

## Medicinal Nitrous oxide

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

#### 1.1. Product identifier

Product form	: Substance
Trade name	: Medicinal Nitrous oxide
SDS code	: 093A_MED
Internal reference no.	: 003042
Chemical description	: Nitrous oxide
CAS-No.	: 10024-97-2
EC-No.	: 233-032-0
EC Index-No.	: -
Registration-No.	: 01-2119970538-25
Chemical formula	: N2O

#### 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. Usò ospedaliero. Contact supplier for more information on uses.
Uses advised against	: Do not inhale product on purpose because of the risk of asphyxiation.

#### 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
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#### 1.4. Emergency telephone number

Emergency telephone number	: +39 0295705444 (24/7)
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### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Physical hazards	Oxidising Gases, Category 1	H270
	Gases under pressure: Liquefied gas	H280
Health hazards	Specific target organ toxicity — Single exposure, Category 3, Narcosis	H336

#### 2.2. Label elements

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

Hazard pictograms (CLP)	:   
	: GHS03                      GHS04                      GHS07
Signal word (CLP)	: Danger
Hazard statements (CLP)	: H270 - May cause or intensify fire; oxidiser. H280 - Contains gas under pressure; may explode if heated. H336 - May cause drowsiness or dizziness.
Precautionary statements (CLP)	: - Prevention : P220 - Keep away from clothing and other combustible materials. P260 - Do not breathe gas, vapours. P244 - Keep valves and fittings free from oil and grease. - Response : P304+P340+P315 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get immediate medical advice / attention. P370+P376 - In case of fire: stop leak if safe to do so. - Storage : P403 - Store in a well-ventilated place.
Supplemental information	: Do not inhale product on purpose because of the risk of asphyxiation.

#### 2.3. Other hazards

Other hazards not contributing to the classification	: Contact with liquid may cause cold burns/frostbite.
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## Medicinal Nitrous oxide

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Medicinal Nitrous oxide	CAS-No.: 10024-97-2 EC-No.: 233-032-0 EC Index-No.: - Registration-No.: 01-2119970538-25	100	Ox. Gas 1, H270 Press. Gas (Liq.), H280 STOT SE 3, H336

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

#### 3.2. Mixtures

Not applicable

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

- Inhalation : Remove victim to uncontaminated area.
- Skin contact : In case of frostbite spray with water for at least 15 minutes. Apply a sterile dressing. Obtain medical assistance.
- Eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes.
- Ingestion : Ingestion is not considered a potential route of exposure.

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

In low concentrations may cause narcotic effects. Symptoms may include dizziness, headache, nausea and loss of co-ordination.  
Refer to section 11.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Obtain medical assistance.

### 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 : Nitric oxide/nitrogen dioxide.

#### 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

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.  
Eliminate ignition sources.  
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.  
Stay upwind.

#### 6.2. Environmental precautions

Try to stop release.

## Medicinal Nitrous oxide

### 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

: Use only lubricants and sealings approved for the specific gas service.

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. Keep equipment free from oil and grease. For more guidance, refer to the EIGA Doc. 33 - Cleaning of Equipment for Oxygen Service downloadable at <http://www.eiga.eu>. Use no oil or grease. 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. For more guidance on safe use, refer to the EIGA Doc.176 "Safe practices for storage and handling of Nitrous oxide", downloadable at <http://www.eiga.eu> and consult your supplier. Temperatures above 150°C (300°F) shall be avoided by all practical means, to reduce the likelihood of an explosive decomposition of the nitrous oxide. Clean all surfaces in direct contact with nitrous oxide as for oxygen service. Nitrous oxide transfer pumps shall be provided with an interlock to prevent dry running. Use self-limiting heating devices. Direct contact electric immersion heaters are not allowed.

Safe handling of the gas receptacle

: Refer to supplier's container handling instructions.

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. Segregate from flammable gases and other flammable materials in store. 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

Nitrous oxide (10024-97-2)		
OEL : Occupational Exposure Limits		
ACGIH	ACGIH TWA (ppm)	50 ppm
	Remark (ACGIH)	TLV® Basis: CNS impair; hematologic eff; embryo/fetal dam. Notations: A4 (Not classifiable as a Human Carcinogen)

## Medicinal Nitrous oxide

	Regulatory reference	ACGIH 2018
<b>Nitrous oxide (10024-97-2)</b>		
DNEL: Derived no effect level (Workers)		
Acute - local effects, inhalation		183 mg/m <sup>3</sup>
Long-term - systemic effects, inhalation		183 mg/m <sup>3</sup>

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

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

Provide adequate general and local exhaust ventilation.  
 Product to be handled in a closed system.  
 Systems under pressure should be regularly checked for leakages.  
 Ensure exposure is below occupational exposure limits (where available).  
 Gas detectors should be used when oxidising 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 goggles when transfilling or breaking transfer connections.  
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.  
Wear cold insulating gloves when transfilling or breaking transfer connections.  
Standard EN 511 - Cold insulating gloves.
  - Other : Consider the use of flame resistant safety clothing.  
Standard EN ISO 14116 - Limited flame spread materials.  
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.  
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.  
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 : Colourless.

Odour : Sweetish. Poor warning properties at high concentrations.

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

pH : Not applicable for gases and gas mixtures.

Melting point / Freezing point : -90,81 °C

Boiling point : -88,5 °C

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] : 50,8 bar(a)

Vapour pressure [50°C] : Not applicable.

## Medicinal Nitrous oxide

Vapour density	: Not applicable.
Relative density, liquid (water=1)	: 1,2
Relative density, gas (air=1)	: 1,5
Water solubility	: 1500 mg/l
Partition coefficient n-octanol/water (Log Kow)	: 0,4
Auto-ignition temperature	: Non flammable.
Decomposition temperature	: Not applicable.
Viscosity	: No reliable data available.
Explosive properties	: Not applicable.
Oxidising properties	: Oxidiser.

### 9.2. Other information

Molar mass	: 44 g/mol
Critical temperature	: 36,4 °C
- Coefficient of oxygen equivalency (Ci)	: 0,6
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.

At temperatures over 575°C and at atmospheric pressure, nitrous oxide decomposes into nitrogen and oxygen.

In the presence of catalysts (e.g. halogen products, mercury, nickel, platinum) the rate of decomposition increases and decomposition can occur at even lower temperatures.

Nitrous oxide dissociation is irreversible and exothermic, leading to a considerable rise in pressure.

### 10.3. Possibility of hazardous reactions

Violently oxidises organic material.

### 10.4. Conditions to avoid

Avoid moisture in installation systems.

### 10.5. Incompatible materials

May react violently with combustible materials.

May react violently with reducing agents.

Keep equipment free from oil and grease. For more guidance, refer to the EIGA Doc. 33 - Cleaning of Equipment for Oxygen Service downloadable at <http://www.eiga.eu>.

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 toxicological effects

**Acute toxicity** : Inhalation causes narcotic effects.

LC50 inhalation rat	500000 ppm/4h
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**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** : May cause drowsiness or dizziness.

**STOT-repeated exposure** : At low concentrations:

Neurologic effect.

Hemotoxic effect.

**Target organ(s)** : Erythrocytes.

Kidneys.

liver.

Central nervous system.

**Aspiration hazard** : Not applicable for gases and gas mixtures.

## Medicinal Nitrous oxide

### SECTION 12: Ecological information

#### 12.1. Toxicity

Assessment	: No ecological damage caused by this product.
EC50 48h - Daphnia magna	: Study scientifically unjustified.
EC50 72h - Algae	: Study scientifically unjustified.
LC50 96 h - Fish	: Study scientifically unjustified.

#### 12.2. Persistence and degradability

Assessment	: Not applicable for inorganic products. Study scientifically unjustified.
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#### 12.3. Bioaccumulative potential

Assessment	: Not expected to bioaccumulate due to the low log Kow (log Kow < 4). Refer to section 9.
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#### 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.
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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. Other adverse effects

Other adverse effects	: No known effects from this product.
Effect on the ozone layer	: None.
Global warming potential [CO <sub>2</sub> =1]	: 298
Effect on global warming	: Contains greenhouse gas(es). When discharged in large quantities may contribute to the greenhouse effect.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

	Contact supplier if guidance is required. May be vented to atmosphere in a well ventilated place. Discharge to atmosphere in large quantities should be avoided. 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 <a href="http://www.eiga.eu">http://www.eiga.eu</a> for more guidance on suitable disposal methods. Return unused product in original receptacle to supplier.
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

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.	: 1070
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#### 14.2. UN proper shipping name

Transport by road/rail (ADR/RID)	: NITROUS OXIDE
Transport by air (ICAO-TI / IATA-DGR)	: Nitrous oxide
Transport by sea (IMDG)	: NITROUS OXIDE

#### 14.3. Transport hazard class(es)

## Medicinal Nitrous oxide

### Labelling



2.2 : Non-flammable, non-toxic gases.

5.1 : Oxidizing substances.

### Transport by road/rail (ADR/RID)

Class : 2  
 Classification code : 20  
 Hazard identification number : 25  
 Tunnel Restriction : C/E - Tank carriage : Passage forbidden through tunnels of category C, D and E. Other carriage : Passage forbidden through tunnels of category E

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

Class / Div. (Sub. risk(s)) : 2.2 (5.1)

### Transport by sea (IMDG)

Class / Div. (Sub. risk(s)) : 2.2 (5.1)  
 Emergency Schedule (EmS) - Fire : F-C  
 Emergency Schedule (EmS) - Spillage : S-W

### 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

#### EU-Regulations

Restrictions on use : None.  
 Seveso Directive : 2012/18/EU (Seveso III) : Covered.

#### National regulations

National legislation : Ensure all national/local regulations are observed.

### 15.2. Chemical safety assessment

A CSA has been carried out.

## Medicinal Nitrous oxide

### 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 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	: None.
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