

1. Identification

Product identifier	Nitric Oxide (<2.3%) Blended with Nitrogen
CAS #	Mixture
Other means of identification	
SDS number	NO2.3
Synonyms	INOmax® * 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	
Supplier	
Company name	INO Therapeutics LLC d/b/a Mallinckrodt Pharmaceuticals
Address	Perryville III Corporate Park 53 Frontage Road, 3rd Floor, P.O. Box 9001 Hampton, New Jersey 08827-9001, USA
Telephone number	1-877-566-9466
Emergency telephone number	1-800-424-9300 (CHEMTREC)

2. Hazard(s) identification

Physical hazards	Gases under pressure	Compressed gas
Health hazards	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Specific target organ toxicity, repeated exposure	Category 2 (blood)
Environmental hazards	Not classified.	
OSHA defined hazards	Simple asphyxiant	

Labeling

Contains NITRIC OXIDE, NITROGEN

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

Response	If on skin: Wash with plenty of 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 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.
Hazard(s) not otherwise classified (HNOC)	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.
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

Flammable properties The product is not flammable.

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

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

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. Store in a cool, dry place. Store in a well-ventilated place. Protect from sunlight. Avoid high temperatures. Low temperatures. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
NITRIC OXIDE (CAS 10102-43-9)	PEL	30 mg/m ³ 25 ppm

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
NITRIC OXIDE (CAS 10102-43-9)	TWA	30 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

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 NO₂ with pungent odor in presence of air.

Odor threshold

0.5 - 5 ppm for NO₂

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 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 Nitrogen oxides (NO_x).

11. Toxicological information

Information on likely routes of exposure

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.

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.

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.

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

Product	Species	Test Results
Nitric Oxide (<2.3%) Blended with Nitrogen (CAS Mixture)		
Acute		
<i>Inhalation</i>		
LC50	Rat	5652.1738 ppm, 4 hours estimated

Components	Species	Test Results
NITRIC OXIDE (CAS 10102-43-9)		
Acute		
<i>Inhalation</i>		
LC50	Rat	130 ppm, 4 hours 115 mg/l, 1 Hours 57.5 mg/l, 4 Hours

Skin corrosion/irritation	Causes skin irritation.
Serious eye damage/eye irritation	Causes serious eye irritation.
Respiratory or skin sensitization	
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	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.

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	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	Waste codes should be assigned by the user based on the application for which the product was used. 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

DOT

UN number	UN1956
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
Packing group	Not applicable.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
ERG number	126

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.
Cargo aircraft only	Allowed.

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.

DOT



IATA; IMDG



15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
All components are on the U.S. EPA TSCA Inventory List.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

NITRIC OXIDE (CAS 10102-43-9) Listed.

SARA 304 Emergency release notification

NITRIC OXIDE (CAS 10102-43-9) 10 lbs

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA (Superfund) reportable quantity

NITRIC OXIDE: 10.0000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - Yes
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
NITRIC OXIDE	10102-43-9	10	100 lbs		

SARA 311/312 Hazardous chemical Yes

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

NITRIC OXIDE (CAS 10102-43-9)

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

NITRIC OXIDE (CAS 10102-43-9)

NITROGEN (CAS 7727-37-9)

US. New Jersey Worker and Community Right-to-Know Act

NITRIC OXIDE (CAS 10102-43-9)

NITROGEN (CAS 7727-37-9)

US. Pennsylvania Worker and Community Right-to-Know Law

NITRIC OXIDE (CAS 10102-43-9)

NITROGEN (CAS 7727-37-9)

US. Rhode Island RTK

NITRIC OXIDE (CAS 10102-43-9)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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
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, including date of preparation or last revision

Issue date 03-29-2016

Version # 01

NFPA Ratings



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