

Nitrogen refrigerated liquid 4 Pharma

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

1.1. Product identifier

Product form	: Substance
Trade name	: Nitrogen refrigerated liquid 4 Pharma
SDS code	: 089B_PHARMA
Internal reference no.	: 002105
Chemical description	: Nitrogen
CAS-No.	: 7727-37-9
EC-No.	: 231-783-9
EC Index-No.	: ---
Registration-No.	: Listed in Annex IV / V REACH, exempted from registration.
Chemical formula	: N2

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. Pharmaceutical industry. Contact supplier for more information on uses.
Uses advised against	: Consumer use.

1.3. Details of the supplier of the safety data sheet

Company identification	: Sapiro Produzione Idrogeno Ossigeno Srl Via S. Pellico, 48 20900 Monza - ITALIA +39 039 83981 +39 039 836068 http://www.sapio.it/ 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	Gases under pressure: Refrigerated liquefied gas	H281
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2.2. Label elements

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

Hazard pictograms (CLP)	: 
	: GHS04
Signal word (CLP)	: Warning
Hazard statements (CLP)	: H281 - Contains refrigerated gas; may cause cryogenic burns or injury.
Precautionary statements (CLP)	: <ul style="list-style-type: none">- Prevention : P282 - Wear cold insulating gloves and either face shield or eye protection.- Response : P336+P315 - Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.- Storage : P403 - Store in a well-ventilated place.

2.3. Other hazards

Other hazards not contributing to the classification	: Asphyxiant in high concentrations.
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SECTION 3: Composition/information on ingredients

3.1. Substances

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Nitrogen refrigerated liquid	CAS-No.: 7727-37-9 EC-No.: 231-783-9 EC Index-No.: --- Registration-No.: *1	100	Press. Gas (Ref. Liq.), H281

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

*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.

3.2. Mixtures

Not applicable

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 : 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 high concentrations may cause asphyxiation. Symptoms may include loss of mobility/consciousness. Victim may not be aware of asphyxiation. 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 : 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.
If leaking do not spray water onto container. Water surrounding area (from protected position) to contain fire. Move containers away from the fire area if this can be done without risk.
- Special protective equipment for fire fighters : In confined space use self-contained breathing apparatus.
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.
- Wear self-contained breathing apparatus when entering area unless atmosphere is proved to be safe.
- Use protective clothing.
- Ensure adequate air ventilation.
- Act in accordance with local emergency plan.
- Stay upwind.
- Oxygen detectors should be used when asphyxiating gases may be released.

6.2. Environmental precautions

- Try to stop release.
- Liquid spillages can cause embrittlement of structural materials.

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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 : 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.
Avoid suck back of water, acid and alkalis.
Do not breathe gas.
Avoid release of product into atmosphere.
- 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.
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

- 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 regularly checked for leakages.
Oxygen detectors should be used when asphyxiating 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.

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- Eye/face protection : Wear goggles and a face shield 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 : Wear safety shoes while handling containers.
Standard EN ISO 20345 - Personal protective equipment - Safety footwear.
- Respiratory protection : Self contained breathing apparatus (SCBA) or positive pressure airline with mask are to be used in oxygen-deficient atmospheres.
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

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 liquid.

Odour : No odour warning properties.

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

pH : Not applicable for gases and gas mixtures.

Melting point / Freezing point : -210 °C

Boiling point : -196 °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] : Not applicable.

Vapour pressure [50°C] : Not applicable.

Vapour density : Not applicable.

Relative density, liquid (water=1) : 0,8

Relative density, gas (air=1) : 0,97

Water solubility : 20 mg/l

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

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 : 28 g/mol

Critical temperature : -147 °C

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

For additional information on compatibility refer to ISO 11114.

Materials such as carbon steel, low alloy carbon steel and plastic become brittle at low temperatures and are

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subject to failure. Use appropriate materials compatible with the cryogenic conditions present in refrigerated liquefied gas systems.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: No known 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

Assessment	: No ecological damage caused by this product.
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.
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12.3. Bioaccumulative potential

Assessment	: No data available.
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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	: No data available.
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12.6. Other adverse effects

Other adverse effects	: Can cause frost damage to vegetation.
Effect on the ozone layer	: None.
Effect on global warming	: None.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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 2001/118/EC) : 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.

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SECTION 14: Transport information

14.1. UN number

UN-No. : 1977

14.2. UN proper shipping name

Transport by road/rail (ADR/RID) : NITROGEN, REFRIGERATED LIQUID
Transport by air (ICAO-TI / IATA-DGR) : Nitrogen, refrigerated liquid
Transport by sea (IMDG) : NITROGEN, REFRIGERATED LIQUID

14.3. Transport hazard class(es)

Labelling :



2.2 : Non-flammable, non-toxic gases.

Transport by road/rail (ADR/RID)

Class : 2
Classification code : 3A
Hazard identification number : 22
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

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) : P203
Transport by air (ICAO-TI / IATA-DGR)
Passenger and Cargo Aircraft : 202.
Cargo Aircraft only : 202.
Transport by sea (IMDG) : P203

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

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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
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 : The hazard of asphyxiation is often overlooked and must be stressed during operator training.
For more guidance, refer to EIGA SL 01 "Dangers of Asphyxiation", downloadable at <http://www.eiga.eu>.

DISCLAIMER OF LIABILITY : Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out.
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