

Safety Data Sheet

MEDICAL NITRIC OXIDE in NITROGEN, Compressed Gas Mixture

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Version: 2.0

SDS reference: ALH003

Warning



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

1.1. Product identifier

Trade name : VasoKINOX® SDS no : ALH003

Chemical description : 450ppm Nitric Oxide in Nitrogen

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

Relevant identified uses : Medical: Treatment of pulmonary arterial pressure in patients with perioperative pulmonary

hypertension in conjunction with heart surgery

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

Company identification : Air Liquide Healthcare Pty Limited

Level 4, Suite 4 247 Coward Street

Mascot NSW 2020 Australia

1800 64 87 42

ALHEnquiries@AirLiquide.com

1.4. Emergency telephone number

Emergency telephone number : 1800 812 588

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to WHS Regulation

Physical hazards Gases under pressure : Compressed gas H280

2.2. Label elements

Classification according to WHS Regulation

Hazard pictograms



GHS04

Signal word : Warning

Hazard statements : H280 - Contains gas under pressure; may explode if heated..

Precautionary statements

- Storage: P403 - Store in a well-ventilated place..



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2.3. Other hazards

: Asphyxiant in high concentrations.

None.

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 WHS Regulation
Nitrogen	(CAS-No.) 7727-37-9 (EC-No.) 231-783-9 (EC Index-No.) (REACH-no) *1	Balance	Press. Gas (Comp.), H280
Nitric oxide	(CAS-No.) 10102-43-9 (EC-No.) 233-271-0 (EC Index-No.) (REACH-no) 01-2120766630-54	0.045	Ox. Gas 1, H270 Press. Gas (Comp.), H280 Skin Corr. 1B, H314 Eye Dam. 1, H318 Acute Tox. 1 (Inhalation:gas), H330

Full text of H- and EUH-statements: see section 16

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

SECTION 4: First aid measures

4.1. Description of first aid measures

- Inhalation : Adverse effects not expected from this product.

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
- Eye contact
- Lingestion
- Adverse effects not expected from this product.
- 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.

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.

EN (English)

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^{*1:} Listed in Annex IV / V REACH, exempted from registration.

^{*3:} Registration not required: Substance manufactured or imported < 1t/y.



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Hazardous combustion products

: Nitric oxide/nitrogen dioxide.

5.3. Advice for fire-fighters

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

: 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.

Hazchem Code : 2TE

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

: Try to stop release if safe to do so.

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.

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.

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 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.

Avoid suck back of water, acid and alkalis.

Do not breathe gas.

Avoid release of product into atmosphere.



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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.

Suck back of water into the container must be prevented. Open valve slowly to avoid pressure shock.

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

Control parameters 8.1

Nitric oxide (10102-43-9)				
OEL : Occupational Exposure Limits				
Australia	TWA (mg/m³)	31 mg/m³		
	TWA (ppm)	25 ppm		

DNEL (Derived-No Effect Level): No data available.

PNEC (Predicted No-Effect Concentration): No data available.

8.2. **Exposure controls**

8.2.1. Appropriate engineering controls

: Provide adequate general and local exhaust ventilation.

Systems under pressure should be regularily checked for leakages. Ensure exposure is below occupational exposure limits (where available). Oxygen detectors should be used when asphyxiating gases may be released. Consider the use of a work permit system e.g. for maintenance activities.

822 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 Australian or EN/ISO standards should be selected.

· Eye/face protection

: Wear safety glasses with side shields. Standard EN 166 - Personal eye-protection – specifications; AS/NZS 1337.1 – Eye and face

protectors for occupational applications.

· Skin protection

1800 64 87 42



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- Hand protection

: Wear working gloves when handling gas containers.

Standard EN 388 - Protective gloves against mechanical risk, performance level 1 or higher.

AS/NZS 2161.3 – Occupational protective gloves, protection against mechanical risks.

- Other

: Wear safety shoes while handling containers.

Standard EN ISO 20345 - Personal protective equipment - Safety footwear; AS/NZS 2210.1 -

Safety, protective and occupational footwear, guide to selection care and use.

· 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

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.

Gas filters do not protect against oxygen deficiency.

Standard EN 14387 - Gas filter(s), combined filter(s) and standard EN136, full face masks . AS/NZS 1715 – Selection, use and maintenance of respiratory protective equipment. Self contained breathing apparatus is recommended, where unknown exposure may be

expected, e.g. during maintenance activities on installation systems.

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.

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 : Mixture contains one or more component(s) which have the following colour(s):

Brownish gas. 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:

Pungent.

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

pH value : Not applicable for gases and gas mixtures.

Molar mass: Not applicable for gas mixtures.Melting point: Not applicable for gas mixtures.Boiling point: Not applicable for gas mixtures.

Flash point : Not applicable for gases and gas mixtures.

Evaporation rate (ether=1) : Not applicable for gases and gas mixtures.

Flammability range : Non flammable.

Vapour pressure [20°C] : Not applicable.

Vapour pressure [50°C] : Not applicable.

Relative density, gas (air=1) : Lighter or similar to air.
Solubility in water : No data available

Partition coefficient n-octanol/water [log Kow] : Not applicable for gas mixtures.

Auto-ignition temperature : Non flammable.

Decomposition point [°C] : Not applicable.

Viscosity [20°C] : No reliable data available.

Explosive Properties : Not applicable.



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Oxidising Properties : Not applicable.

9.2. Other information

Other data : None.

SECTION 10: Stability and reactivity

10.1. Reactivity

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

Data for mixtures are not available

10.2. Chemical stability

: Stable under normal conditions.

10.3. Possibility of hazardous reactions

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

10.4. Conditions to avoid

Nitrogen (7727-37-9)

: 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 toxicological effects

Acute toxicity : Classification criteria are not met.

Nillogen (1121-31-3)	
LC50 inhalation rat (ppm)	820000 ppm/4h
Nitric oxide (10102-43-9)	
LC50 Inhalation - Rat [ppm]	57.5 ppm/4h
Skin corrosion/irritation	: Classification criteria are not met.
Serious eye damage/irritation	: Classification criteria are not met.
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.
Other information	: The substance/mixture has no endocrine disrupting properties.

SECTION 12: Ecological information

12.1. Toxicity

Assessment : No data available.

12.2. Persistence and degradability

Assessment : No data available.

12.3. Bioaccumulative potential



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· No data available Assessment

Mobility in soil

Assessment : Because of its high volatility, the product is unlikely to cause ground or water pollution.

Partition into soil is unlikely.

Results of PBT and vPvB assessment

Assessment No data available.

Not classified as PBT or vPvB.

Other adverse effects

: No known effects from this product.

Effect on the ozone layer · None

Effect on global warming : No known effects from this product.

SECTION 13: Disposal considerations

Waste treatment methods

Contact supplier if guidance is required.

May be vented to atmosphere in a well ventilated place.

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.

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.

Additional information

: External treatment and disposal of waste should comply with applicable local and/or national regulations

SECTION 14: Transport information

UN number 14.1.

UN-No. : 1956

UN proper shipping name 14.2.

Transport by road/rail (ADR/RID) : COMPRESSED GAS, N.O.S. (Nitrogen, Nitric oxide)

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

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

14.3. Transport hazard class(es)

Labelling



2.2: Non-flammable, non-toxic gases

Transport by road/rail (ADG)

Class : 2 Hazchem Code : 2TE Hazard identification number : 20

Tunnel Restriction : E - Passage forbidden through tunnels of category E



Reference number: ALH003

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

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

Environmental hazards

Transport by road/rail (ADR/RID) : None. Transport by air (ICAO-TI / IATA-DGR) : None. Transport by sea (IMDG) : None.

Special precautions for user

No additional information availablePacking 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.

Do not load or transport cylinders other than in accordance with load restraint guidelines and

relevant road safety laws

HAZCHEM CODE : 2TE

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: Not applicable.

SECTION 15: Regulatory information



Reference number: ALH003

National regulations

: Classified as a Schedule 4 (S4) Poison in accordance with the standard for the Uniform Poisons Schedule

Scheduling of Medicines and Poisons (SUSMP)

: Registered prescription medicine on the Australian Register of Therapeutic Goods (ARTG ID Therapeutic Goods

235184).

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 and relevant Work, Health and Safety guidelines.

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.

: None. The hazard of asphyxiation is often overlooked and must be stressed during operator Training advice training. For more guidance, refer to EIGA SL 01 "Dangers of Asphyxiation", downloadable at

http://www.eiga.eu..

Full text of H-statements

Acute Tox. 1 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H270	May cause or intensify fire; oxidiser.
H280	Contains gas under pressure; may explode if heated.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
Ox. Gas 1	Oxidising Gases, Category 1
Press. Gas (Comp.)	Gases under pressure : Compressed gas
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B

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.