


1. Identification

Product identifier	INOmax®
Other means of identification	
SDS number	NO123
Item Code	NO123
Synonyms	INOmax® (800 ppm) * Nitric Oxide (0.08%) Blended with Nitrogen (99.92%) * INOflo®
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	
Company name	Mallinckrodt Manufacturing LLC
Address	675 James S. McDonnell Blvd. Hazelwood, MO 63042
E-mail	Brands.SDS@mnk.com
Emergency phone number	1 866 519 4752/ 760 476 3962 (Access Code: 335277)
Telephone number	Customer Service +1-314-654-2000 (Worldwide) Supplier:
Company name	Ikaria Canada Inc.
Address	6435 Dixie Road, Unit 1 Mississauga, Ontario ON L5T 2E6 Canada

2. Hazard identification

Physical hazards	Gases under pressure	Compressed gas
	Simple asphyxiants	Category 1
Health hazards	Not classified.	
Environmental hazards	Not classified.	
Label elements		
Signal word	Warning	
Hazard statement	Contains gas under pressure; may explode if heated. May displace oxygen and cause rapid suffocation.	
Precautionary statement		
Prevention	Do not handle until all safety precautions have been read and understood. Keep container tightly closed. Use only outdoors or in a well-ventilated area. Wear respiratory protection.	
Response	IF exposed or concerned: Call a POISON CENTER/doctor.	
Storage	Store locked up. 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

The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labeling) provides the necessary drug safety information.

All Mallinckrodt finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert (approved labeling) which provides necessary drug safety information.

3. Composition/information on ingredients**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
NITRIC OXIDE		10102-43-9	0.1-1% wt/wt
NITROGEN	Nitrogen; Nitrogen NF; LIN; Cryogenic Liquid Nitrogen; Refrigerated Liquid Nitrogen	7727-37-9	80-100% wt/wt

Composition comments

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

The exact concentrations of the above listed chemicals are being withheld as a trade secret.

4. First-aid measures**Inhalation**

Remove from further exposure. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory tract irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation. 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

Not likely, due to the form of the product. 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

Headache. Dizziness. Fatigue. Nausea, vomiting. Very high exposure can cause suffocation from lack of oxygen. Symptoms may include loss of mobility/consciousness. Victim may not be aware of asphyxiation. Asphyxiation may bring about unconsciousness without warning and so rapidly that victim may be unable to protect themselves. Coughing. Discomfort in the chest. Shortness of breath. Exposure to rapidly expanding gas or vaporizing liquid may cause frostbite ("cold burn"). May cause redness and pain. Dermatitis. 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.

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.

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.

General information 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

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂). Use fire-extinguishing media appropriate for surrounding materials. 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 and/or explosion do not breathe fumes. 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

Personal precautions, protective equipment and emergency procedures Many gases are heavier than air and will spread along ground and collect in low or confined areas (sewers, basements, tanks). 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.

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. Following product recovery, flush area with water.

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

7. Handling and storage

Precautions for safe handling Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Close valve after each use and when empty. Protect cylinders 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. Suck back of water into the container must be prevented. Do not allow backfeed into the container. Purge air from system before introducing gas. Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt. Oxygen concentration should not fall below 19.5 % at sea level (pO₂ = 135 mmHg). Mechanical ventilation or local exhaust ventilation may be required. 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 Cylinders should be stored upright, with valve protection cap in place, and firmly secured to prevent falling or being knocked over. Stored containers should be periodically checked for general condition and leakage. 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.

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 occupational health and safety)

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

Good general ventilation 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 control banding. If exposure limits have not been established, maintain airborne levels to an acceptable level. Use explosion-proof equipment. 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. If airborne concentrations are above the applicable exposure limits, use an approved respiratory protection. Use an air-supplied or air-purifying cartridge if the action level is exceeded. Ensure that the respirator has the appropriate protection factor for the exposure level. If cartridge type respirators are used, the cartridge must be appropriate for the chemical exposure. For emergencies or instances with unknown exposure levels, use a self-contained breathing apparatus (SCBA).

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

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

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

Inhalation	Suffocation (asphyxiant) hazard - if allowed to accumulate to concentrations that reduce oxygen below safe breathing levels. Prolonged inhalation may be harmful.
Skin contact	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

Headache. Dizziness. Fatigue. Nausea, vomiting. Very high exposure can cause suffocation from lack of oxygen. Symptoms may include loss of mobility/consciousness. Victim may not be aware of asphyxiation. Asphyxiation may bring about unconsciousness without warning and so rapidly that victim may be unable to protect themselves. Coughing. Discomfort in the chest. Shortness of breath. Exposure to rapidly expanding gas or vaporizing liquid may cause frostbite ("cold burn"). May cause redness and pain. Dermatitis.

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		
Gas		
LC50	Rat	130 ppm, 4 hours
LC50	Rat	115 ppm, 1 Hours

Skin corrosion/irritation May cause frostbite or freezing of skin.

Serious eye damage/eye irritation Exposure to rapidly expanding gas or vaporizing liquid may cause frostbite ("cold burn").

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 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 Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard None known.

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 available.
Environmental hazards	No
Special precautions for user	Not available.

IATA

UN number	UN1956
UN proper shipping name	Compressed gas, n.o.s. (Nitrogen, Nitric Oxide)
Transport hazard class(es)	
Class	2.2
Subsidiary risk	-
Packing group	Not available.
Environmental hazards	No
ERG Code	2L
Special precautions for user	Not available.
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. (Nitrogen, Nitric Oxide)
Transport hazard class(es)	
Class	2.2
Subsidiary risk	-
Packing group	Not available.
Environmental hazards	
Marine pollutant	No
EmS	F-C, S-V
Special precautions for user	Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.



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
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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

Issue date 09-13-2016
Revision date 09-03-2019

Version # 03

References
EPA: ACQUIRE database
NLM: Hazardous Substances Data Base
HSDB® - Hazardous Substances Data Bank
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices
US. IARC Monographs on Occupational Exposures to Chemical Agents
IARC Monographs. Overall Evaluation of Carcinogenicity

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. Mallinckrodt cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.

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