

Promethazine Hydrochloride

Safety Data Sheet

258989

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 3.0

Date of issue: 15/11/2012 Revision date 17/06/2019

Supersedes 06/01/2017

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

1.1. Product identifier

Product form : Substance
Substance name : Promethazine Hydrochloride
EC-No. : 200-375-2
CAS-No. : 58-33-3
Product code : 258989
Formula : C17H21ClN2S
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

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
Serious eye damage/eye irritation, Category 1 H318
Skin sensitisation, Category 1 H317
Hazardous to the aquatic environment — Chronic Hazard, Category 2 H411

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Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS05



GHS07



GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P273 - Avoid release to the environment.
P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352 - IF ON SKIN: Wash with plenty of water/...
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Promethazine Hydrochloride	(CAS-No.) 58-33-3 (EC-No.) 200-375-2	≈ 100	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Chronic 2, H411

Full text of H-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 inhalation : Allow the victim to rest. Assure fresh air breathing. If experiencing respiratory symptoms: Call a poison center or a doctor.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

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- First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. Contact ophthalmologist immediately.
- First-aid measures after ingestion : Do NOT induce vomiting. Rinse mouth. Seek medical advice.

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 : Carbon dioxide, dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂). Water spray.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Precautionary measures fire : Exercise caution when fighting any chemical fire.
- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Protective equipment : Wear recommended personal protective equipment.
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
- Emergency procedures : Ensure adequate air ventilation. Evacuate unnecessary personnel.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. Hose down area with water.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Protect from light. Store in dry, well-ventilated area.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Protective goggles. Dust/aerosol mask with filter type P2. Gloves.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P2



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Crystalline powder.
Molecular mass : 320.9 g/mol
Colour : white to slightly yellow.
Odour : nearly odourless.
Odour threshold : No data available
pH : 4 (10% solution)
Relative evaporation rate (butylacetate=1) : No data available
Melting point : 222 °C

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Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: 390 °C
Decomposition temperature	: 200 °C
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water. Soluble in ethanol.

Log Pow	: -0.72
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Light (daylight). Moisture.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Sulphur oxides. Nitrogen oxides. Carbon oxides (CO, CO₂). Hydrogen chloride.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

Promethazine Hydrochloride (58-33-3)	
LD50 oral rat	765 mg/kg

Skin corrosion/irritation	: Not classified pH: 4 (10% solution)
Serious eye damage/irritation	: Causes serious eye damage. pH: 4 (10% solution)

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Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Promethazine Hydrochloride (58-33-3)	
LC50 fish 1	1.5 mg/l
EC50 Daphnia 1	1.5 mg/l Daphnia magna 48 h

12.2. Persistence and degradability

Promethazine Hydrochloride (58-33-3)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Promethazine Hydrochloride (58-33-3)	
Log Pow	-0.72

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste treatment methods : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN



ADR	IATA
14.1. UN number	
3077	3077
14.2. UN proper shipping name	
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
14.3. Transport hazard class(es)	
9	9

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ADR	IATA
	
14.4. Packing group	
III	III
14.5. Environmental hazards	
Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available	

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 (ADR)	: TP33
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 and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 

Tunnel restriction code (ADR)	: -
EAC code	: 2Z

- 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

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

ERG code (IATA) : 9L

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

No REACH Annex XVII restrictions

Promethazine Hydrochloride is not on the REACH Candidate List

Promethazine Hydrochloride is not on the REACH Annex XIV List

Seveso Information : E2 environmental hazards

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.2	Use of the substance/mixture	Added	
1.4	Emergency telephone	Modified	Added additional information
2	R-phrases	Removed	Obsolete
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Added	H317 + H318
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Removed	H312 + H332 + H319
7.2	Storage temperature	Added	
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added sentence on choosing type of clothing according to concentration levels
8.2	Respiratory protection	Added	

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose
LC50	Median lethal concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

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Data sources : EP. Supplier.

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
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H411	Toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II) Version 2018

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product