------------------|---------------------------------------|
| Other adverse effects | : No known effects from this product. |
| Effect on the ozone layer | : None. |
| Effect on global warming | : None. |

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Contact supplier if guidance is required.

May be vented to atmosphere in a well ventilated place.

Do not discharge into any place where its accumulation could be dangerous.

Ensure that the emission levels from local regulations or operating permits are not exceeded.

Refer to the EIGA code of practice Doc.30 "Disposal of Gases", downloadable at <http://www.eiga.eu> for more guidance on suitable disposal methods.

Return unused product in original receptacle to supplier.

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List of hazardous waste codes (from Commission Decision 2001/118/EC) : 16 05 04 *: Gases in pressure containers (including halons) containing dangerous substances.

13.2. Additional information

External treatment and disposal of waste should comply with applicable local and/or national regulations.

SECTION 14: Transport information

14.1. UN number

UN-No. : 1072

14.2. UN proper shipping name

Transport by road/rail (ADR/RID) : OXYGEN, COMPRESSED

Transport by air (ICAO-TI / IATA-DGR) : Oxygen, compressed

Transport by sea (IMDG) : OXYGEN, COMPRESSED

14.3. Transport hazard class(es)

Labelling :



2.2 : Non-flammable, non-toxic gases.

5.1 : Oxidizing substances.

Transport by road/rail (ADR/RID)

Class : 2

Classification code : 10

Hazard identification number : 25

Tunnel Restriction : E - Passage forbidden through tunnels of category E

Transport by air (ICAO-TI / IATA-DGR)

Class / Div. (Sub. risk(s)) : 2.2 (5.1)

Transport by sea (IMDG)

Class / Div. (Sub. risk(s)) : 2.2 (5.1)

Emergency Schedule (EmS) - Fire : F-C

Emergency Schedule (EmS) - Spillage : S-W

14.4. Packing group

Transport by road/rail (ADR/RID) : Not applicable

Transport by air (ICAO-TI / IATA-DGR) : Not applicable

Transport by sea (IMDG) : Not applicable

14.5. Environmental hazards

Transport by road/rail (ADR/RID) : None.

Transport by air (ICAO-TI / IATA-DGR) : None.

Transport by sea (IMDG) : None.

14.6. Special precautions for user

Packing Instruction(s)

Transport by road/rail (ADR/RID) : P200

Transport by air (ICAO-TI / IATA-DGR)

Passenger and Cargo Aircraft : 200.

Cargo Aircraft only : 200.

Transport by sea (IMDG) : P200

Special transport precautions

: Avoid transport on vehicles where the load space is not separated from the driver's compartment.
 Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.
 Before transporting product containers:
 - Ensure there is adequate ventilation.
 - Ensure that containers are firmly secured.
 - Ensure container valve is closed and not leaking.
 - Ensure valve outlet cap nut or plug (where provided) is correctly fitted.
 - Ensure valve protection device (where provided) is correctly fitted.

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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

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

EU-Regulations

Restrictions on use : None.
Seveso Directive : 2012/18/EU (Seveso III) : Listed.

National regulations

National legislation : Ensure all national/local regulations are observed.

15.2. Chemical safety assessment

A CSA does not need to be carried out for this product.

SECTION 16: Other information

Indication of changes : Revised safety data sheet in accordance with commission regulation (EU) No 453/2010.

Abbreviations and acronyms : ATE: Acute Toxicity Estimate
CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstract Service
PPE: Personal Protection Equipment
LC50 - Lethal Concentration to 50 % of a test population
RMM: Risk Management Measures
PBT - Persistent, Bioaccumulative and Toxic
vPvB - Very Persistent and Very Bioaccumulative
STOT- SE: Specific Target Organ Toxicity - Single Exposure
CSA: Chemical Safety Assessment
EN: European Standard
UN: United Nations
ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road
IATA - International Air Transport Association
IMDG code - International Maritime Dangerous Goods
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail
WGK: Water Hazard Class
STOT - RE: Specific Target Organ Toxicity - Repeated Exposure

Training advice : Ensure operators understand the hazard of oxygen enrichment.

DISCLAIMER OF LIABILITY : Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out.
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Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use can be accepted.