



## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 31/01/2023 Version: 1.0

# SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product form : Mixture

Product name : N-nitroso-dimethylamine (solution in Methanol)

Product code : 202000236

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.

Use of the substance/mixture : For professional use only Function or use category : Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare

EDQM, Council of Europe 7, Allée Kastner, CS30026

F-67081 Strasbourg

France

T +33(0)388412035 - F +33(0)388412771

sds@edqm.eu - www.edqm.eu

#### 1.4. Emergency telephone number

Emergency number : +33(0)390215608

#### **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

## Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2

Acute toxicity (oral), Category 3

Acute toxicity (dermal), Category 3

H311

Acute toxicity (inhalation:vapour) Category 3

H331

Carcinogenicity, Category 1B

Specific target organ toxicity – single exposure, Category 1

H370

Full text of H- and EUH-statements: see section 16

#### Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

#### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)





GHS02

GHS06

GHS08

Signal word (CLP) : Danger

Contains : methanol; dimethylnitrosoamine; N-nitrosodimethylamine

Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.

H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.

H350 - May cause cancer.

H370 - Causes damage to organs.

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Precautionary statements (CLP)

: P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 - Keep container tightly closed.

P240 - Ground and bond container and receiving equipment.

P241 - Use explosion-proof electrical/ventilating/lighting equipment.

P260 - Do not breathe dust/fume/gas/mist/vapours/spray.

P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

P311 - Call a POISON CENTER or doctor.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P330 - Rinse mouth.

P361+P364 - Take off immediately all contaminated clothing and wash it before reuse.

P370+P378 - In case of fire: Use media other than water to extinguish.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P403+P235 - Store in a well-ventilated place. Keep cool.

P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP)





GHS06

GHS08

Hazardous ingredients : methanol; dimethylnitrosoamine; N-nitrosodimethylamine

#### 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## **SECTION 3: Composition/information on ingredients**

## 3.1. Substances

Not applicable

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#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
methanol	CAS-No.: 67-56-1 EC-No.: 200-659-6 EC Index-No.: 603-001-00-X	≥90 - ≤100	Flam. Liq. 2, H225 Acute Tox. 3 (Inhalation), H331 (ATE=3 mg/l/4h) Acute Tox. 3 (Dermal), H311 (ATE=300 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) STOT SE 1, H370
dimethylnitrosoamine; N-nitrosodimethylamine	CAS-No.: 62-75-9 EC-No.: 200-549-8 EC Index-No.: 612-077-00-3	≥0.001 - <0.1	Carc. 1B, H350 Acute Tox. 2 (Inhalation), H330 (ATE=0.5 mg/l/4h) Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) STOT RE 1, H372 Aquatic Chronic 2, H411

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
methanol	CAS-No.: 67-56-1 EC-No.: 200-659-6 EC Index-No.: 603-001-00-X	( 3 ≤C < 10) STOT SE 2, H371 ( 10 ≤C < 100) STOT SE 1, H370
dimethylnitrosoamine; N-nitrosodimethylamine	CAS-No.: 62-75-9 EC-No.: 200-549-8 EC Index-No.: 612-077-00-3	( 0.001 ≤C ≤ 100) Carc. 1B, H350

Full text of H- and EUH-statements: see section 16

## **SECTION 4: First aid measures**

## 4.1. Description of first aid measures

First-aid measures after inhalation : Move to fresh air. Allow affected person to breathe fresh air.

First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of

water and detergent.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open.

First-aid measures after ingestion : Rinse mouth. Immediately call a POISON CENTER/doctor. Prolonged medical observation

may be indicated.

## 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : Delayed adverse effects possible.
Symptoms/effects after inhalation : Insufficient data available.
Symptoms/effects after skin contact : Insufficient data available.
Symptoms/effects after eye contact : Insufficient data available.

## 4.3. Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label.

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#### **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

## 5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2.

#### 5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

## **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

6.1.1. For non-emergency personnel

Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.

6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

No additional information available

## 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable

remainder with: Sodium hypochlorite solution.

## 6.4. Reference to other sections

No additional information available

## **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Additional hazards when processed : The attention of the user is drawn to the risks possibly incurred by using the product for any

other purpose than that for which it was intended.

Precautions for safe handling : Material should be handled with caution. Avoid any direct contact with the product. Material

should be handled in a laboratory hood whenever possible.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

#### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Store locked up.

#### 7.3. Specific end use(s)

See Heading 1.

## SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

## 8.1.1 National occupational exposure and biological limit values

No additional information available

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#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

## 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

#### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

#### Eye protection:

Safety glasses. DIN EN 166

## 8.2.2.2. Skin protection

#### Skin and body protection:

Use chemically protective clothing. DIN EN 13034

#### Hand protection:

Chemically resistant protective gloves. ISO 374-1

## 8.2.2.3. Respiratory protection

## Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product: Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

No additional information available

## **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state : Liquid Colour : Not available Odour : Not applicable. Odour threshold : Not available : Not available Melting point Freezing point : Not available Boiling point Not available Flammability : Not available **Explosive limits** : Not available Lower explosion limit : Not available Upper explosion limit : Not available Flash point : Not available Auto-ignition temperature : Not available : Not available Decomposition temperature : Not available Viscosity, kinematic : Not available Solubility : Not available

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Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C Not available Density Not available Relative density Not available Relative vapour density at 20°C : Not available Particle characteristics : Not applicable

#### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

Stable under normal conditions.

#### 10.2. Chemical stability

No additional information available

## 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

No additional information available

## 10.5. Incompatible materials

None under normal use. See Section 7.

#### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

# **SECTION 11: Toxicological information**

## 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Toxic if swallowed. Acute toxicity (dermal) Toxic in contact with skin. Acute toxicity (inhalation) : Toxic if inhaled.

N-nitroso-dimethylamine (solution in Methanol)		
ATE CLP (oral)	100.06 mg/kg bodyweight	
ATE CLP (dermal)	300.18 mg/kg bodyweight	
ATE CLP (vapours)	3.002 mg/l/4h	
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)	

Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met) Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met) Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)

Carcinogenicity : May cause cancer.

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : Causes damage to organs.

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methanol (67-56-1)		
STOT-single exposure	Causes damage to organs.	
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)	
dimethylnitrosoamine; N-nitrosodimethylamine (62-75-9)		
STOT-repeated exposure	OT-repeated exposure Causes damage to organs through prolonged or repeated exposure.	

: Not classified (Based on available data, the classification criteria are not met)

## 11.2. Information on other hazards

No additional information available

# **SECTION 12: Ecological information**

#### 12.1. Toxicity

Aspiration hazard

Ecology - general : Hazardous waste. Use suitable disposal containers.

Hazardous to the aquatic environment, short-term : Not classified (Based on available data, the classification criteria are not met)

acute)

Hazardous to the aquatic environment, long-term : Not classified (Based on available data, the classification criteria are not met)

(chronic)

### 12.2. Persistence and degradability

No additional information available

## 12.3. Bioaccumulative potential

No additional information available

## 12.4. Mobility in soil

No additional information available

## 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Endocrine disrupting properties

No additional information available

## 12.7. Other adverse effects

No additional information available

## **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Product/Packaging disposal recommendations : Do not empty into drains, dispose of this material and its container at hazardous or special

waste collection point.

## **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 2929	UN 2929	UN 2929

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ADR	IMDG	IATA	
14.2. UN proper shipping name			
TOXIC LIQUID, FLAMMABLE, ORGANIC, N.O.S.	TOXIC LIQUID, FLAMMABLE, ORGANIC, N.O.S.	Toxic liquid, flammable, organic, n.o.s.	
Transport document description			
UN 2929 TOXIC LIQUID, FLAMMABLE, ORGANIC, N.O.S., 6.1 (3), II, (D/E)	UN 2929 TOXIC LIQUID, FLAMMABLE, ORGANIC, N.O.S., 6.1 (3), II	UN 2929 Toxic liquid, flammable, organic, n.o.s., 6.1 (3), II	
14.3. Transport hazard class(es)			
6.1 (3)	6.1 (3)	6.1 (3)	
6	6	6	
14.4. Packing group			
П	II	П	
14.5. Environmental hazards			
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	
No supplementary information available			

## 14.6. Special precautions for user

## Overland transport

Classification code (ADR) : TF1 Special provisions (ADR) 274 Limited quantities (ADR) : 100ml Excepted quantities (ADR) : E4 : P001, IBC02 Packing instructions (ADR) : MP15 Mixed packing provisions (ADR) Portable tank and bulk container instructions (ADR) : T11 Portable tank and bulk container special provisions : TP2, TP27 (ADR) Tank code (ADR) : L4BH

Tank special provisions (ADR) : TU15, TE19
Vehicle for tank carriage : FL
Transport category (ADR) : 2

Special provisions for carriage - Loading, unloading : CV13, CV28

and handling (ADR)

Special provisions for carriage - Operation (ADR) : S2, S9, S19

Hazard identification number (Kemler No.) : 63
Orange plates : 63

63 2929

Tunnel restriction code (ADR) : D/E

Transport by sea

Special provisions (IMDG) : 274
Limited quantities (IMDG) : 100 ml
Excepted quantities (IMDG) : E4
Packing instructions (IMDG) : P001
IBC packing instructions (IMDG) : IBC02
Tank instructions (IMDG) : T11

Tank special provisions (IMDG) : TP2, TP13, TP27

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EmS-No. (Fire): F-EEmS-No. (Spillage): S-DStowage category (IMDG): BStowage and handling (IMDG): SW2

Properties and observations (IMDG) : Toxic if swallowed, by skin contact or by inhalation.

#### Air transport

PCA Excepted quantities (IATA) : E4 : Y641 PCA Limited quantities (IATA) PCA limited quantity max net quantity (IATA) : 1L PCA packing instructions (IATA) : 654 : 5L PCA max net quantity (IATA) : 662 CAO packing instructions (IATA) CAO max net quantity (IATA) : 60L Special provisions (IATA) : A4, A137 ERG code (IATA)

#### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## **SECTION 15: Regulatory information**

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

#### **REACH Annex XVII (Restriction List)**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

## **REACH Annex XIV (Authorisation List)**

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Contains no substance(s) listed on the REACH Candidate List

## **PIC Regulation (Prior Informed Consent)**

Not applicable.

#### **POP Regulation (Persistent Organic Pollutants)**

Not applicable.

### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### **Drug Precursors Regulation (273/2004)**

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

## 15.2. Chemical safety assessment

No additional information available

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## **SECTION 16: Other information**

Full text of H- and EUF	Full text of H- and EUH-statements:		
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2		
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3		
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3		
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3		
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2		
Carc. 1B	Carcinogenicity, Category 1B		
Flam. Liq. 2	Flammable liquids, Category 2		
H225	Highly flammable liquid and vapour.		
H301	Toxic if swallowed.		
H311	Toxic in contact with skin.		
H330	Fatal if inhaled.		
H331	Toxic if inhaled.		
H350	May cause cancer.		
H370	Causes damage to organs.		
H371	May cause damage to organs.		
H372	Causes damage to organs through prolonged or repeated exposure.		
H411	Toxic to aquatic life with long lasting effects.		
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1		
STOT SE 1	Specific target organ toxicity – single exposure, Category 1		
STOT SE 2	Specific target organ toxicity – Single exposure, Category 2		

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Flam. Liq. 2	H225	Expert judgment
Acute Tox. 3 (Oral)	H301	Calculation method
Acute Tox. 3 (Dermal)	H311	Calculation method
Acute Tox. 3 (Inhalation:vapour)	H331	Calculation method
Carc. 1B	H350	Calculation method
STOT SE 1	H370	Calculation method

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.