



Safety Data Sheet

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

Issue date: 18/03/2025 Version: 1.0

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

1.1. Product identifier

Product form : Substance

Substance name : Procaine for system suitability
Chemical name : Procaine hydrochloride

EC-No. : 200-077-2 CAS-No. : 51-05-8 Product code : 202500226

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development

Technical testing and analysis For professional use only

Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

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 Skin sensitisation, Category 1 H317

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

Adverse physicochemical, human health and environmental effects

Toxic if swallowed. May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS06

Signal word (CLP) : Danger

Hazard statements (CLP) : H301 - Toxic if swallowed.

H317 - May cause an allergic skin reaction.

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.

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.

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.

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)



2.3. Other hazards

Other information : Active substance (in pharmaceutical products).

Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Procaine hydrochloride	CAS-No.: 51-05-8 EC-No.: 200-077-2	≤ 100	Acute Tox. 3 (Oral), H301 (ATE=200 mg/kg bodyweight) Skin Sens. 1, H317

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 general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If

the person feels unwell: Get medical advice/attention.

First-aid measures after skin contact : Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms

persist, call a physician.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking

or redness persists.

First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth

to an unconscious person. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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

No additional information available

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry

powder. Extinguishing blanket.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other

toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

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".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and

direct sunlight.

Packaging materials : Keep in original containers.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use: Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Colour almost white. white. Appearance : Crystalline powder. : 272.77 g/mol Molecular mass : Not available Odour Odour threshold : Not available : ≈ 155 °C Melting point Freezing point Not available : Not available Boiling point Flammability : Not available Lower explosion limit : Not applicable Upper explosion limit : Not applicable Flash point : Not applicable Auto-ignition temperature : Not applicable Decomposition temperature : Not available 5 - 6.5 (0.1 M)pH solution : Not available Viscosity, kinematic : Not applicable Solubility : Water: > 1 g/l Partition coefficient n-octanol/water (Log Kow) : Not available Not available Vapour pressure : Not available Vapour pressure at 50°C Density : Not available : Not available Relative density Relative vapour density at 20°C : Not applicable

9.2. Other information

Particle size

No additional information available

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: Not available

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SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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

No additional information available

10.6. Hazardous decomposition products

No additional information available

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

Procaine I	hydroc	hloride ((51-05-8)
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LD50 oral rat 200 m	g/kg (RTECS No DG2275000)
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Skin corrosion/irritation : Not classified (Lack of data)

pH: 5 - 6.5 (0.1 M)

Serious eye damage/irritation : Not classified (Lack of data)

pH: 5 - 6.5 (0.1 M)

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 (Lack of 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)

: Not classified (Lack of data)

Hazardous to the aquatic environment, long-term

: Not classified (Lack of data)

(chronic)

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12.2. Persistence and degradability

Procaine hydrochloride (51-05-8)

Persistence and degradability Not rapidly degradable

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 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)	UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III	UN 2811 Toxic solid, organic, n.o.s., 6.1, III
14.3. Transport hazard class(es)		
6.1	6.1	6.1
6	6	6
14.4. Packing group		
III	III	III

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ADR	IMDG	IATA
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-A	Dangerous for the environment: No
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 : TP33

(ADR)

Tank code (ADR): SGAH, L4BHTank special provisions (ADR): TU15, TE19Vehicle 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 2811

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 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 : 200kg CAO max net quantity (IATA) Special provisions (IATA) : A3, A5 ERG code (IATA) : 6L

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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

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

Ozone Regulation (1005/2009)

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

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

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)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

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