



SAFETY DATA SHEET

1. Identification

Product identifier	N-Nitroso Bisoprolol Solution	
Other means of identification		
Catalog number	1A04250	
Chemical name	N-(2-Hydroxy-3-(4-((2-isopropoxyethoxy)methyl)phenoxy)propyl)-N-isopropylnitrous amide	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	Customer Service	301-881-0666
Website	www.usp.org	
E-mail	PAITech@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Flammable liquids	Category 2
Health hazards	Acute toxicity, oral	Category 3
	Acute toxicity, dermal	Category 3
	Acute toxicity, inhalation	Category 3
	Carcinogenicity	Category 2
	Reproductive toxicity	Category 2
	Specific target organ toxicity, single exposure	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Highly flammable liquid and vapor. Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled. Suspected of causing cancer. Causes damage to organs. Suspected of damaging fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use explosion-proof electrical/ventilating/lighting equipment. Keep container tightly closed. Use only non-sparking tools. Take precautionary measures against static discharge. Do not breathe mist/vapors. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Use only outdoors or in a well-ventilated area.

Response	If exposed: Call a poison center/doctor. If swallowed: Rinse mouth. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. In case of fire: Use appropriate media to extinguish.
Storage	Keep cool. Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Methanol	Wood alcohol	67-56-1	99.9
N-Nitroso Bisoprolol		2820170-76-9	0.1

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

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. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a poison center or doctor/physician.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical advice/attention if you feel unwell. Get medical attention if irritation develops and persists. 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	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Thermal burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Keep victim warm. Keep affected person under observation. Symptoms may be delayed.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	By heating and fire, harmful vapors/gases may be formed.
Special protective equipment and precautions for firefighters	Use protective equipment appropriate for surrounding materials.
Fire fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Highly flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate personal protective equipment. Avoid inhalation of vapors. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Absorb spillage with suitable absorbent material. Remove sources of ignition. Keep combustibles (wood, paper, oil, etc.) away from spilled material. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground. Use appropriate containment to avoid environmental contamination.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

U.S. - OSHA Components

Components	Type	Value	Form
Methanol (CAS 67-56-1)	PEL	200 ppm	Skin

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

Components	Type	Value
Methanol (CAS 67-56-1)	PEL	260 mg/m3 200 ppm

ACGIH

Components

Components	Type	Value	Form
Methanol (CAS 67-56-1)	STEL	250 ppm	Skin

US. ACGIH Threshold Limit Values Components

Components	Type	Value
Methanol (CAS 67-56-1)	STEL	250 ppm
	TWA	200 ppm

U.S. - NIOSH Components

Components	Type	Value	Form
Methanol (CAS 67-56-1)	IDLH	6000 ppm	
	STEL	250 ppm	Skin

US. NIOSH: Pocket Guide to Chemical Hazards Components

Components	Type	Value
Methanol (CAS 67-56-1)	STEL	325 mg/m3 250 ppm
	TWA	260 mg/m3 200 ppm

Biological limit values

ACGIH Biological Exposure Indices Components

Components	Value	Determinant	Specimen	Sampling Time
Methanol (CAS 67-56-1)	15 mg/l	Methanol	Urine	*

* - For sampling details, please see the source document.

Exposure guidelines

US - California OELs: Skin designation

Methanol (CAS 67-56-1)

Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

Methanol (CAS 67-56-1)

Skin designation applies.

US - Tennessee OELs: Skin designation

Methanol (CAS 67-56-1)

Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Methanol (CAS 67-56-1)

Danger of cutaneous absorption

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Methanol (CAS 67-56-1)

Can be absorbed through the skin.

Appropriate engineering controls

No open handling. For laboratory operation, use an engineered local exhaust ventilation (LEV) and/or enclosure or isolator system for procedures where aerosolization of solutions may occur (e.g., vortexing, pipetting, pumping). Control the potential for spills and leaks by securing all connections. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Liquid.

Form

Liquid.

Color

Colorless.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the decomposition temperature. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Toxic if inhaled. May cause damage to organs by inhalation.
Skin contact	Toxic in contact with skin.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Toxic if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics
 Difficulty in breathing. Central nervous system effects. Visual disturbances. Gastrointestinal disturbances. Metabolic acidosis. Seizures.

Information on toxicological effects

Acute toxicity
 Toxic if inhaled. Toxic in contact with skin. Toxic if swallowed.

Components	Species	Test Results
Methanol (CAS 67-56-1)		
<u>Acute</u>		
Oral		
LD50	Rat	1187 - 2769 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Local effects		
Methanol		Eye irritation Result: Non-irritant. Species: Rabbit Skin irritation Result: Non-irritant. Species: Rabbit
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about sensitization hazard is incomplete.	
Skin sensitization	Knowledge about sensitization hazard is incomplete.	
Methanol		Maximisation Test Result: Non-sensitizing Species: Guinea pig Organ: Skin
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	

Mutagenicity

Methanol

Ames test (Salmonella typhimurium)
 Result: Negative (+/- activation)
 Mutagenicity: Chromosome damage in mice
 Result: Negative
 Mutagenicity: Grasshoppers
 Result: Positive
 Mutagenicity: Yeast
 Result: Positive

Carcinogenicity

Suspected of causing cancer.

No specific information regarding the carcinogenic potential of this material has been found.
 Nitrosamines as a class are considered to be carcinogens based on results of animal studies.

Methanol

10 - 1000 ppm Carcinogenicity
 Result: Not carcinogenic
 Species: Rat
 Organ: Inhalation
 Test Duration: 18 months
 Carcinogenicity: 25mL/twice weekly
 Result: One tumor out of 80 specimens.
 Species: Mouse
 Organ: Dermal
 Test Duration: 50 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Some beta-adrenergic blocking agents have been reported to cause fetal and neonatal bradycardia, hypotension, and hypoglycemia when administered during pregnancy, and may also be associated with fetal growth retardation. It is not known if this material causes the same effects.

Reproductivity

Methanol

20000 ppm Gestational study, Increased incidence of anomalies and maternal effects at high doses.
 Species: Rat
 Organ: Inhalation
 Developmental Toxicity, Behavioral effects in offspring; increased incidence of anomalies; maternal toxicity.
 Species: Rat
 Gestational study, High doses increased fetal resorptions and malformations, including neural, cranial, and ocular defects.
 Species: Mouse

Specific target organ toxicity - single exposure

Causes damage to organs.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

Knowledge about health hazard is incomplete.

12. Ecological information**Ecotoxicity**

Product		Species	Test Results
N-Nitroso Bisoprolol Solution			
Aquatic			
Crustacea	EC50	Daphnia	17200.5332 mg/l, 48 hours estimated
Fish	LC50	Fish	20495.4961 mg/l, 96 hours estimated
Components			
Species			
Test Results			
Methanol (CAS 67-56-1)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 48 hours

Components	Species	Test Results
Fish	LC50	Fathead minnow (Pimephales promelas) > 100 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.	
Bioaccumulative potential		
Mobility in soil	No data available.	
Other adverse effects	The product contains volatile organic compounds which have a photochemical ozone creation potential.	

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	D001: Waste Flammable material with a flash point <140 F U154: Waste Methyl alcohol The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN1230
UN proper shipping name	Methanol, solution (Methanol RQ = 5005 LBS)
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II
Packaging exceptions	150
Packaging non bulk	202
Packaging bulk	242

IATA

UN number	UN1230
UN proper shipping name	Methanol solution (Methanol)
Transport hazard class(es)	
Class	3
Subsidiary risk	6.1(PGI, II)
Packing group	II
Other information	

Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

DOT



IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Methanol (CAS 67-56-1)

Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Flammable (gases, aerosols, liquids, or solids)
Acute toxicity (any route of exposure)
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Hazard not otherwise classified (HNOC)

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
Methanol	67-56-1	99.9

Other federal regulations

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

Methanol (CAS 67-56-1)

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

Not regulated.

Safe Drinking Water Act (SDWA)

Contains component(s) regulated under the Safe Drinking Water Act.

US state regulations

California Proposition 65



WARNING: This product can expose you to Methanol, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Methanol (CAS 67-56-1)

Listed: March 16, 2012

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Methanol (CAS 67-56-1)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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	05-22-2023
Version #	01
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