## **SAFETY DATA SHEET**



#### 1. Identification

Product identifier N-Nitroso N-Desmethyl Nizatidine Solution

Other means of identification

Catalog number 1A09540

Chemical name N-Methyl-N-((4-(((2-(((1-(methylamino)-2-nitrovinyl)amino)ethyl)thio)methyl)thiazol-2-

yl)methyl)nitrous 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 AMTech@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

## 2. Hazard(s) identification

Physical hazardsFlammable liquidsCategory 2Health hazardsAcute toxicity, oralCategory 3Acute toxicity, dermalCategory 3Acute toxicity, inhalationCategory 3CarcinogenicityCategory 2

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Specific target organ toxicity, single exposure

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.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Keep away from heat, hot surfaces, sparks, open flames and other ignition

Category 1

sources. No smoking. Keep container tightly closed. Use explosion-proof

electrical/ventilating/lighting equipment. Take action to prevent static discharges. Do not breathe mist/vapors. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.

Wear protective gloves/protective clothing/eye protection/face protection.

Response If exposed: Immediately 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 container tightly closed. Store in a well-ventilated place. Keep cool. 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 Pharmaceutical related compound of unknown potency.

## 3. Composition/information on ingredients

#### **Mixture**

| Chemical name                    | Common name and synonyms | CAS number | %    |
|----------------------------------|--------------------------|------------|------|
| Methanol                         |                          | 67-56-1    | 99.9 |
| N-Nitroso N-Desmethyl Nizatidine |                          | No Data    | 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 person 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 the substance is inhaled. 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. 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 substance is ingested. 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. Central nervous system effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

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. Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods

the chemical

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to cool unopened containers. Use standard firefighting procedures and consider the hazards of other involved materials.

### 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. 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.

## 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.

Value

## 8. Exposure controls/personal protection

#### Occupational exposure limits

Components

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.

| Components             | туре | value     |
|------------------------|------|-----------|
| Methanol (CAS 67-56-1) | PEL  | 260 mg/m3 |
|                        |      | 200 ppm   |

Typo

## **US. ACGIH Threshold Limit Values (TLV)**

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

#### NIOSH. Immediately Dangerous to Life or Health (IDLH) Values, as amended

| Components             | Туре | Value    |
|------------------------|------|----------|
| Methanol (CAS 67-56-1) | IDLH | 6 %      |
|                        |      | 6000 ppm |

# US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)

| 03. NOSTI. Pocket Guide to Chemical Hazards Necommended Exposure Limits (NEL) |      |           |  |
|---|------|-----------|--|
| Components  | Туре | 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 (BEI)** 

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

<sup>\* -</sup> 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. Not available. Odor **Odor threshold** Not available. pН Not available. Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

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.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition tomporature

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

## 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 Heat, flames and sparks. Temperatures exceeding the flash point. Contact with incompatible

materials.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition** 

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 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

Methyl Alcohol: Central nervous system effects. Difficulty breathing. 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)

**Acute** 

Dermal

LD50 Rabbit 17100 mg/kg

15800 mg/kg

Inhalation

Vapor

LC50 Rat 128.2 mg/l, 4 Hours

82.1 mg/l, 6 Hours

Oral

LD50 Rat 1187 - 2769 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Local effects

Methanol Eye irritation

Result: Negative. Species: Rabbit Skin irritation Result: Negative. Species: Rabbit

Respiratory or skin sensitization

**Respiratory sensitization** Knowledge about health hazard is incomplete.

**Skin sensitization** Knowledge about health hazard is incomplete.

Methanol Guinea pig maximization test

Result: Negative.

**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

Mutagenicity

Methanol Ames test (Salmonella typhimurium)

Result: Negative (+/- activation)

Mutagenicity, Chromosomal aberration assays in yeast and

grasshoppers 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: Negative. Species: Rat

Test Duration: 18 months

Carcinogenicity, 25 mL/twice daily. One tumor out of 80

specimens;.
Species: Mouse

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** Knowledge about health hazard is incomplete.

Reproductivity

Methanol 20000 ppm Reproductivity, Increased incidence of

anomalies and maternal effects at high doses.

Species: Rat

Reproductivity, Behavioral effects in offspring; increased

incidence of anomalies; maternal toxicity.

Species: Rat

Reproductivity, 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.

Further information Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components Species Test Results

Methanol (CAS 67-56-1)

Aquatic Acute

Crustacea EC50 Water flea (Daphnia magna) > 10000 mg/l, 48 hours

Components **Species Test Results** 

Fish LC50 Fathead minnow (Pimephales > 100 mg/l, 96 hours

promelas)

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

-0.77Methanol

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 of contents/container in accordance with local/regional/national/international

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

Methanol, solution (Methanol RQ = 5005 LBS)

is emptied.

### 14. Transport information

DOT

UN1230 **UN** number

**UN** proper shipping name

Transport hazard class(es)

3 Class

Subsidiary hazard Ш

Packing group

**Environmental hazards** 

Marine pollutant No.

IATA

UN1230 **UN** number

**UN** proper shipping name

Transport hazard class(es)

Class 3

**Subsidiary hazard** 

Packing group

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

Not established.

6.1

Methanol solution (Methanol)

DOT





**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)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

**Classified hazard** 

Flammable (gases, aerosols, liquids, or solids)

categories

Acute toxicity (any route of exposure)

Carcinogenicity

Specific target organ toxicity (single or repeated exposure)

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)

Not regulated.

### **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

### International Inventories

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

Australia Australian Inventory of Industrial Chemicals (AICIS)

USP SDS US

No

| Country(s) or region | Inventory name   | On inventory (yes/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                     |

<sup>\*</sup>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).

Toxic Substances Control Act (TSCA) Inventory

## 16. Other information, including date of preparation or last revision

**Issue date** 06-11-2025

Version # 01

United States & Puerto Rico

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information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been compiled by USP staff from sources considered to be scientifically reliable but has not been independently verified by USP. USP does not guarantee the accuracy or completeness of the information from these sources included herein nor should

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No