

Safety Data Sheet

DANGER



1. IDENTIFICATION OF SUBSTANCE/PREPARATION AND OF COMPANY

1.1 Identification of preparation

Product name: Innocor® rebreathing gas
 Product code: GAS00001
 Product form: Product is a gaseous mixture at atmospheric pressure/room temperature.
 Product is sold in pressurised bottles (see picture) with water capacity 0.15 litres and a max pressure of 124 bar.



1.2 Use of substance/preparation

Place of use: Hospitals, medical practices, laboratories
 Principle of use: Innocor® rebreathing gas is an integral part of the Innocor medical device.
 The gas is used clinically for non-invasive measurement of cardiopulmonary parameters, where a patient breathes minute quantities of a blood soluble gas (N₂O) and a blood insoluble gas (SF₆).
 The Innocor device – and therefore the Innocor rebreathing gas - should only be used by professional health care providers who have received training in the use of the equipment.

1.3 Identification of company

Distributed by:	Innovision ApS Skovvænget 2 DK-5620 Glamsbjerg DENMARK	Telephone:	(+45) 6595 9100 (08:00-16:00 CET)
		Fax:	(+45) 6595 7800
		Mail:	qa@innovision.dk
		Web:	www.innovision.dk

2. HAZARDS IDENTIFICATION

Oxygen: May cause or intensify fire; oxidiser
 Pressurised gas: Contains gas under pressure, cylinder may rupture or explode if heated
 CLP labelling Hazard pictograms: GHS03 and GHS04
 Signal word: Danger
 Hazard statements: H270 and H280
 See section 16 for full text of CLP H-phrases and Precautionary statements

3. COMPOSITION/INFORMATION ON INGREDIENTS

Name	Chemical formula	Einecs. No.	CAS no.	Classification DSD/DPD	w/w%
Oxygen	O ₂	231-956-9	7782-44-7	O; R8	94
Sulphur hexafluoride	SF ₆	219-854-2	2551-62-4	-	5
Nitrous oxide	N ₂ O	233-032-0	10024-97-2	O; R8	1

4. FIRST AID MEASURES

Inhalation:	Supply fresh air/oxygen. Apply artificial respiration if breathing has stopped. Consult a doctor if complaints are persistent.
Ingestion:	Ingestion is not considered a potential route of exposure, product is a gas.
Skin/eye contact:	Not relevant. Product does not irritate the skin/eyes.
Other:	When seeking medical advice, bring this SDS and/or container with label.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

All known extinguishants can be used.

5.2 Special exposure hazards

Pressurized gas containers may rupture or explode at high temperatures.

If involved in a fire, the following toxic and/or corrosive fumes may be produced by thermal decomposition:

- Hydrogen fluoride
- Sulphur dioxide
- Nitrogen oxides (nitric oxide/nitrogen dioxide)

5.3 Advice for firefighters

In case of fire – evacuate area. Use water spray to cool containers. If safe to do so – remove containers.

Use self-contained breathing apparatus and chemically protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution

General measures:	Ensure adequate ventilation.
	Close doors and windows of adjacent premises.
	Do not smoke or use open fire.

6.2 Environmental precautions

Aqueous release:	No risk of water contamination – product is gaseous at ambient temperature/pressure.
Atmospheric release:	Try to stop release if safe to do so.
	Ensure adequate ventilation, avoid use of open flame.
Release to soil:	No risk of soil contamination – product is gaseous at ambient temperature/pressure.

6.3 Containment and clean-up

General measures: Try to stop release if safe to do so.
Ventilate area.

7. HANDLING AND STORAGE

7.1 Handling

Vigorously accelerates combustion - use no oil or grease on valve.
Open and close valve slowly to avoid pressure shock.
High pressure aluminium cylinder. Do not alter or modify cylinder and/or valve in any way.
Do not use any caustic or corrosive paints and cleaners on container.
Avoid jolting, friction and impact which may cause cylinder/valve to rupture.
Keep valve protection cap on cylinders when not in use on device.

7.2 Storage

Keep container at room temperature (below 40 °C) in a well ventilated area away from sunlight, heat and open flame.
Segregate from flammable gases and other flammable materials in place of storage.
Refer to local fire code/building code for additional applicable regulations.

7.3 Specific uses.

See section 1.2

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

Exposure limit values (OEL) on the components of the gas mixture. See section 3 for composition of mixture:

		Nitrous oxide	Sulphur hexafluoride	Oxygen
Austria	MAK (AU) Tagesmittelwert [mg/m ³]	180	6000	-
	STEL (AT) OEL 15min [ppm]	400	2000	-
	MAK (AU) Kurzzeitwerte [mg/m ³]	720	12000	-
	TWA (AT) OEL 8h [ppm]	100	1000	-
Belgium	TWA (BE) OEL 8h [mg/m ³]	91	6057	-
	TWA (BE) OEL 8h [ppm]	50	1000	-
Estonia	TWA (EE) OEL 8h [mg/m ³]	180	6000	-
	TWA (EE) OEL 8h [ppm]	100	1000	-
	STEL (EE) OEL 15min [mg/m ³]	900	-	-
France	STEL (EE) OEL 15min [ppm]	500	-	-
	VME – France [mg/m ³]	-	6000	-
Germany	VME – France [ppm]	-	1000	-
	AGW (8h) [mg/m ³] TRGS 900	180	6100	-
	AGW (8h) [ppm] TRGS 900	100	1000	-
Greece	Peak exposure limitation factor (DE) OEL TRGS 900	2	8	-
	Time weighted avg. (GR) 8h [mg/m ³]	-	6000	-
	Time weighted avg. (GR) 8h [ppm]	-	1000	-
	Short time exposure level (GR) 15min [mg/m ³]	-	7500	-
Spain	Short time exposure level (GR) 15min [ppm]	-	1250	-
	VLA-ED – Spain [mg/m ³]	92	6075	-
	VLA-ED – Spain [ppm]	50	1000	-

		Nitrous oxide	Sulphur hexafluoride	Oxygen
Switzerland	TWA (CH) OEL 8h [mg/m ³]	-	6000	-
Great Britain	TWA (UK) OEL 8h [mg/m ³]	183	6070	-
	TWA (UK) OEL 8h [ppm]	100	1000	-
	STEL (EE) OEL 15min [mg/m ³]	-	7590	-
Czech Republic	STEL (EE) OEL 15min [ppm]	-	1250	-
	TWA (CZ) OEL 8h [mg/m ³]	180	-	-
	TWA (CZ) OEL 8h [ppm]	100	-	-
	STEL (CZ) OEL 15min [mg/m ³]	360	-	-
	STEL (CZ) OEL 15min [ppm]	200	-	-
Denmark	Grænseværdi (DK) 8t [mg/m ³]	90	6000	-
	Grænseværdi (DK) 8t [ppm]	50	1000	-
Finland	TWA (FI) OEL 8h [mg/m ³]	180	6100	-
	TWA (FI) OEL 8h [ppm]	100	1000	-
	STEL (FI) OEL 15min [mg/m ³]	-	7900	-
	STEL (FI) OEL 15min [ppm]	-	1300	-
Hungary	ÁK-érték (HU) 8h [mg/m ³]	180	-	-
	CK-érték (HU) 15min [mg/m ³]	720	-	-
Ireland	OEL (IE)-(8 hour reference period) [mg/m ³]	90	6000	-
	OEL (IE)-(8 hour reference period) [ppm]	50	1000	-
	OEL (IE)-(15min reference period) [mg/m ³]	-	7500	-
	OEL (IE)-(15min reference period) [ppm]	-	1250	-
Lithuania	TWA (LT) OEL 8h [mg/m ³]	180	6000	-
	TWA (LT) OEL 8h [ppm]	100	1000	-
	STEL (LT) OEL 15min [mg/m ³]	900	-	-
	STEL (LT) OEL 15min [ppm]	500	-	-
Norway	TWA (NO) OEL 8h [mg/m ³]	90	6000	-
	TWA (NO) OEL 8h [ppm]	50	1000	-
Poland	8-Hour TWA (PL) (NDS) [mg/m ³]	90	6000	-
Slovakia	TWA (SK) OEL 8h [mg/m ³]	183	6100	-
	TWA (SK) OEL 8h [ppm]	100	1000	-
Sweden	TWA (SV) OEL 8h [mg/m ³]	180	6000	-
	TWA (SV) OEL 8h [ppm]	100	1000	-
	STEL (SV) OEL 15min [mg/m ³]	900	-	-
	STEL (SV) OEL 15min [ppm]	500	-	-
Portugal	TWA (PT) 8h [ppm]	50	1000	-

8.2 Exposure controls

Do not smoke while handling product.

Ensure adequate ventilation.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Gas
Colour:	Colourless
Odour:	Odourless
Flammability:	Not flammable, however mixture contains oxygen which may vigorously accelerate combustion.
Other:	Gas/vapour heavier than air. May accumulate in confined spaces, particularly at low level.

10. STABILITY AND REACTIVITY

10.1 Conditions to avoid

The product is generally stable at normal conditions of use and storage.

At temperatures over 575 °C and at atmospheric pressure, nitrous oxide decomposes into nitrogen and oxygen. Decomposition may also take place if gas is pressurized at temperatures at or above 300 °C. Nitrous oxide dissociation is irreversible and exothermic, leading to a considerable rise in pressure.

10.2 Materials to avoid

Avoid contact with:

- Combustible materials
- Flammable materials
- Reducing agents

10.3 Hazardous decomposition products

Under normal conditions of use or storage, decomposition products are not likely to form.

Decomposition products may form in case of fire (see section 5.2)

11. TOXICOLOGICAL INFORMATION

Adverse effects are not expected from this product.

Toxicological information on the components of the gas mixture as follows. Refer to section 3 for composition of mixture:

Oxygen:	No known toxicological effects from this component LC50 inhalation rat (ppm) 800000 ppm/4h
Sulphur hexafluoride:	No known toxicological effects from this component LC50 inhalation rat (ppm) 800000 ppm/4h
Nitrous oxide:	Nitrous oxide (a.k.a. laughing gas) has a slightly narcotic effect in larger doses. Reduced fertility for occupationally exposed staff (health care) has been reported in some epidemiological studies. The effect was related to repeated exposure to levels of nitrous oxide above the stated limit in inadequately ventilated rooms. LC50 inhalation rat (ppm) 250000 ppm/4h

12. ECOLOGICAL INFORMATION

Ecological information on the components of the gas mixture as follows. Refer to section 3 for composition of mixture:

Oxygen:	No known ecological effects from this component
Sulphur hexafluoride:	No known ecotoxicity effects of this compound. Sulphur hexafluoride is a potent greenhouse gas: GWP ₁₀₀ = 22200 (CO ₂ = 1)
Nitrous oxide:	No known ecotoxicity effects of this compound. Nitrous oxide is a greenhouse gas. GWP ₁₀₀ = 298 (CO ₂ = 1)

Mobility, persistence and degradability, bioaccumulative potential: Not assessed - not relevant for inorganic gases with low aqueous solubilities, low log K_{ow} and high volatility.

13. DISPOSAL CONSIDERATIONS

Empty pressure containers or pressure containers containing residual gas should be returned to distributor (see section 1.3) with valve protection cap in place for reuse/disposal.

Do not release gases into any place where accumulation could be dangerous.

Contact supplier if guidance is required.

14. TRANSPORT INFORMATION

UN no.	3156
Proper shipping name:	Compressed gas, oxidising, n.o.s. (oxygen mixture)
Class/division:	2.2
Subsidiary risk:	5.1
Labelling ADR:	Label 2.2 Non-flammable compressed gas (Non-toxic) Label 5.1 Oxidising agent



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 emergency. Ensure all cylinder valves are closed and not leaking and the load is firmly secured and complies with the applicable regulations.

Transport of empty gas cylinders:

In general, the empty gas cylinders are bound by the same dangerous goods legislation that apply for the full cylinders. For road transport (ADR), there is an exception to transport cylinders as normal goods if the pressure in the cylinder is less than 2 bar and the dangerous goods labels removed or hidden (ADR-1.1.3.2(c)).

15. REGULATORY INFORMATION

EU limitations in use: None known

Seveso directive 18/2012/EC: Oxygen is listed in Annex I.

16. OTHER INFORMATION

Full text of CLP Directive (EC 1272/2008) hazard statements and precautionary statements

H270: May cause or intensify fire; oxidiser.

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

P220: Keep/Store away from clothing/.../combustible materials.

P244: Keep reduction valves free from grease and oil

P370 + P376: In case of fire: Stop leak if safe to do so.

P403: Store in a well-ventilated place.

P410: Protect from sunlight.

This Safety Data Sheet has been established in accordance with the applicable European Directives and applies to all countries that have translated the Directives into their national laws. The SDS has been prepared from information supplied by the manufacturer of the gases on physical/chemical properties of the contents.

DISCLAIMER OF LIABILITY

Innocor rebreathing gas should only be used in the Innocor device by trained personnel. Operators should be aware of the hazards of oxygen enrichment. If using this product in any new process or experiment outside of its intended use, a thorough study on material compatibility and risk/safety issues should be conducted. The information given in this document is believed to be accurate and correct at the time of publication. Innovision has exercised all proper care in the preparation of the document, and cannot accept any liability from its use.