

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 1475
Revision date: 27/06/2024
Version: 1.0

Danger



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

1.1. Product identifier

Trade name : Special mixture Spiro 5 for medical application
SDS no : 1475
UFI : YN24-G0J3-100S-CQ4V

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.
Medical applications.
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
Health hazards	Reproductive toxicity, Category 1A	H360D
	Specific target organ toxicity – Repeated exposure, Category 2	H373

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.
H373 - May cause damage to organs through prolonged or repeated exposure.

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
 Reference number: 1475

Precautionary statements (CLP)

- Prevention : P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
- Response : P314 - Get medical advice/attention if you feel unwell.
- Storage : P405 - Store locked up.

2.3. Other hazards

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 Compressed	CAS-No.: 7727-37-9 EC-No.: 231-783-9 EC Index-No.: --- REACH-no: *1	78	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	21	Ox. Gas 1, H270 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	1	Flam. Gas 1B, H221 Press. Gas (Comp.), H280 Acute Tox. 3 (Inhalation:gas), H331 Repr. 1A, H360D STOT RE 1, H372

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

Obtain medical assistance.

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 1475

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 : 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 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.
- Monitor concentration of released product.
- Wear self-contained breathing apparatus when entering area unless atmosphere is proved to be safe.
- 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

- See also sections 8 and 13.

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
 Reference number: 1475

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.
 Avoid exposure, obtain special instructions before use.
 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.
- 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

Carbon monoxide (630-08-0)	
EU - Binding Occupational Exposure Limit (BOEL)	
Local name	Carbon monoxide
BOEL TWA	23 mg/m ³

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 1475

BOEL TWA [ppm]	20 ppm
BOEL STEL	117 mg/m ³
BOEL STEL [ppm]	100 ppm
Regulatory reference	DIRECTIVE (EU) 2022/431 (amending Directive 2004/37/EC)
Belgium - Occupational Exposure Limits	
Local name	Carbone (monoxyde de) # Koolstofmonoxide
OEL TWA	23 mg/m ³
OEL TWA	20 ppm
OEL STEL	117 mg/m ³
OEL STEL	100 ppm
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021

Carbon monoxide (630-08-0)	
DNEL: Derived no effect level (Workers)	
Acute - local effects, inhalation	117 ppm
Acute - systemic effects, inhalation	117 mg/m ³
Long-term - local effects, inhalation	23 ppm
Long-term - systemic effects, inhalation	23 mg/m ³

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).
Gas detectors should be used when toxic 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

- 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.

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 1475

- 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.
 - Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask.
 - Consult respiratory device supplier's product information for the selection of the appropriate device.
 - Gas filters do not protect against oxygen deficiency.
 - Standard EN 14387 - Gas filter(s), combined filter(s) and standard EN136, full face masks .
 - Keep self contained breathing apparatus readily available for emergency use.
 - Self contained breathing apparatus is recommended, where unknown exposure may be expected, e.g. during maintenance activities on installation systems.
- Thermal hazards
 - : None necessary.

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	: Colourless.
Odour	: Odourless.
	Odour threshold is subjective and inadequate to warn of overexposure.
	Odour threshold is subjective and inadequate to warn of overexposure.
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: Nitrogen Compressed -196 °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.

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
 Reference number: 1475

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 : Can form explosive mixture with air. May react violently with oxidants. Violently oxidises organic material.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

10.5. Incompatible materials

None.

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

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 cause harm to the unborn child.
STOT-single exposure : No known effects from this product.
STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.
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 : 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.

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
 Reference number: 1475

12.2. Persistence and degradability

Assessment : No data available.

12.3. Bioaccumulative potential

Assessment : No data available.

12.4. Mobility in soil

Assessment : No data available.

12.5. Results of PBT and vPvB assessment

Assessment : Not classified as PBT or vPvB.

12.6. Endocrine disrupting properties

Assessment :

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.

Avoid discharge to atmosphere.

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.org> for more guidance on suitable disposal methods.

List of hazardous waste codes (from Commission Decision 2000/532/EC as amended) : 16 05 04 *: Gases in pressure containers (including halons) containing hazardous substances.

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 , carbon monoxide)

Transport by air (ICAO-TI / IATA-DGR) : Compressed gas, n.o.s. (Nitrogen Compressed , carbon monoxide)

Transport by sea (IMDG) : COMPRESSED GAS, N.O.S. (Nitrogen Compressed , 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

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 1475

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

Restrictions on use : Restricted to professional users (Annex XVII REACH).

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.

Safety Data Sheet

Special mixture Spiro 5 for medical application

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 1475

SECTION 16: Other information

- Indication of changes : Safety data sheet in accordance with commission regulation (EU) No 2020/878.
- Training advice : Users of breathing apparatus must be trained.
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	
Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Flam. Gas 1B	Flammable gases, Category 1B
H221	Flammable gas.
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.
H373	May cause damage to organs through prolonged or repeated exposure.
Ox. Gas 1	Oxidising Gases, Category 1
Press. Gas (Comp.)	Gases under pressure : Compressed gas
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

- 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