

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

000A_MED_SINT

Revision date: 30/03/2019 Version: 1.0

Air sintetica medicinale

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

1.1. Product identifier

Product form : Mixture

Trade name : Air sintetica medicinale SDS code : 000A_MED_SINT Internal reference no. : 003040

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.

Uso ospedaliero.

Contact supplier for more information on uses.

Uses advised against : None.

1.3. Details of the supplier of the safety data sheet

Company identification : Sapio Life Srl

Via S. Pellico, 48 20900 Monza - ITALIA

+39 039 83981 | +39 039 836068

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

Hazard pictograms (CLP)

Labelling according to Regulation (EC) No. 1272/2008 [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 : None.

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	76,37 - 80,05	Press. Gas (Comp.), H280
Oxygen	CAS-No.: 7782-44-7 EC-No.: 231-956-9 EC Index-No.: 008-001-00-8 Registration-No.: *1	19,95 - 23,62	Ox. Gas 1, H270 Press. Gas (Comp.), H280

Full text of H-statements: see section 16

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

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^{*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.



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SECTION 4: First aid measures

4.1. Description of first aid measures

- Inhalation
- Skin contact
- Eye contact
- Ingestion
- Adverse effects not expected from this product.
- Adverse effects not expected from this product.
- Ingestion is not considered a potential route of exposure.

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

No effect on living tissue. 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

Act in accordance with local emergency plan.

Stay upwind.

6.2. Environmental precautions

None.

6.3. Methods and material for containment and cleaning up

None

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.

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.

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.

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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

Nitrogen (7727-37-9)				
OEL : Occupational Exposure Limits				
ACGIH	Remark (ACGIH)	TLV® Basis: Simple Asphyxiant		
	Regulatory reference	ACGIH 2018		

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 regularily checked for leakages. 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

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

- 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 : None necessary.

· 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

Colour

Physical state at 20°C / 101.3kPa

Gas

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

Colourless

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Odour : 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 known.
Boiling point : Not known.

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) : Not applicable.

Relative density, gas (air=1) : 1

Water solubility : Not known, but considered to have low solubility.

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

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 : 29 g/mol Critical temperature : Not known.

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

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : No 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

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: No ecological damage caused by this product. Assessment

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 : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

May be vented to atmosphere.

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 2000/532/EC as amended)

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.

SECTION 14: Transport information

14.1. UN number

UN-No. : 1002

14.2. UN proper shipping name

Transport by road/rail (ADR/RID) : AIR, COMPRESSED Transport by air (ICAO-TI / IATA-DGR) : Air, compressed Transport by sea (IMDG) : AIR. COMPRESSED

14.3. Transport hazard class(es)

Labelling



2.2: Non-flammable, non-toxic gases.

Transport by road/rail (ADR/RID)

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

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

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

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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)

: 200. Passenger and Cargo Aircraft : 200. Cargo Aircraft only 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

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

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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 : Not Full wording of relevant H Statements and classification codes

Ox. Gas 1	Oxidising Gases, Category 1
Press. Gas (Comp.)	Gases under pressure: Compressed gas
H270	May cause or intensify fire; oxidiser.
H280	Contains as 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.

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