

# Safety Data Sheet

## Special mixture Spiro 4 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Reference number: 1474  
Revision date: 27/06/2024  
Version: 1.0

### Warning



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

### 1.1. Product identifier

Trade name : Special mixture Spiro 4 for medical application  
SDS no : 1474

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

Relevant identified uses : Industrial and professional uses. Perform risk assessment prior to use.  
Test gas/Calibration gas.  
Laboratory use.  
Contact supplier for more information on uses.  
Medical applications.

Uses advised against : Consumer use.

### 1.3. Details of the supplier of the safety data sheet

Company identification : SOL B S.r.l  
Zoning Ouest 15  
7860 Lessines - Belgique-België  
T 32 068 270333  
<http://www.sol.it/msds2/msds.asp>  
msds@sol.it

### 1.4. Emergency telephone number

Emergency telephone number : +32 070 245245

## 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) :



GHS04

Signal word (CLP) : Warning  
Hazard statements (CLP) : H280 - Contains gas under pressure; may explode if heated.  
Precautionary statements (CLP)  
- Storage : P410+P403 - Protect from sunlight. Store in a well-ventilated place.

### 2.3. Other hazards

None.

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### **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 Compressed	CAS-No.: 7727-37-9 EC-No.: 231-783-9 EC Index-No.: --- REACH-no: *1	71.7	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	19	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	9.3	Press. Gas (Comp.), 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 : Adverse effects not expected from this product.
- 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**

No effect on living tissue.  
 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.
- 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.

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### **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 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.  
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 regularly) 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.  
Do not breathe gas.  
Avoid release of product into work area.

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### Safe handling of the gas receptacle

- : Refer to supplier's container handling instructions.
- 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.
- Containers should be stored in the vertical position and properly secured to prevent them from falling over.

### 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

No additional information 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.
- Consider the use of a work permit system e.g. for maintenance activities.

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

- Eye/face protection
  - : 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.
  - : 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 risks, performance level 1 or higher.
  - Other
    - : Wear safety shoes while handling containers.
    - Standard EN ISO 20345 - Personal protective equipment - Safety footwear.

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- Respiratory protection : Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask.  
Self contained breathing apparatus (SCBA) or positive pressure airline with mask are to be used in oxygen-deficient atmospheres.
- Thermal hazards : None necessary.

### 8.2.3. Environmental exposure controls

None necessary.

## **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 : Colourless.

Odour : Odourless.

Odour threshold is subjective and inadequate to warn of overexposure.

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

Boiling point : Not applicable for gas mixtures.

It is technically not possible to determine the boiling point or range of this mixture.

Component with lowest boiling point: Helium -269 °C

Flammability : Not available

Lower explosion limit : Not available

Upper explosion limit : Not available

Flash point : Not applicable for gas mixtures.

Auto-ignition temperature : Non flammable.

Decomposition temperature : Not available

pH : Not applicable for gas mixtures.

Viscosity, kinematic : Not applicable.

Water solubility [20°C] : Mixture is partially soluble in water

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

Vapour pressure [20°C] : Not applicable.

Vapour pressure [50°C] : Not applicable.

Density and/or relative density : Not applicable.

Relative vapour density (air=1) : Lighter or similar to air.

Particle characteristics : Not applicable.

### **9.2. Other information**

#### **9.2.1. Information with regard to physical hazard classes**

Explosive properties : Not applicable.

Explosion limits : Non flammable.

Oxidising properties : Not applicable.

#### **9.2.2. Other safety characteristics**

Molar mass : Not applicable for gas mixtures.

Evaporation rate : Not applicable for gas mixtures.

Other data : None.

## **SECTION 10: Stability and reactivity**

### **10.1. Reactivity**

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

This mixture contains components with the following reactivity : Violently oxidises organic material.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None.

### 10.4. Conditions to avoid

None.

### 10.5. Incompatible materials

None.

### 10.6. Hazardous decomposition products

None.

## SECTION 11: Toxicological information

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

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.

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Assessment	: No ecological damage caused by this product.
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.

### 12.2. Persistence and degradability

Assessment	: No data available.
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### 12.3. Bioaccumulative potential

Assessment	: No data available.
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### 12.4. Mobility in soil

Assessment	: No data available.
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### 12.5. Results of PBT and vPvB assessment

Assessment	: Not classified as PBT or vPvB.
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### 12.6. Endocrine disrupting properties

Assessment	:
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### 12.7. Other adverse effects

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

Contact supplier if guidance is required.  
 May be vented to atmosphere.  
 Do not discharge into any place where its accumulation could be dangerous.  
 Refer to the EIGA code of practice Doc.30 "Disposal of Gases", downloadable at <http://www.eiga.org> for more guidance on suitable disposal methods.

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

None.

## 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 Compressed , Helium)  
**Transport by air (ICAO-TI / IATA-DGR)** : Compressed gas, n.o.s. (Nitrogen Compressed , Helium)  
**Transport by sea (IMDG)** : COMPRESSED GAS, N.O.S. (Nitrogen Compressed , Helium)

### 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.

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### 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

Restrictions on use : Contains no substance(s) listed on the REACH Candidate List.  
 Other information, restriction and prohibition regulations : Ensure all national/local regulations are observed.  
 Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals).  
 Seveso Directive : 2012/18/EU (Seveso III) : Not covered.

#### National regulations

No additional information available

### 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.  
 Training advice : Receptacle under pressure.  
 Further information : This Safety Data Sheet has been established in accordance with the applicable European Union legislation.  
 Classification in accordance with the procedures and calculation methods of Regulation (EC) 1272/2008 (CLP).

Full text of H- and EUH-statements	
H270	May cause or intensify fire; oxidiser.
H280	Contains gas under pressure; may explode if heated.
Ox. Gas 1	Oxidising Gases, Category 1
Press. Gas (Comp.)	Gases under pressure : Compressed gas



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### 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.

**End of document**