

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 27/11/2023 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Cetylpyridinium chloride
Chemical name : Cetylpyridinium chloride monohydrate
Product code : 201600178

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	
Acute toxicity (inhalation:dust,mist) Category 2	H330	
Skin corrosion/irritation, Category 2	H315	
Serious eye damage/eye irritation, Category 1	H318	
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335	
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400	(M=100)
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410	

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)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed.
H315 - Causes skin irritation.

Cetylpyridinium chloride

Safety Data Sheet

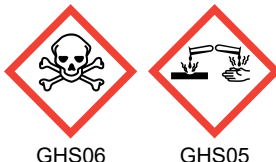
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Precautionary statements (CLP)

H318 - Causes serious eye damage.
H330 - Fatal if inhaled.
H335 - May cause respiratory irritation.
H410 - Very toxic to aquatic life with long lasting effects.
: 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.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P284 - Wear respiratory 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.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor.
P312 - Call a POISON CENTRE or doctor if you feel unwell.
P320 - Specific treatment is urgent (see supplemental first aid instruction on this label).
P321 - Specific treatment (see supplemental first aid instruction on this label).
P330 - Rinse mouth.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P391 - Collect spillage.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
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

GHS05

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]
Cetylpyridinium chloride monohydrate	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=560 mg/kg bodyweight) Acute Tox. 2 (Inhalation:dust,mist), H330 (ATE=0,05 mg/l/4h) Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410

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

3.2. Mixtures

Not applicable

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Immediately flush the contact area with plenty of water.
First-aid measures after inhalation	: 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 effects, both acute and delayed

Symptoms/effects	: Causes burns.
Symptoms/effects after inhalation	: Insufficient data available. May cause shortness of breath, tightness of the chest, a sore throat and cough.
Symptoms/effects after skin contact	: Insufficient data available. Redness, pain.
Symptoms/effects after eye contact	: Insufficient data available. Redness, pain.
Symptoms/effects after ingestion	: 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 substance 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 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

No additional information available

6.1.2. For emergency responders

Protective equipment	: See Section 8.
----------------------	------------------

6.2. Environmental precautions

No additional information available

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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.

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. In aqueous medium : Corrosive to eyes, respiratory system and skin.

Precautions for safe handling : 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 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

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

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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	: 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
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 33,3 – 100 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

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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) : Harmful if swallowed.
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Fatal if inhaled.

Cetylpyridinium chloride monohydrate

LD50 oral rat	560 mg/kg (female)
LD50 dermal rat	> 5000 mg/kg
LC50 Inhalation - Rat	> 0,05 – < 0,05 mg/l/4h

Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye damage.
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 : Not classified (Lack of data)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : May cause respiratory irritation.
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

Ecology - general : Hazardous waste. Use suitable disposal containers.
Hazardous to the aquatic environment, short-term (acute) : Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term (chronic) : Very toxic to aquatic life with long lasting effects.

Cetylpyridinium chloride monohydrate

LC50 - Fish [1]	0,16 mg/l (96 Hours, Oncorhynchus mykiss (Rainbow trout)) (OECD 203 method)
EC50 - Crustacea [1]	0,0041 – 0,00965 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method)
ErC50 algae	0,0269 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)
NOEC chronic algae	0,0032 mg/l (72 Hours, Selenastrum capricornutum (Green algae)) (OECD 201 method)

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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 waste regulation : 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 2811	UN 2811	UN 2811
14.2. UN proper shipping name		
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
Transport document description		
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/ENVIRONMENTALLY 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
		
14.4. Packing group		
III	III	III

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
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		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: T2
Special provisions (ADR)	: 274, 614
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
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 (ADR)	: TP33
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 and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9
Hazard identification number (Kemler No.)	: 60
Orange plates	:



Tunnel restriction code (ADR)	: E
-------------------------------	-----

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

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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			
Section	Changed item	Change	Comments
	Supersedes version of	Added	
	Revision date	Added	
1.1	Name	Modified	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Hazard pictograms (CLP)	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
4.1	First-aid measures general	Added	
4.1	First-aid measures after skin contact	Modified	
4.1	First-aid measures after inhalation	Modified	

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes			
Section	Changed item	Change	Comments
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
4.2	Symptoms/effects	Added	
4.2	Symptoms/effects after ingestion	Modified	
4.2	Symptoms/effects after skin contact	Modified	
4.2	Symptoms/effects after inhalation	Modified	
4.2	Symptoms/effects after eye contact	Modified	
5.2	Fire hazard	Modified	
6.1	Protective equipment	Added	
6.3	Methods for cleaning up	Modified	
7.1	Additional hazards when processed	Modified	
11.1	Reason for no classification	Modified	
11.1	ATE CLP (vapours)	Added	
11.1	ATE CLP (dermal)	Added	
11.1	Reason for no classification	Added	
11.1	LD50 dermal rat	Added	
11.1	LC50 Inhalation - Rat	Added	
11.1	ATE CLP (oral)	Modified	
11.1	LD50 oral rat	Modified	
11.1	ATE CLP (dust,mist)	Added	
11.1	ATE CLP (gases)	Added	
12.1	ErC50 algae	Added	
12.1	EC50 72h - Algae [1]	Added	
12.1	NOEC chronic algae	Added	
12.1	EC50 - Crustacea [1]	Added	
12.1	LC50 - Fish [1]	Added	

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H330	Fatal if inhaled.

Cetylpyridinium chloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Full text of H- and EUH-statements:

H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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.