



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form : Substance

Substance name : N-methyl-3-(10H-phenothiazin-10-yl)propan-1-amine hydrochloride

Product code : 202100389

Synonyms : Promazine hydrochloride impurity B

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]

Acute toxicity (oral), Category 4 H302
Skin sensitisation, Category 1 H317
Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411

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) :



GHS07

GHS09

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.

H317 - May cause an allergic skin reaction.

H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

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

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

P272 - Contaminated work clothing should not be allowed out of the workplace.

P273 - Avoid release to the environment.

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

P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.

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

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

P330 - Rinse mouth.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P391 - Collect spillage.

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

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
N-methyl-3-(10H-phenothiazin-10-yl)propan-1-amine hydrochloride	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Sens. 1, H317 Aquatic Chronic 2, H411

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

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

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

First-aid measures after eye contact : Rinse eyes with water as a precaution.

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

No additional information available

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

No additional information available

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.

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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

6.1.1. For non-emergency personnel

Emergency procedures : Avoid all unnecessary exposure.

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

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

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

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. Both local exhaust and general room ventilation are usually required.

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8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

8.2.2.2. Skin protection

Skin and body protection:

Lab coat

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

No additional information available

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 : Solid Colour : Not available Odour : Not available Odour threshold : Not available Melting point : Not available Freezing point : Not available Boiling point : Not available Flammability : Not available **Explosive limits** : Not applicable Lower explosion limit : Not applicable : Not applicable Upper explosion limit Flash point : Not applicable Auto-ignition temperature : Not applicable Decomposition temperature : Not available : Not available pH solution : Not available Viscosity, kinematic : Not applicable Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available : Not available Vapour pressure Vapour pressure at 50°C : Not available Density : Not available Relative density : Not available Relative vapour density at 20°C : Not applicable : Not available Particle size

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

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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

None known.

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) : Harmful if swallowed.

Acute toxicity (dermal) : Not classified (Lack of data)

Acute toxicity (inhalation) : Not classified (Lack of data)

N-methyl-3-(10H-phenothiazin-10-yl)propan-1-amine hydrochloride

LD50 oral rat 300 – 2000 (estimated value)

Skin corrosion/irritation: Not classified (Lack of data)Serious eye damage/irritation: Not classified (Lack of data)Respiratory or skin sensitisation: May cause an allergic skin reaction.Germ cell mutagenicity: Not classified (Lack of data)

Carcinogenicity : Not classified (Lack of data)
Reproductive toxicity : Not classified (Lack of data)
STOT-single exposure : Not classified (Lack of data)
STOT-repeated exposure : Not classified (Lack of data)

Aspiration hazard : Not classified (Technical impossibility to obtain the data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term : Not classified (Lack of data)

(acute)

Hazardous to the aquatic environment, long-term : Toxic to aquatic life with long lasting effects.

(chronic)

Not rapidly degradable

12.2. Persistence and degradability

No additional information available

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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

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		

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14.6. Special precautions for user

Overland transport

Classification code (ADR) : M7

Special provisions (ADR) : 274, 335, 375, 601

Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1

Packing instructions (ADR) : P002, IBC08, LP02, R001

Special packing provisions (ADR) : PP12, B3 Mixed packing provisions (ADR) : MP10

Portable tank and bulk container instructions (ADR) : T1, BK1, BK2, BK3

Portable tank and bulk container special provisions : TP33

(ADR)

Tank code (ADR) : SGAV, LGBV

Vehicle for tank carriage : AT

Transport category (ADR) : 3

Special provisions for carriage - Packages (ADR) : V13

Special provisions for carriage - Bulk (ADR) : VC1, VC2

Special provisions for carriage - Loading, unloading : CV13

and handling (ADR)

Hazard identification number (Kemler No.) : 90

Orange plates :

90 3077

Tunnel restriction code (ADR) : -

Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969

Limited quantities (IMDG) : 5 kg
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : LP02, P002
Special packing provisions (IMDG) : PP12
IBC packing instructions (IMDG) : IBC08
IBC special provisions (IMDG) : B3

Tank instructions (IMDG) : BK1, BK2, BK3, T1

Tank special provisions (IMDG) : TP33
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-F
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg

Special provisions (IATA) : A97, A158, A179, A197, A215

ERG code (IATA) : 9L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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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)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

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

SECTION 16: Other information

Full text of H- and EUH-statements:		
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4	
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2	
H302	Harmful if swallowed.	
H317	May cause an allergic skin reaction.	
H411	Toxic to aquatic life with long lasting effects.	
Skin Sens. 1	Skin sensitisation, Category 1	

Safety Data Sheet (SDS), EU

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