

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision date: 04/07/2018 Version: 1.0

SDS_Ind.Mix_001

4 Pharma 130

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

1.1. Product identifier

 Product form
 : Mixture

 Trade name
 : 4 Pharma 130

 SDS code
 : SDS_Ind.Mix_001

 Internal reference no.
 : 001720

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 Gases under pressure: Compressed gas H280

2.2. Label elements

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

Hazard pictograms (CLP)

 \Diamond

GHS04

Signal word (CLP) : Warning

Hazard statements (CLP) : H280 - Contains gas under pressure; may explode if heated.

Precautionary statements (CLP)

- Storage : P403 - Store in a well-ventilated place.

2.3. Other hazards

Other hazards not contributing to the classification : Asphyxiant in high concentrations.

In high concentrations CO2 cause rapid circulatory insufficiency. Symptoms are headache, nausea and

vomiting, which may lead to unconsciousness.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Nitrogen	CAS-No.: 7727-37-9 EC-No.: 231-783-9 EC Index-No.: Registration-No.: *1	70	Press. Gas (Comp.), H280
Carbon dioxide	CAS-No.: 124-38-9 EC-No.: 204-696-9 EC Index-No.: Registration-No.: *1	30	Press. Gas (Liq.), H280

Full text of H-statements: see section 16

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



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SDS_Ind.Mix_001

Revision date: 04/07/2018 Version: 1.0

4 Pharma 130

- *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.

SECTION 4: First aid measures

4.1. Description of first aid measures

- Inhalation Remove victim to uncontaminated area wearing self contained breathing apparatus. Keep victim warm and

rested. Call a doctor. Perform cardiopulmonary resuscitation if breathing stopped.

- Skin contact Adverse effects not expected from this product. Adverse effects not expected from this product. - Eve contact

- Ingestion Ingestion is not considered a potential route of exposure.

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

In high concentrations may cause asphyxiation. Symptoms may include loss of mobility/consciousness.

Victim may not be aware of asphyxiation.

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 : Exposure to fire may cause containers to rupture/explode.

Hazardous combustion products

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 In confined space use self-contained breathing apparatus.

Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters. Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask. 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.

Wear self-contained breathing apparatus when entering area unless atmosphere is proved to be safe.

Ensure adequate air ventilation

Prevent from entering sewers, basements and workpits, or any place where its accumulation can be

dangerous

Act in accordance with local emergency plan.

Stav upwind.

Oxygen detectors should be used when asphyxiating gases may be released.

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

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.

Sapio Produzione Idrogeno Ossigeno Srl EN (English) Internal reference no.: 001720



Safe handling of the gas receptacle

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SDS_Ind.Mix_001

Revision date: 04/07/2018 Version: 1.0

4 Pharma 130

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 regularily) checked for leaks before use.

Do not smoke while handling product.

Use only properly specified equipment which is suitable for this product, its supply pressure and temperature.

Contact your gas supplier if in doubt.

Avoid suck back of water, acid and alkalis.

Do not breathe gas.

Avoid release of product into atmosphere.

: 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.

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

Carbon dioxide (124-38-9)				
OEL: Occupational Exposure Limits				
ACGIH	ACGIH TWA (ppm)	5000 ppm		
	ACGIH STEL (ppm)	30000 ppm		
	Remark (ACGIH)	Asphyxia		
	Regulatory reference	ACGIH 2017		
Italy	TWA (IT) OEL 8h [mg/m³]	9000 mg/m³		
	TWA (IT) OEL 8h [ppm]	5000 ppm		
	Regulatory reference	Allegato XXXVIII del D.Lgs. 9 aprile 2008, n. 81 e s.m.i.		

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 regularily checked for leakages.

Ensure exposure is below occupational exposure limits (where available).

Oxygen detectors should be used when asphyxiating 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.

• Eye/face protection : Wear safety glasses with side shields

Standard EN 166 - Personal eye-protection - specifications.

Skin protection

Sapio Produzione Idrogeno Ossigeno Srl EN (English) Internal reference no.: 001720 3/



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SDS_Ind.Mix_001

Revision date: 04/07/2018 Version: 1.0

4 Pharma 130

- Hand protection : Wear working gloves when handling gas containers.

Standard EN 388 - Protective gloves against mechanical risk.

- Other : Wear safety shoes while handling containers.

Standard EN ISO 20345 - Personal protective equipment - Safety footwear.

• Respiratory protection : Gas filters may be used if all surrounding conditions e.g. type and concentration of the contaminant(s) and

duration of use are known.

Use gas filters with full face mask, where exposure limits may be exceeded for a short-term period, e.g.

connecting or disconnecting containers.

Gas filters do not protect against oxygen deficiency.

Self contained breathing apparatus (SCBA) or positive pressure airline with mask are to be used in oxygen-

deficient atmospheres.

Standard EN 14387 - Gas filter(s), combined filter(s) and full face mask - EN 136.

Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask.

• Thermal hazards : None in addition to the above sections.

8.2.3. Environmental exposure controls

None necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Odour

Physical state at 20°C / 101.3kPa
 Gas

. Mixture contains one or more component(s) which have the following colour(s):

Colourless.

Odourless.

Odour threshold : Odour threshold is subjective and inadequate to warn of overexposure.

pH : Not applicable for gases and gas mixtures.

Melting point / Freezing point : Not applicable for gas mixtures. Boiling point : Not applicable for gas mixtures.

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, gas (air=1) : Heavier than air.

Partition coefficient n-octanol/water (Log Kow) : Not applicable for gas mixtures.

Auto-ignition temperature : Non flammable.

Decomposition temperature : Not applicable.

Viscosity : No reliable data available.

Explosive properties : Not applicable.

Oxidising properties : Not applicable.

9.2. Other information

Molar mass : Not applicable for gas mixtures.

Other data : Gas/vapour heavier than air. May accumulate in confined spaces, particularly at or below ground level.

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

None.

10.4. Conditions to avoid

Avoid moisture in installation systems.

10.5. Incompatible materials

None

For additional information on compatibility refer to ISO 11114.

10.6. Hazardous decomposition products

Sapio Produzione Idrogeno Ossigeno Srl EN (English) Internal reference no.: 001720 4/



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision date: 04/07/2018 Version: 1.0

SDS_Ind.Mix_001

4 Pharma 130

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Toxicological effects not expected from this product if occupational exposure limit values are not exceeded.

: Not applicable for gases and gas mixtures.

Unlike simple asphyxiants, carbon dioxide has the ability to cause death even when normal oxygen levels (20-21%) are maintained. 5% CO2 has been found to act synergistically to increase the toxicity of certain other gases (CO, NO2). CO2 has been shown to enhance the production of carboxy- or met-hemoglobin by these gases possibly due to carbon dioxide's stimulatory effects on the respiratory and circulatory systems. For more information, see EIGA Safety Info 24: "Carbon Dioxide, Physiological hazards" at www.eiga.eu.

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. : No known effects from this product. Carcinogenicity 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.

SECTION 12: Ecological information

12.1. Toxicity

Aspiration hazard

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 : Not classified as PBT or vPvB.

12.6. Other adverse effects

Other adverse effects : No known effects from this product.

Effect on the ozone layer : None

Effect on global warming : Contains greenhouse gas(es).

SECTION 13: Disposal considerations

13.1. Waste treatment methods

May be vented to atmosphere in a well ventilated place.

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

Return unused product in original receptacle to supplier.

List of hazardous waste codes (from Commission

Decision 2001/118/EC)

: $16\ 05\ 05$: Gases in pressure containers other than those mentioned in $16\ 05\ 04$.

13.2. Additional information

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

Sapio Produzione Idrogeno Ossigeno Srl EN (English) Internal reference no.: 001720 5/7



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision date: 04/07/2018 Version: 1.0

SDS_Ind.Mix_001

4 Pharma 130

SECTION 14: Transport information

14.1. UN number

UN-No. : 1956

14.2. UN proper shipping name

Transport by road/rail (ADR/RID)

: COMPRESSED GAS, N.O.S. (Nitrogen, Carbon dioxide)

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

: Compressed gas, n.o.s. (Nitrogen, Carbon dioxide)

Transport by sea (IMDG)

: COMPRESSED GAS, N.O.S. (Nitrogen, Carbon dioxide)

14.3. Transport hazard class(es)

Labelling



2.2 : Non-flammable, non-toxic gases.

Transport by road/rail (ADR/RID)

Class : 2
Classification code : 1A
Hazard identification number : 20

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

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

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

Transport by sea (IMDG)

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

 Emergency Schedule (EmS) - Fire
 : F-C

 Emergency Schedule (EmS) - Spillage
 : S-V

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.

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

Sapio Produzione Idrogeno Ossigeno Srl EN (English) Internal reference no.: 001720 6/7



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision date: 04/07/2018 Version: 1.0

SDS_Ind.Mix_001

4 Pharma 130

EU-Regulations

Restrictions on use : None.
Seveso Directive : 2012/18/EU (Seveso III) : Not covered.

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 : The hazard of asphyxiation is often overlooked and must be stressed during operator training.

For more guidance, refer to EIGA SL 01 "Dangers of Asphyxiation", downloadable at http://www.eiga.eu..

Further information : Classification using data from databases maintained by the European Industrial Gases Association (EIGA).

Classification in accordance with the calculation methods of Regulation (EC) 1272/2008 CLP.

Full wording of relevant H Statements and classification codes

Press. Gas (Comp.)	Gases under pressure: Compressed gas
Press. Gas (Liq.)	Gases under pressure: Liquefied gas
H280	Contains gas under pressure; may explode if heated.

DISCLAIMER OF LIABILITY

: Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out.

Details given in this document are believed to be correct at the time of going to press.

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.

Sapio Produzione Idrogeno Ossigeno Srl EN (English) Internal reference no.: 001720 7/7