

1. Identification

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| Product identifier | INOmax® | |
| Other means of identification | | |
| SDS number | NO123 | |
| Synonyms | Nitric Oxide (<2.3%) Blended with Nitrogen * INOflo® * INOcal® | |
| 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. | |
| Recommended restrictions | None known. | |
| Manufacturer/Importer/Supplier/Distributor information | | |
| Manufacturer | | |
| Manufacturer | | |
| Company name | Mallinckrodt Manufacturing LLC | |
| Address | 1060 Allendale Drive Port Allen, LA 70767 | |
| Supplier | | |
| Company name | Ikaria Canada Inc. | |
| Address | 6345 Dixie Road, Unit 1 Mississauga Ontario ON L5T 2E6 Canada | |
| Telephone number | 877-566-9466. | |
| Emergency telephone number | 1-800-424-9300 (CHEMTREC)/ 703-527-3887 | |
| Supplier | Not available. | |

2. Hazard(s) identification

| | | |
|------------------------------|---|---|
| Physical hazards | Gases under pressure Simple asphyxiants | Compressed gas Category 1 |
| Health hazards | Skin corrosion/irritation Serious eye damage/eye irritation Specific target organ toxicity, repeated exposure | Category 2 Category 2A Category 2 (blood) |
| Environmental hazards | Not classified. | |
| Label elements | | |

**Signal word**

Warning

Hazard statement

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. May displace oxygen and cause rapid suffocation.

Precautionary statement

Prevention

Do not breathe gas. Keep container tightly closed. Wash thoroughly after handling. Wear protective gloves. Wear respiratory protection. Use only outdoors or in a well-ventilated area. Wear eye protection/face protection.

Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN: Wash with plenty of water. Get medical advice/attention if you feel unwell. If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Storage

Protect from sunlight. Store in a well-ventilated place.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards

Exposure to rapidly expanding gas or vaporizing 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.

Federal law prohibits dispensing without a prescription. 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.

Supplemental information

None.

3. Composition/information on ingredients

Mixtures

| Chemical name | Common name and synonyms | CAS number | % |
|---------------|---|------------|--------|
| 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

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.

Most important symptoms/effects, acute and delayed

Exposure to rapidly expanding gas or vaporizing 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.

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| Indication of immediate medical attention and special treatment needed | Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed. |
| General information | 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. If you feel unwell, seek medical advice (show the label where possible). In case of cold burns (frostbite) caused by rapidly expanding gas or vaporizing liquids, get medical attention promptly. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |

5. Fire-fighting measures

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| 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 firefighters | 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. |
| Specific methods | Cool containers exposed to flames with water until well after the fire is out. |
| General fire hazards | Pressurized container may explode when exposed to heat or flame. |

6. Accidental release measures

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| Personal precautions, protective equipment and emergency procedures | 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 of the SDS. |
| 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 vapors or divert vapor 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. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

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. Always wear NIOSH approved, positive pressure air supplied respirator when handling this material. 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/personal protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

| Components | Type | Value |
|-------------------------------|------|--------|
| NITRIC OXIDE (CAS 10102-43-9) | TWA | 25 ppm |

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

| Components | Type | Value |
|-------------------------------|------|----------------------|
| NITRIC OXIDE (CAS 10102-43-9) | TWA | 31 mg/m ³ |
| | | 25 ppm |

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

| Components | Type | Value |
|-------------------------------|------|--------|
| NITRIC OXIDE (CAS 10102-43-9) | TWA | 25 ppm |

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

| Components | Type | Value |
|-------------------------------|------|--------|
| NITRIC OXIDE (CAS 10102-43-9) | TWA | 25 ppm |

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

| Components | Type | Value |
|-------------------------------|------|--------|
| NITRIC OXIDE (CAS 10102-43-9) | TWA | 25 ppm |

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

| Components | Type | Value |
|-------------------------------|------|----------------------|
| NITRIC OXIDE (CAS 10102-43-9) | TWA | 31 mg/m ³ |
| | | 25 ppm |

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, such as personal protective equipment

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

If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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

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|--|---|
| Physical state | Gas. |
| Form | Compressed gas. |
| Color | Colorless - Nitric oxide can produce brownish nitrogen dioxide after reaction with oxygen. |
| Odor | Odorless in product concentration, may form NO ₂ with pungent odor in presence of air. |
| Odor threshold | 0.5 - 5 ppm for NO ₂ |
| pH | Not available. |
| Melting point/freezing point | -263 °F (-163.89 °C) @ 1 atm |
| Initial boiling point and boiling range | -241 °F (-151.67 °C) @ 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. |
| Vapor pressure | Not applicable. |
| Vapor 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. |
| 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 polymerization 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 | Strong oxidizing agents. Strong acids. Strong bases. Metals. Metal oxides. |
| Hazardous decomposition products | No hazardous decomposition products are known. |

11. Toxicological information

Information on likely routes of exposure

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|--------------|--|
| Inhalation | Suffocation (asphyxiant) hazard - if allowed to accumulate to concentrations that reduce oxygen below safe breathing levels. |
| Skin contact | Causes skin irritation. May cause frostbite or freezing of skin. |

Eye contact Causes serious eye irritation. Exposure to rapidly expanding gas or vaporizing liquid may cause frostbite ("cold burn"). Permanent eye damage including blindness could result.

Ingestion Exposure to rapidly expanding gas or vaporizing liquid may cause frostbite ("cold burn"). However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Exposure to rapidly expanding gas or vaporizing 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.

Information on toxicological effects

Acute toxicity May displace oxygen and cause rapid suffocation.

| Components | Species | Test Results |
|-------------------------------|---------|------------------|
| NITRIC OXIDE (CAS 10102-43-9) | | |
| Acute | | |
| Inhalation | | |
| <i>Gas</i> | | |
| LC50 | Rat | 130 ppm, 4 hours |
| LC50 | Rat | 115 ppm, 1 Hours |

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory or skin sensitization

Canada - British Columbia OELs: Simple asphyxiant

NITROGEN (CAS 7727-37-9) Simple asphyxiant.

Canada - Manitoba OELs Hazard: Asphyxiant

NITROGEN (CAS 7727-37-9) Simple asphyxiant.

Canada - Ontario OELs: Asphyxiant

NITROGEN (CAS 7727-37-9) Simple asphyxiant.

Canada - Quebec OELs: Asphyxiant

NITROGEN (CAS 7727-37-9) Simple asphyxiant.

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

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. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

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.

Bioaccumulative potential

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

Mobility in soil No data available.

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

13. Disposal considerations

Disposal instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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

TDG

| | |
|-------------------------------------|---|
| UN number | UN1956 |
| 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 |
| Special precautions for user | Read safety instructions, SDS and emergency procedures before handling. |

IATA

| | |
|-------------------------------------|---|
| UN number | UN1956 |
| 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 | UN1956 |
| 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.

IATA; IMDG; TDG

**15. Regulatory information**

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

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 |

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| 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 |
| 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

Issue date 09-13-2016

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Version # 02

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Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Disclosure Overrides
Handling and storage: Conditions for safe storage, including any incompatibilities
Disposal considerations: Disposal instructions
HazReg Data: Pacific Rim