

Mallinckrodt™

**SAFETY DATA SHEET****1. Identification**

<b>Product identifier</b>	<b>INOmax®</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Nitric Oxide (<2.3%) Blended with Nitrogen * INOflo® * INOcal®
<b>SDS No.</b>	NO123
<b>Recommended use of the chemical and restrictions on use</b>	
<b>Recommended use</b>	Pharmaceutical grade nitric oxide for inhalation balanced in nitrogen. Nitric oxide is a pulmonary vasodilator and the active substance in these products. The gaseous blend of nitric oxide and nitrogen gas is supplied in aluminum cylinders as a compressed gas. INOcal is used in the calibration of medical devices.
<b>Restrictions on use</b>	Not available.
<b>Details of manufacturer or importer</b>	
<b>Manufacturer</b>	
<b>Manufacturer</b>	
<b>Company name</b>	Mallinckrodt Manufacturing LLC
<b>Address</b>	1060 Allendale Drive Port Allen, LA 70767
<b>Supplier</b>	
<b>Company name</b>	Ikaria Australia Pty Ltd
<b>Address</b>	Ground Floor   17-27 Cotham Road   Kew VIC 3101 Australia
<b>Telephone number</b>	877-566-9466.
<b>Emergency telephone number</b>	61 3 9851 9100 Monday - Friday 8AM to 5PM

**2. Hazard(s) identification****Classification of the hazardous chemical**

<b>Physical hazards</b>	Gases under pressure	Compressed gas
<b>Health hazards</b>	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Specific target organ toxicity following repeated exposure	Category 2 (blood)
<b>Environmental hazards</b>	Not classified.	

**Label elements, including precautionary statements****Hazard symbol(s)**

Gas cylinder

Health hazard

Exclamation mark

**Signal word**

Warning

**Hazard Statement(s)**

Contains gas under pressure; may explode if heated. Causes skin irritation. Causes serious eye irritation. May cause damage to organs (blood) through prolonged or repeated exposure.

**Precautionary Statement(s)****Prevention**

Do not breathe gas. Wear protective gloves/eye protection/face protection. Wash thoroughly after handling.

<b>Response</b>	IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Get medical advice/attention if you feel unwell. Take off contaminated clothing and wash before reuse.
<b>Storage</b>	Protect from sunlight. Store in a well-ventilated place.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Other hazards which do not result in classification</b>	May displace oxygen and cause rapid suffocation. Exposure to rapidly expanding gas or vapourizing liquid may cause frostbite ("cold burn"). Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Those with pre-existing heart, lung, or blood disorders may be more susceptible to the symptoms of asphyxia. Nitric oxide converts to nitrogen dioxide when exposed to air.  Used in the treatment of prescribed medical disorders. Administration of this gas mixture may be hazardous or contraindicated. Use only under the supervision of an experienced licensed practitioner familiar with the indications for use, dosages, methods, hazards, contraindications, and side effects.
<b>Supplemental information</b>	None.

### 3. Composition/information on ingredients

#### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Nitrogen Nitrogen; Nitrogen NF; LIN; Cryogenic Liquid Nitrogen; Refrigerated Liquid Nitrogen	7727-37-9	>=97.7
NITRIC OXIDE	10102-43-9	<=2.3

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

### 4. First-aid measures

#### Description of necessary first aid measures

<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Get medical attention if symptoms persist.
<b>Skin contact</b>	Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical attention if symptoms occur.

**Personal protection for first-aid responders** If you feel unwell, seek medical advice (show the label where possible). In case of cold burns (frostbite) caused by rapidly expanding gas or vapourizing liquids, get medical attention promptly. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

**Symptoms caused by exposure** Exposure to rapidly expanding gas or vapourizing liquid may cause frostbite ("cold burn"). Skin irritation. May cause redness and pain. Dermatitis. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Prolonged exposure may cause chronic effects.

Symptoms of overexposure can include shortness of breath, drowsiness, headaches, confusion, decreased coordination, visual disturbances and vomiting, and are reversible if exposure is stopped.

Continued exposure can lead to hypoxia (inadequate oxygen), cyanosis (bluish discoloration of the skin), numbness of the extremities, unconsciousness and death.

**Medical attention and special treatment** Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed.

Frostbite: Do not remove clothes, but flush with copious amounts of lukewarm water. Call an ambulance and continue to flush during transportation to hospital. Do not rub affected area.

## 5. Fire-fighting measures

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### Extinguishing media

**Suitable extinguishing media** Use any media suitable for the surrounding fires.

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

### Specific hazards arising from the chemical

Contents under pressure. Fire or excessive heat may result in rupture of container due to release of significant amounts of gases. Ruptured cylinders may rocket. During fire, gases hazardous to health may be formed such as: Nitrogen oxides. Carbon oxides.

### Special protective equipment and precautions for fire fighters

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

### Fire fighting equipment/instructions

In case of fire: Stop leak if safe to do so. Do not move cargo or vehicle if cargo has been exposed to heat. ALWAYS stay away from tanks engulfed in flame. Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. For massive fire in cargo area, use unmanned hose holder or monitor nozzles, if possible. If not, withdraw and let fire burn out.

### Hazchem Code

None.

### General fire hazards

Pressurised container may explode when exposed to heat or flame.

### Specific methods

Cool containers exposed to flames with water until well after the fire is out.

## 6. Accidental release measures

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### Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

In the event of a leak evacuate all personnel until ventilation can restore oxygen concentrations to safe levels. Keep away from sources of ignition - No smoking. Keep out of low areas. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not breathe gas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Emergency personnel need self-contained breathing equipment. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

#### For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

### Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

### Methods and materials for containment and cleaning up

Stop leak if you can do it without risk. Eliminate sources of ignition. Isolate area until gas has dispersed. Use water spray to reduce vapours or divert vapour cloud drift. Collect spillage. Transfer to a container for disposal. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

## 7. Handling and storage

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### Precautions for safe handling

DO NOT PRESSURIZE, CUT, WELD, BRAZE, SOLDER, DRILL, GRIND, OR EXPOSE SUCH CONTAINERS TO HEAT, STATIC ELECTRICITY, OR OTHER SOURCES OF IGNITION; THEY MAY EXPLODE AND CAUSE INJURY OR DEATH. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Do not breathe gas. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Use only outdoors or in a well-ventilated area. Wear appropriate personal protective equipment. Wash thoroughly after handling. Observe good industrial hygiene practices.

### Conditions for safe storage, including any incompatibilities

Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Store in original tightly closed container. Protect against physical damage and/or friction. For storage condition, see finished product label. Store in a well-ventilated place. Protect from sunlight. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls and personal protection

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### Control parameters

Follow standard monitoring procedures.

### Occupational exposure limits

No exposure limits noted for ingredient(s).

### Biological limit values

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** Use explosion-proof equipment. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ensure adequate ventilation, especially in confined areas. Eye wash facilities and emergency shower must be available when handling this product.

**Individual protection measures, for example personal protective equipment (PPE)**

**Eye/face protection** Wear safety glasses with side shields (or goggles). Chemical goggles are recommended.

**Skin protection**

**Hand protection** Wear protective gloves. Thermally protective, chemical resistant gloves are recommended. If contact with forearms is likely, wear gauntlet style gloves.

**Other** Wear suitable protective clothing.

**Respiratory protection** Wear positive pressure self-contained breathing apparatus (SCBA).

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures** When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

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**Appearance**

**Physical state** Gas.

**Form** Compressed gas.

**Colour** Colorless - Nitric oxide can produce brownish nitrogen dioxide after reaction with oxygen.

**Odour** Odorless in product concentration, may form NO<sub>2</sub> with pungent odor in presence of air.

**Odour threshold** 0.5 - 5 ppm for NO<sub>2</sub>

**pH** Not available.

**Melting point/freezing point** -163.89 °C (-263 °F) @ 1 atm

**Initial boiling point and boiling range** -151.67 °C (-241 °F) @ 1 atm

**Flash point** Not flammable.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not flammable.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)** Not flammable.

**Flammability limit - upper (%)** Not flammable.

**Explosive limit - lower (%)** Not available.

**Explosive limit – upper (%)** Not available.

**Vapour pressure** Not applicable.

**Vapour density** 1.3 kg/l @ NTP (20 °C, 1atm)

**Relative density** Relative gas density = 1.04 @ NTP (20 °C, 1atm)

**Solubility(ies)**

**Solubility (water)** 7.4 ml/100 ml (NO in water at 0 °C)

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not flammable.

**Decomposition temperature** Not available.

**Viscosity** Not applicable.

## 10. Stability and reactivity

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**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

<b>Chemical stability</b>	Contains gas under pressure; may explode if heated. Nitric oxide converts to nitrogen dioxide when exposed to air.
<b>Possibility of hazardous reactions</b>	Hazardous polymerisation does not occur.
<b>Conditions to avoid</b>	Protect against direct sunlight. Avoid heat, sparks, open flames and other ignition sources. Avoid high temperatures. Low temperatures. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidising agents. Strong acids. Strong bases. Metals. Metal oxides.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on possible routes of exposure

<b>Inhalation</b>	Suffocation (asphyxiant) hazard - if allowed to accumulate to concentrations that reduce oxygen below safe breathing levels.
<b>Skin contact</b>	Causes skin irritation. May cause frostbite or freezing of skin.
<b>Eye contact</b>	Causes serious eye irritation. Exposure to rapidly expanding gas or vapourizing liquid may cause frostbite ("cold burn"). Permanent eye damage including blindness could result.
<b>Ingestion</b>	Exposure to rapidly expanding gas or vapourizing liquid may cause frostbite ("cold burn"). However, ingestion is not likely to be a primary route of occupational exposure.
<b>Symptoms related to exposure</b>	Exposure to rapidly expanding gas or vapourizing liquid may cause frostbite ("cold burn"). Skin irritation. May cause redness and pain. Dermatitis. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

Symptoms of overexposure can include shortness of breath, drowsiness, headaches, confusion, decreased coordination, visual disturbances and vomiting, and are reversible if exposure is stopped.

Continued exposure can lead to hypoxia (inadequate oxygen), cyanosis (bluish discoloration of the skin), numbness of the extremities, unconsciousness and death.

<b>Acute toxicity</b>	May displace oxygen and cause rapid suffocation.
<b>Skin corrosion/irritation</b>	Causes skin irritation.
<b>Serious eye damage/irritation</b>	Causes serious eye irritation.
<b>Respiratory or skin sensitisation</b>	
<b>Respiratory sensitisation</b>	Due to lack of data the classification is not possible.
<b>Skin sensitisation</b>	Due to lack of data the classification is not possible.
<b>Germ cell mutagenicity</b>	Nitric oxide has demonstrated genotoxicity in Salmonella (Ames Test), human lymphocytes, and after in vivo exposure in rats.
<b>Carcinogenicity</b>	Due to lack of data the classification is not possible.
	Not carcinogenic at inhalation exposures up to 20 ppm in rats for 20 hr/day for up to 2 years. Higher exposures have not been investigated.
<b>Reproductive toxicity</b>	Due to lack of data the classification is not possible.
<b>Specific target organ toxicity - single exposure</b>	Due to lack of data the classification is not possible.
<b>Specific target organ toxicity - repeated exposure</b>	May cause damage to organs (blood) through prolonged or repeated exposure.
<b>Aspiration hazard</b>	Due to lack of data the classification is not possible.
<b>Chronic effects</b>	Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

## 12. Ecological information

<b>Ecotoxicity</b>	This product has no known eco-toxicological effects. The nitric oxide component of this gas mixture will react with air to form nitrogen dioxide, which in contact with water or moist air will form nitrous and nitric acid.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	

Partition coefficient  
n-octanol / water (log Kow) 0.67  
Nitrogen

Mobility in soil Not available.

Other adverse effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

### 13. Disposal considerations

**Disposal methods** Waste containing this product is classified as Industrial Waste. Do not puncture, incinerate or crush. Waste materials should not be released into the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Residual waste** Dispose of in accordance with local regulations.

**Contaminated packaging** Empty gas cylinders should be returned to the vendor for recycling or refilling. Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### ADG

**UN number** 1956  
**UN proper shipping name** COMPRESSED GAS, N.O.S. (Nitric Oxide, Nitrogen)  
**Transport hazard class(es)**  
**Class** 2.2  
**Subsidiary risk** -  
**Packing group** Not applicable.  
**Environmental hazards** No  
**Hazchem Code** 2TE  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

#### RID

**UN number** 1956  
**UN proper shipping name** COMPRESSED GAS, N.O.S. (Nitric Oxide, Nitrogen)  
**Transport hazard class(es)**  
**Class** 2.2  
**Subsidiary risk** -  
**Label(s)** 2.2 (+13)  
**Packing group** Not applicable.  
**Environmental hazards** No  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

#### IATA

**UN number** 1956  
**UN proper shipping name** Compressed gas, n.o.s. (Nitric Oxide, Nitrogen)  
**Transport hazard class(es)**  
**Class** 2.2  
**Subsidiary risk** -  
**Packing group** Not applicable.  
**Environmental hazards** No  
**ERG Code** 2L  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.  
**Other information**  
**Passenger and cargo aircraft** Allowed with restrictions.  
**Cargo aircraft only** Allowed with restrictions.

#### IMDG

**UN number** 1956  
**UN proper shipping name** COMPRESSED GAS, N.O.S. (NITRIC OXIDE, NITROGEN)  
**Transport hazard class(es)**  
**Class** 2.2  
**Subsidiary risk** -  
**Packing group** Not applicable.  
**Environmental hazards**  
**Marine pollutant** No  
**EmS** F-C, S-V

**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.  
**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**ADG**



**IATA; IMDG; RID**



## 15. Regulatory information

### Safety, health and environmental regulations

#### National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

Australia. SUSMP, Sch. 4, Prescription Only Medicine (Standard for Uniform Scheduling of Medicines & Poisons No. 12, Poisons Standard June 2016, June 2016) CAS RN: 10102-43-9  
Name: NITRIC OXIDE Minimum concentration: 10 Operator for minimum concentration: >  
Concentration unit: mg per L or kg.

#### **Australia Medicines & Poisons Appendix A**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix B**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix C**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix D**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix E**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix F**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix G**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix H**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix I**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix J**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix K**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 2**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 3**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 4**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 5**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 6**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 7**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 8**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 9**

Poisons schedule number not allocated.

**High Volume Industrial Chemicals (HVIC)**

Not listed.

**Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)**

Not listed.

**National Pollutant Inventory (NPI) substance reporting list**

Not listed.

**Prohibited Carcinogenic Substances**

Not regulated.

**Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)**

Not listed.

**Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)**

Not listed.

**Restricted Carcinogenic Substances**

Not regulated.

**International regulations****Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Not applicable.

**Kyoto protocol**

Not applicable.

**Montreal Protocol**

Not applicable.

**Basel Convention**

Not applicable.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes



Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information

<b>Issue date</b>	11-November-2016
<b>Disclaimer</b>	Mallinckrodt provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.
<b>Revision information</b>	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties Toxicological Information: Toxicological Data Transport Information: Material Transportation Information Regulatory Information: United States HazReg Data: Pacific Rim GHS: Qualifiers