



CONSEIL DE L'EUROPE

Chlorpromazine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 01/04/2023 Version: 1.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Chlorpromazine hydrochloride
Chemical name	Chlorpromazine hydrochloride
Product code	: 201600189
Synonyms	: Chlorpromazine, hydrates, isomers and impurities where applicable
1.2. Relevant identified uses of the substant	nce or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category Use of the substance/mixture Function or use category	 The product is intended for research, analysis and scientific education. For professional use only 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 3	H301
Acute toxicity (dermal), Category 3	H311
Serious eye damage/eye irritation, Category 1	H318
Skin sensitisation, Category 1	H317
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410
Full text of H- and EUH-statements: see section 16	

2.2. Label ele

Adverse physicochemical, human health and en Expert judgement and weight of evidence determina	
2.2. Label elements	
Labelling according to Regulation (EC) No. 1272	/2008 [CLP]
Hazard pictograms (CLP)	
	GHS05 GHS06 GHS09
Signal word (CLP)	: Danger
Hazard statements (CLP)	: H301+H311 - Toxic if swallowed or in contact with skin.

H317 - May cause an allergic skin reaction.

H318 - Causes serious eye damage.

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	H362 - May cause harm to breast-fed children.
	H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP) :	P201 - Obtain special instructions before use.
	P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
	P263 - Avoid contact during pregnancy and while nursing.
	P264 - Wash hands, forearms and face thoroughly after handling.
	P204 - Wash hands, forearns and face thoroughly after handling. 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+P310 - IF SWALLOWED: Immediately call a doctor.
	P302+P352 - IF ON SKIN: Wash with plenty of water.
	P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove
	contact lenses, if present and easy to do. Continue rinsing.
	P308+P313 - IF exposed or concerned: Get medical advice/attention.
	P310 - Immediately call a POISON CENTER or doctor.
	P312 - Call a POISON CENTRE or doctor if you feel unwell.
	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.
	P361+P364 - Take off immediately all contaminated clothing and wash it before reuse.
	P362+P364 - Take off contaminated clothing and wash it before reuse.
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	P391 - Collect spillage.
	P405 - Store locked up.
	P501 - Dispose of contents/container to hazardous or special waste collection point, in
Labelling according to examption for inner postaging	accordance with local, regional, national and/or international regulation.
Labelling according to: exemption for inner packaging	
Hazard pictograms (CLP) :	

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]
Chlorpromazine hydrochloride	-	≤ 100	Acute Tox. 3 (Oral), H301 (ATE=145 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE=300 mg/kg bodyweight) Eye Dam. 1, H318 Skin Sens. 1, H317 Lact., H362 Aquatic Chronic 1, H410

GHS05

GHS06

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

3.2. Mixtures

Not applicable

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SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures general First-aid measures after inhalation	 Immediately flush the contact area with plenty of water. Move to fresh air. Allow affected person to breathe fresh air. Immediate medical attention and special treatment, if necessary.
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. Flush with lukewarm water for 15 minutes. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, consult an eye specialist.
First-aid measures after ingestion	: Rinse mouth. Immediately call a POISON CENTER/doctor. Do not induce vomiting. Specific medical surveillance.
4.2. Most important symptoms and ef	fects, both acute and delayed
Symptoms/effects Symptoms/effects after inhalation	 Causes burns. Insufficient data available. May cause shortness of breath, tightness of the chest, a sore throat and cough.
Symptoms/effects after skin contact Symptoms/effects after eye contact Symptoms/effects after ingestion	 insufficient data available. Redness, pain. insufficient data available. Redness, pain. Burns to the gastric/intestinal mucosa. Symptoms may include dizziness, headache, nausea and loss of coordination.

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. Active substance. Pharmaceutical.

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	: Extinguishing blanket.
5.2. Special hazards arising from the subst	ance or mixture
Fire hazard	: See Heading 2.2. Beware, risk of formation of toxic and corrosive gases.
5.3. Advice for firefighters	
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.
SECTION 6: Accidental release measur	res
6.1. Personal precautions, protective equip	ment 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 No additional information available	
6.1.2. For emergency responders	
Protective equipment	: See Section 8.
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. Material should be handled with caution. In aqueous medium : Corrosive to eyes, respiratory system and skin.

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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 Precautions for safe handling	 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. In aqueous medium : Corrosive to eyes, respiratory system and skin. Material should be handled with caution. Avoid any direct contact with the product.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.
7.2. Conditions for safe storage, including a	any incompatibilities
Technical measures Storage conditions	Comply with applicable regulations.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

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

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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	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not applicable.
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
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
рН	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: > 1000 g/l
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 applicable
Particle size	: Not available

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

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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) Acute toxicity (dermal)	: Toxic if swallowed. : Toxic in contact with skin.	
Acute toxicity (inhalation)	: Not classified (Lack of data)	
Chlorpromazine hydrochloride		
LD50 oral rat	145 mg/kg (RTECS No : SO1750000)	
LD50 oral	> – ≤ mg/kg	
LD50 dermal rat	> 200 – ≤ 1000 mg/kg (estimated value)	
Skin corrosion/irritation	: Not classified (Lack of data)	
Serious eye damage/irritation	: Causes serious eye damage.	
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	: May cause harm to breast-fed children.	
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 (acute)	 Hazardous waste. Use suitable disposal containers. Not classified (Lack of data) Very toxic to aquatic life with long lasting effects. 		
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			

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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)

- Product/Packaging disposal recommendations
- : Dispose in a safe manner in accordance with local/national regulations.

: 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	ΙΑΤΑ		
14.1. UN number or ID n	umber			
UN 2811	UN 2811	UN 2811		
14.2. UN proper shippin	g name			
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.		
Transport document descr	iption			
UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E), ENVIRONMENTALLY HAZARDOUS	UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, MARINE POLLUTANT/ENVIRONME NTALLY HAZARDOUS	UN 2811 Toxic solid, organic, n.o.s., 6.1, III, ENVIRONMENTALLY HAZARDOUS		
14.3. Transport hazard	class(es)			
6.1	6.1	6.1		
		6		
14.4. Packing group				
III	III	III		
14.5. Environmental haz	ards			
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes		
No supplementary information	on available	1		
14.6. Special precaution	s for user			
Overland transport				
Classification code (ADR)	: T2			
Special provisions (ADR)		1 614		
imited quantities (ADR)	: 274, 614			
Excepted quantities (ADR)	: 5kg : E1			
,	: P002, IBC08, LP02, R001			
Packing instructions (ADR)	. 200	UZ, IDUUU, LF UZ, NUU I		

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3 - 3 (-)	, , , , , , , , , , , , , , , , , , , ,
Special packing provisions (ADR)	: B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1
Portable tank and bulk container special provisions	: TP33
(ADR)	
Tank code (ADR)	: SGAH, L4BH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Bulk (ADR)	: VC1, VC2, AP7
Special provisions for carriage - Loading, unloading	: CV13, CV28
and handling (ADR)	
Special provisions for carriage - Operation (ADR)	: S9
Hazard identification number (Kemler No.)	: 60
Orange plates	
	60
	0011
	2811
Tunnel restriction code (ADR)	: E
	. L
Transport by sea	
Special provisions (IMDG)	: 223, 274
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	P002
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-A
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: Toxic if swallowed, by skin contact or by inhalation.
Air transport	
PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y645
PCA limited quantity max net quantity (IATA)	: 10kg
PCA packing instructions (IATA)	: 670
PCA max net quantity (IATA)	: 100kg
CAO packing instructions (IATA)	: 677
CAO max net quantity (IATA)	: 200kg
Special provisions (IATA)	: A3, A5
ERG code (IATA)	: 6L

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)

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

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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

Indication of changes:

Classification of the substance or mixture. Ecological information. Toxicological information. Transport information. Identification of the substance/mixture and of the company/undertaking.

Full text of H- and EUH-statements:		
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
H301	Toxic if swallowed.	
H311	Toxic in contact with skin.	
H317	May cause an allergic skin reaction.	
H318	Causes serious eye damage.	
H362	May cause harm to breast-fed children.	
H410	Very toxic to aquatic life with long lasting effects.	
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation	
Skin Sens. 1	Skin sensitisation, Category 1	

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.