Danger

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

1.1. Product identifier

Trade name : SpiroxiLife MD 5

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

Relevant identified uses : Spirometry

Uses advised against : Consumer use.
Uses other than those listed above are not supported, contact your supplier for more information on other uses.

1.3. Details of the supplier of the safety data sheet

Sapio Life Srl
Via S. Pellico, 48 20900 Monza (MB)
+39 039 83981 | +39 039 836068
http://www.sapiolife.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
Health hazards	Reproductive toxicity, Category 1A	H360D

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS04 GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H280 - Contains gas under pressure; may explode if heated.
H360D - May damage the unborn child.

Precautionary statements (CLP)

- Prevention : P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing, eye protection.
- Response : P308+P313 - IF exposed or concerned: Get medical advice/attention.
- Storage : P403 - Store in a well-ventilated place.
P405 - Store locked up.

Supplemental information : Restricted to professional users.

2.3. Other hazards

Not classified as PBT or vPvB.
The substance/mixture has no endocrine disrupting properties.

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.: --- REACH-no: *1	Balance	Press. Gas (Comp.), H280
oxygen	CAS-No.: 7782-44-7 EC-No.: 231-956-9 EC Index-No.: 008-001-00-8 REACH-no: *1	20	Ox. Gas 1, H270 Press. Gas (Comp.), H280
Helium	CAS-No.: 7440-59-7 EC-No.: 231-168-5 EC Index-No.: --- REACH-no: *1	7 - 15	Press. Gas (Comp.), H280
carbon monoxide	CAS-No.: 630-08-0 EC-No.: 211-128-3 EC Index-No.: 006-001-00-2 REACH-no: 01-2119480165-39	0,3	Flam. Gas 1B, H221 Press. Gas (Comp.), H280 Acute Tox. 3 (Inhalation:gas), H331 Repr. 1A, H360D STOT RE 1, H372
acetylene (dissolved)	CAS-No.: 74-86-2 EC-No.: 200-816-9 EC Index-No.: 601-015-00-0 REACH-no: 01-2119457406-36	0,3	Flam. Gas 1A - Chem. Unst. Gas A, H220;H230 Press. Gas (Diss.), H280

Full text of H- and EUH-statements: see section 16
Contains no other components or impurities which will influence the classification of the product.
**1: Listed in Annex IV / V REACH, exempted from registration.*
**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.
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

See 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.
Product does not burn, use fire control measures appropriate for the surrounding fire.

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 : carbon monoxide. carbon monoxide.

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 : Wear gas tight chemically protective clothing in combination with self contained breathing apparatus.
Standard EN 943-2: Protective clothing against liquid and gaseous chemicals, aerosols and solid particles. Gas-tight chemical protective suits for emergency teams.
Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Act in accordance with local emergency plan.
Evacuate area.
Ensure adequate air ventilation.
Stay upwind.
See section 8 of the SDS for more information on personal protective equipment

For emergency responders : Wear self-contained breathing apparatus when entering area unless atmosphere is proved to be safe.
See section 5.3 of the SDS for more information.

6.2. Environmental precautions

No additional information available

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 : Avoid exposure, obtain special instructions before use.
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.
Use only oxygen approved lubricants and oxygen approved sealings.
Avoid suck back of water, acid and alkalis.
Do not breathe gas.
Avoid release of product into work area.

Safe handling of the gas receptacle : Do not allow backfeed into the container.
Protect containers from physical damage; do not drag, roll, slide or drop.
When moving cylinders, even for short distances, use a cart (trolley, hand truck, etc.) designed to transport cylinders.
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 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 cylinder/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 content of the container.
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)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Nitrogen

Remark (ACGIH)	TLV® Basis: Simple Asphyxiant
Regulatory reference	ACGIH 2019

Helium (7440-59-7)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Helium
Remark (ACGIH)	TLV® Basis: Simple Asphyxiant
Regulatory reference	ACGIH 2019

carbon monoxide (630-08-0)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Carbon monoxide
IOEL TWA	23 mg/m³
IOEL TWA [ppm]	20 ppm
IOEL STEL	117 mg/m³
IOEL STEL [ppm]	100 ppm
Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164
Italy - Occupational Exposure Limits	
Local name	Monossido di carbonio
OEL TWA	23 mg/m³
OEL TWA [ppm]	20 ppm
OEL STEL	117 mg/m³
OEL STEL [ppm]	100 ppm
Regulatory reference	Allegato XXXVIII del D.Lgs. 9 aprile 2008, n. 81 e s.m.i.
USA - ACGIH - Occupational Exposure Limits	
Local name	Carbon monoxide
ACGIH OEL TWA [ppm]	25 ppm
Remark (ACGIH)	TLV® Basis: COHb-emia. Notations: BEI
Regulatory reference	ACGIH 2019

acetylene (dissolved) (74-86-2)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Acetylene
Remark (ACGIH)	TLV® Basis: Simple Asphyxiant
Regulatory reference	ACGIH 2019

carbon monoxide (630-08-0)
DNEL: Derived no effect level (Workers)

Acute - local effects, inhalation	117 ppm
Acute - systemic effects, inhalation	117 mg/m³
Long-term - local effects, inhalation	23 ppm
Long-term - systemic effects, inhalation	23 mg/m³

acetylene (dissolved) (74-86-2)	
DNEL: Derived no effect level (Workers)	
Acute - systemic effects, inhalation	2675 mg/m³
Long-term - systemic effects, inhalation	2675 mg/m³

PNEC (Predicted No-Effect Concentration) : None established.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Product to be handled in a closed system and under strictly controlled conditions.
Provide adequate general and local exhaust ventilation.
Preferably use permanent leak-tight installations (e.g. welded pipes).
Systems under pressure should be regularly checked for leakages.
Ensure exposure is below occupational exposure limits (where available).
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

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 : When indicated by a risk assessment, Respiratory Protective Equipment must be used. The selection of the Respiratory Protective Device (RPD) must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected RPD.
Self contained breathing apparatus is recommended, where unknown exposure may be expected, e.g. during maintenance activities on installation systems.
Keep self contained breathing apparatus readily available for emergency use.
Consult respiratory device supplier´s product information for the selection of the appropriate device.
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

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

- Physical state at 20°C / 101.3kPa : Gas

- Colour	:	Mixture contains one or more component(s) which have the following colour(s): Colourless.
Odour	:	There may be no odour warning properties, odour is subjective and inadequate to warn of overexposure. Mixture contains one or more component(s) which have the following odour: Garlic like. 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 gases and gas mixtures.
Boiling point	:	Not applicable for gas mixtures.
Flash point	:	Not applicable for gases and gas mixtures.
Flammability	:	Non flammable.
Explosive limits	:	Non flammable.
Lower explosive limit (LEL)	:	Not available
Upper explosive limit (UEL)	:	Not available
Vapour pressure [20°C]	:	Not applicable.
Vapour pressure [50°C]	:	Not applicable.
Density	:	Not applicable
Vapour density	:	Not applicable for gases and gas mixtures.
Relative density, liquid (water=1)	:	Not applicable
Relative density, gas (air=1)	:	Lighter or similar to air.
Water solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not applicable for gas mixtures.
Auto-ignition temperature	:	Non flammable.
Decomposition temperature	:	Not applicable.
Viscosity, kinematic	:	Not applicable for gases and gas mixtures.
Particle characteristics	:	Not applicable for gases and gas mixtures.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Oxidising properties	:	No oxidising properties.
	:	

9.2.2. Other safety characteristics

Other data	:	None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Data for mixture are not available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None.

Reactivity	:	This mixture contains components with the following reactivity : Violently oxidises organic material. May decompose violently at high temperature and/or pressure or in the presence of a catalyst. Can form explosive mixture with air. May react violently with oxidants. May react explosively even in the absence of air.

10.4. Conditions to avoid

Avoid moisture in installation systems.

10.5. Incompatible materials

For additional information on compatibility refer to ISO 11114.

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity : Classification criteria are not met.

carbon monoxide (630-08-0)	
LC50 Inhalation - Rat [ppm]	3760 ppm/1h (ADR) 1300 ppm/4h (CLP)

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 : May damage the unborn child.

STOT-single exposure : No known effects from this product.

STOT-repeated exposure : Classification criteria are not met.

Aspiration hazard : Not applicable for gases and gas mixtures.

11.2. Information on other hazards

Other information : The substance/mixture has no endocrine disrupting properties.

SECTION 12: Ecological information

12.1. Toxicity

Assessment : Classification criteria are not met.

EC50 48h - Daphnia magna [mg/l] : No data available.

EC50 72h - Algae [mg/l] : No data available.

LC50 96 h - Fish [mg/l] : No data available.

acetylene (dissolved) (74-86-2)	
EC50 48h - Daphnia magna [mg/l]	242 mg/l
EC50 72h - Algae [mg/l]	57 mg/l
LC50 96 h - Fish [mg/l]	545 mg/l

12.2. Persistence and degradability

Assessment : No data available.

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. Endocrine disrupting properties

The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Other adverse effects : No known effects from this product.
Effect on the ozone layer : No effect on the ozone layer.
Effect on global warming : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Contact supplier if guidance is required.
Must not be discharged to atmosphere.
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 container 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 or ID number

In accordance with ADR / RID / IMDG / IATA / ADN
UN-No. : 1956

14.2. UN proper shipping name

Transport by road/rail (ADR/RID) : COMPRESSED GAS, N.O.S. (Nitrogen, carbon monoxide)
Transport by air (ICAO-TI / IATA-DGR) : Compressed gas, n.o.s. (Nitrogen, carbon monoxide)
Transport by sea (IMDG) : COMPRESSED GAS, N.O.S. (Nitrogen, carbon monoxide)

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 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. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

EU-Regulations

Seveso Directive : 2012/18/EU (Seveso III) : Not covered.

National regulations

Regulatory reference : 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 : Safety data sheet in accordance with commission regulation (EU) No 2020/878.

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 number
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
UFI : Unique Formula Identifier

Training advice : None.

Further information : Classification using data from databases maintained by the European Industrial Gases Association (EIGA). Data is maintained in EIGA doc 169 : 'Classification and Labelling Guide', downloadable at : http://www.eiga.eu.
Classification in accordance with the procedures and calculation methods of Regulation (EC) 1272/2008 (CLP).

Full text of H- and EUH-statements	
Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Flam. Gas 1A - Chem. Unst. Gas A	Flammable gases, Category 1A, Chemically unstable gas A
Flam. Gas 1B	Flammable gases, Category 1B
H220	Extremely flammable gas.
H221	Flammable gas.
H230	May react explosively even in the absence of air.
H270	May cause or intensify fire; oxidiser.
H280	Contains gas under pressure; may explode if heated.
H331	Toxic if inhaled.
H360D	May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
Ox. Gas 1	Oxidising Gases, Category 1
Press. Gas (Comp.)	Gases under pressure : Compressed gas
Press. Gas (Diss.)	Gases under pressure : Dissolved gas
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 1	Specific target organ toxicity — Repeated exposure, Category 1

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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