1. Identification

Product identifier: INOmax®

Other means of identification:
- Synonyms: Nitric Oxide (<2.3%) Blended with Nitrogen * INOflo® * INOcal®
- SDS No.: NO123

Recommended use of the chemical and restrictions on use:

Recommended use: 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.

Restrictions on use: Not available.

Details of manufacturer or importer:

Manufacturer:
- Company name: Mallinckrodt Manufacturing LLC
- Address: 1060 Allendale Drive
  Port Allen, LA 70767

Supplier:
- Company name: Ikaria Australia Pty Ltd
- Address: Ground Floor | 17-27 Cotham Road | Kew VIC 3101 Australia
- Telephone number: 877-566-9466.

Emergency telephone number: 61 3 9851 9100 Monday - Friday 8AM to 5PM

2. Hazard(s) identification

Classification of the hazardous chemical:

Physical hazards: Gases under pressure
- Category 2

Health hazards:
- Skin corrosion/irritation: Category 2
- Serious eye damage/eye irritation: Category 2A
- Specific target organ toxicity following repeated exposure: Category 2 (blood)

Environmental hazards: 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.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Mixture</th>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrogen</td>
<td>Nitrogen; Nitrogen NF; LIN; Cryogenic Liquid Nitrogen; Refrigerated Liquid Nitrogen</td>
<td>7727-37-9</td>
<td>&gt;=97.7</td>
</tr>
<tr>
<td>NITRIC OXIDE</td>
<td></td>
<td>10102-43-9</td>
<td>&lt;=2.3</td>
</tr>
</tbody>
</table>

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

Inhalation

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.

Skin contact

Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Eye contact

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.

Ingestion

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

<table>
<thead>
<tr>
<th>Extinguishing media</th>
<th>Use any media suitable for the surrounding fires.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suitable extinguishing media</td>
<td>Use any media suitable for the surrounding fires.</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>Do not use water jet as an extinguisher, as this will spread the fire.</td>
</tr>
<tr>
<td>Specific hazards arising from the chemical</td>
<td>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.</td>
</tr>
<tr>
<td>Special protective equipment and precautions for fire fighters</td>
<td>Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.</td>
</tr>
<tr>
<td>Fire fighting equipment/instructions</td>
<td>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.</td>
</tr>
</tbody>
</table>

6. Accidental release measures

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>For non-emergency personnel</td>
</tr>
<tr>
<td>For emergency responders</td>
</tr>
<tr>
<td>Environmental precautions</td>
</tr>
<tr>
<td>Methods and materials for containment and cleaning up</td>
</tr>
</tbody>
</table>

7. Handling and storage

<table>
<thead>
<tr>
<th>Precautions for safe handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Conditions for safe storage, including any incompatibilities</td>
</tr>
</tbody>
</table>

8. Exposure controls and personal protection

<table>
<thead>
<tr>
<th>Control parameters</th>
<th>Follow standard monitoring procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational exposure limits</td>
<td>No exposure limits noted for ingredient(s).</td>
</tr>
<tr>
<td>Biological limit values</td>
<td>No biological exposure limits noted for the ingredient(s).</td>
</tr>
</tbody>
</table>
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**: Wear protective gloves. Thermally protective, chemical resistant gloves are recommended. If contact with forearms is likely, wear gauntlet style gloves.
- **Hand protection**: Wear suitable protective clothing.
- **Respiratory protection**: Wear positive pressure self-contained breathing apparatus (SCBA).
- **Thermal hazards**: Wear appropriate thermal protective clothing, when necessary.
- **Eye/face protection**: Wear safety glasses with side shields (or goggles). Chemical goggles are recommended.

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

**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 NO2 with pungent odor in presence of air.
- **Odour threshold**: 0.5 - 5 ppm for NO2
- **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
- **Reactivity**: The product is stable and non-reactive under normal conditions of use, storage and transport.
**Chemical stability**  
Contains gas under pressure; may explode if heated. Nitric oxide converts to nitrogen dioxide when exposed to air.

**Possibility of hazardous reactions**  
Hazardous polymerisation does not occur.

**Conditions to avoid**  
Protect against direct sunlight. Avoid heat, sparks, open flames and other ignition sources. Avoid high temperatures. Low temperatures. Contact with incompatible materials.

**Incompatible materials**  

**Hazardous decomposition products**  
No hazardous decomposition products are known.

### 11. Toxicological information

#### Information on possible routes of exposure

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalation</strong></td>
<td>Suffocation (asphyxiant) hazard - if allowed to accumulate to concentrations that reduce oxygen below safe breathing levels.</td>
</tr>
<tr>
<td><strong>Skin contact</strong></td>
<td>Causes skin irritation. May cause frostbite or freezing of skin.</td>
</tr>
<tr>
<td><strong>Eye contact</strong></td>
<td>Causes serious eye irritation. Exposure to rapidly expanding gas or vapourizing liquid may cause frostbite (“cold burn”). Permanent eye damage including blindness could result.</td>
</tr>
<tr>
<td><strong>Ingestion</strong></td>
<td>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. 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.</td>
</tr>
</tbody>
</table>

**Acute toxicity**  
May displace oxygen and cause rapid suffocation.

**Skin corrosion/irritation**  
Causes skin irritation.

**Serious eye damage/irritation**  
Causes serious eye irritation.

**Respiratory or skin sensitisation**

<table>
<thead>
<tr>
<th>Type</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory sensitisation</strong></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Skin sensitisation</strong></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**  
Nitric oxide has demonstrated genotoxicity in Salmonella (Ames Test), human lymphocytes, and after in vivo exposure in rats.

**Carcinogenicity**  
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.

**Reproductive toxicity**  
Due to lack of data the classification is not possible.

**Specific target organ toxicity - single exposure**  
Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**  
May cause damage to organs (blood) through prolonged or repeated exposure.

**Aspiration hazard**  
Due to lack of data the classification is not possible.

**Chronic effects**  
Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

### 12. Ecological information

**Ecotoxicity**  
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.

**Persistence and degradability**  
No data is available on the degradability of this product.
Partition coefficient
n-octanol / water (log Kow)
Nitrogen 0.67

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) 2.2
Class
Subsidiary risk -
Packing group
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) 2.2
Class
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) 2.2
Class
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) 2.2
Class
Subsidiary risk -
Packing group Not applicable.
Environmental hazards No
EmS F-C, S-V

Material name: INOmax®
SDS ID: NO123 Version No.: 01 Revision date: 11-November-2016
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
ADG

IATA; IMDG; RID

15. Regulatory information

Safety, health and environmental 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).

National regulations
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 Deleting 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

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

Issue date
11-November-2016

Disclaimer
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.

Revision information
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