

CHONGQING CUSTOMS TECHNICAL CENTER
NATIONAL KEY LABORATORY OF HAZARDOUS
CHEMICALS TESTING (CHONGQING)
DESIGN REPORT OF SAFETY DATA SHEET

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ORIGIN

No: 3523006960-4

Date: 2023-08-29

Chinese Name of the Sample	盐酸普鲁卡因		
English Name of the Sample	PROCAINE HYDROCHLORIDE		
Applicant	Chongqing Southwest No.2 Pharmaceutical Factory Co., Ltd.		
Supplier	Chongqing Southwest No.2 Pharmaceutical Factory Co., Ltd.		
Analysis/Test Requirements	SDS design	Business Type	Commissioned inspection
Testing Standard	Globally Harmonized System of Classification and Labelling of Chemicals (GHS)(Tenth revised edition)		
Delivery Date	2023.08.25	Specification Model	CP/EP/USP/BP
Test Date	2023.08.28	Sample Batch Number	/

1. SAMPLE INFORMATION

1. Components (Enterprise Declaration): The sample contains 2-(diethylamino)ethyl 4-aminobenzoate hydrochloride.

2. Sample properties: White or almost white crystalline powder.



Approver:

马名良

Verifier:

简红梅

Designer:

唐璜

Date:

August 30, 2023

Date:

August 29, 2023

Date:

August 29, 2023

This SDS is valid before the implementation of the eleventh revised version GHS.

SAFETY DATA SHEET

PROCAINE HYDROCHLORIDE

Chongqing Southwest No.2 Pharmaceutical Factory Co.,Ltd.

• According to GHS(Tenth Revised Edition)

SDS

Part 1 Product and Company Identification

> Product Identification

Chinese Name of Product

盐酸普鲁卡因

English Name of Product

PROCAINE HYDROCHLORIDE

Synonyms

—

CAS NO.

51-05-8

EC NO.

200-077-2

Molecular Formula

$C_{13}H_{21}ClN_2O_2$

> Product Recommendations and Limited Use

Recommended Uses of the Product Please consult manufacturer.

Limited Uses of the Product Please consult manufacturer.

> Safety Data Sheet Provider Information

Applicant Name

Chongqing Southwest No.2 Pharmaceutical Factory Co.,
Ltd.

Applicant Address

No.555, Lanxi Road, Degan Street, Jiangjin District,
Chongqing, China.

Applicant Post Code

402263

Applicant Contact Number

+86-23-63012195

Applicant Fax

—

Applicant Email

—

Supplier Name

Chongqing Southwest No.2 Pharmaceutical Factory Co.,
Ltd.

Supplier Address

No.555, Lanxi Road, Degan Street, Jiangjin District,
Chongqing, China.

Supplier Post Code

402263

Supplier Contact Number

+86-23-63012195

Supplier Fax

—

Supplier E-Mail

—

Emergency Phone Number

+86-23-47855535

Part 2 Hazards Identification

Hazard class and label elements of the product according to GHS (the tenth revised edition):

>Emergency Overview

No information available

>GHS Hazard Class

Acute Toxicity–Oral	Category 3
Skin Corrosion/Irritation	Category 2
Serious eye damage/eye irritation	Category 2
Skin Sensitization	Category 1

>GHS Label Elements

Pictogram



Signal Word

Danger

>Hazard Statements

H301	Toxic if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.

>Precautionary Statements

Prevention

P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P264 + P265	Wash hand [and...]thoroughly after handling. Do not touch eyes.
P270	Do not eat, drink or smoke when using this product.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.

Response

P301 + P316	IF SWALLOWED: Get emergency medical help immediately.
P321	Specific treatment (see part 4).
P330	Rinse mouth.
P302 + P352	IF ON SKIN: Wash with plenty of water/...
P333 + P317	If skin irritation or rash occurs: Get medical help.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P317	If eye irritation persists: Get medical help.
Storage	
P405	Store locked up.
Disposal	
P501	Dispose of contents/containers in accordance with local/regional/national/international regulations.

>Other Hazards

Physical and Chemical Hazards

No information available

Environmental Hazards

No information available

Part 3 Composition/Information on Ingredients

Component	Content (mass fraction, %)	CAS No.	EC No.
2-(diethylamino)ethyl 4-aminobenzoate hydrochloride	Business secret	51-05-8	200-077-2

Part 4 First-Aid Measures

> Description of First Aid Measures

General Advice	Consult the doctor and show this safety data sheet (SDS) to the doctor at the scene.
Eye Contact	Remove eyelids immediately and rinse thoroughly with plenty of running water for at least 15 minutes. Call poison control center or get emergency medical help immediately. After the eyes are injured, contact lenses can only be removed by specially trained personnel.
Skin Contact	Take off the contaminated clothes immediately. Wash the contaminated area with plenty of soapy water and running water. If skin irritation persists, get medical help. Contaminated clothing should be placed in a double-layer, appropriately labeled, sealable waste disposal bag and washed before reuse.
Ingestion	Rinse mouth with water immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.
Inhalation	Remove person to fresh air and keep comfortable for breathing. If breathing is difficult, give oxygen. If not breathing, give cardio-pulmonary resuscitation and consult a physician immediately.
Protection of First-aiders	Ensure that medical staff are aware of the product involved. Take precautions to protect themselves and prevent the spread of contamination.

> **Most Important Symptoms and Effects , Both Acute and Delayed**

The product can cause respiratory discomfort and can be toxic if ingested in large quantities. This product can cause severe skin burns and eye damage if exposed for a long time or repeatedly.

> **Indication of Any Emergency Medical Treatment and Special Treatment**

Perform targeted treatment according to the symptoms. Symptoms may be delayed.

Part 5 Fire-Fighting Measures

> **Extinguishing Media**

Suitable Extinguishing Medium Water, foam, carbon dioxide, dry powder.

Unsuitable Extinguishing Medium Avoid extinguishing fire with too strong water vapor, as it may spread the flames.

> **Special Hazards Arising from the Substance or Mixture**

- 1 Toxic fumes may be produced when burned.
- 2 Expansion or explosive decomposition may occur when exposed to heat or flame.
- 3 Containers may explode when heated.
- 4 Containers exposed to fire may leak contents through pressure relief valves.

> **Advice for Firefighters**

- 1 As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear.
- 2 Extinguish the fire at a safe distance with adequate protection..
- 3 Prevent fire extinguishing water from contaminating surface water or the ground water system.

Part 6 Accidental Release Measures

> **Personal Precautions, Protective Equipment and Emergency Procedures**

- 1 Immediately evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
- 2 Use personal protective equipment.
- 3 Ensure adequate ventilation of the leakage area.
- 4 Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.

> **Environmental Precautions**

Contact the manufacturers, and accept the instructions of manufacturers. Report to the emergency department and inform them of the location and nature of the accident. The contaminated surface is scrubbed with soap or detergent, and the near dilution of the sewage is placed in the wastewater system. Avoid spillover diffusion and direct contact into soil, rivers, sewers and sewer lines.

> **Storage, Elimination Methods and Disposal Materials Used for Leaking Chemicals**

- 1 Take all means to collect the leakage and avoid the diffusion of the leakage.
- 2 Attachments or collections shall be stored in suitable airtight containers and disposed of in accordance with relevant local laws and regulations.
- 3 Wear protective clothing, gloves, and safety goggles to avoid contact with skin and eyes.

Part 7 Handling and Storage

> Precautions for Handling

- 1 Wear appropriate personal protective equipment.
- 2 Handling is performed in a well-ventilated place.
- 3 Avoid contact with skin and eyes.
- 4 Don't eat, drink or smoke during operation.
- 5 Wash hands with soap and water after operation.

> Precautions for Storage

- 1 Keep containers tightly closed.
- 2 Store in cool, dry, well-ventilated location. Avoid high temperatures and direct sunlight.
- 3 Keep away from heat sources, sparks, open flames and hot surfaces.
- 4 Store away from incompatible materials and foodstuff containers.

Part 8 Exposure Controls/Personal Protection

> Control Parameters

Occupational Exposure Limit Values

No information available

Biological Limit Values

No information available

Monitoring Methods

- 1 EN 14042 Workplace air. Guidelines for procedures for assessing exposure to chemical or biological agents .
- 2 GBZ/T 160 Determination of toxic substances in workplace air (Series standard) and GBZ/T 300 Determination of toxic substances in workplace air (Series standard).

Engineering Controls

- 1 Ensure adequate ventilation, especially in confined areas.
- 2 Make sure there are eyewash and shower facilities near the workplace.
- 3 Set up emergency exit and necessary risk-elimination area.

> Personal protective equipment

Eye Protection

Wear chemical safety goggles (approved by EN 166(EU) or NIOSH (US)).

Hand Protection

Wear chemical protective gloves (e.g. butyl rubber gloves), passing the test according to EN 374(EU), US F739 or AS/NZS 2161.1 standard.

Respiratory

Use a full-face respirator with multi-purpose combination (US) or type

Protection	AXBK (EN 14387) respirator cartridges if vapor concentrations exceed occupational exposure limits or when symptoms such as irritation occur.
Skin and Body Protection	Wear adhesive clothing, anti-penetration clothing, fire/flame-resistant retardant clothing and antistatic boots.

Part 9 Physical and Chemical Properties

Appearance: White or almost white crystalline powder	Odor : Odourless
Odor Thresholds : No information available	pH : No information available
Melting Point/Freezing Point (°C) : No information available	Initial Boiling Point and Boiling Range (°C) : No information available
Flash Point (°C) (Closed Cup) : No information available	Evaporation Rate : No information available
Flammability : No information available	Upper/Lower Limit of Explosion [% (V/V)] : Not applicable
Vapor Pressure : No information available	Relative Vapor Density (Air =1) : Not applicable
Relative Density (Water =1) : No information available	Solubility : No information available
n-Octanol/Water Partition Coefficient : No information available	Auto-ignition Temperature (°C) : Not applicable
Decomposition Temperature (°C) : Not applicable	Kinematic Viscosity (mm²/s) : Not applicable

Part 10 Stability and Reactivity

Reactivity	Decomposition or other chemical reactions may occur in contact with incompatible substances.
Chemical Stability	Stable under proper operation and storage conditions.
Possibility of Hazardous Reactions	No information available.
Conditions to Avoid	Heat, flame and spark.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	When heated to decomposition, will release nitrogen oxides (NO _x), carbon oxides, hydrogen chloride gas and other harmful substances.

Part 11 Toxicological Information

> Acute toxicity

Component	CAS No.	LD50(Oral)	LD50(Dermal)	LC50(Inhalation)
2-(diethylamino)ethyl 4-aminobenzoate hydrochloride	51-05-8	200mg/kg (rat)	No information available	No information available

> **Skin Corrosion/Irritation**

Causes skin irritation.

> **Severe Eye Damage/Irritation**

Causes serious eye irritation.

> **Skin Sensitization**

May cause an allergic skin reaction.

> **Respiratory Sensitization**

No information available.

> **Germ Cell Mutagenicity**

No information available.

> **Carcinogenicity**

No information available.

> **Reproductive Toxicity**

No information available.

> **Additional Harm of Reproductive Toxicity**

No information available.

> **Specific Target Organ Toxicity - Single Exposure**

No information available.

> **Specific Target Organ Toxicity - Repeated Exposure**

No information available.

> **Aspiration Hazard**

No information available.

Part 12 Ecological Information

> **Acute Aquatic Toxicity**

No information available.

> **Chronic Aquatic Toxicity**

No information available.

> **Others**

Persistence and Degradability

No information available

Bioaccumulation

No information available

Mobility in Soil

No information available

Results of PBT and vPvB Assessment

This product does not meet the classification criteria of PBT and vPvB in Annex XIII of European Union (EC) Regulation No. 1907/2006.

Part 13 Disposal Considerations

Waste Chemicals	Relevant national and local laws and regulations should be referred to before disposal.
Contaminated Packaging	Containers may still present chemical hazard when empty. Do your personal protection. Return to supplier for recycling if possible.
Dispose Recommendations	Dispose of waste as follows: Consult the manufacturer about the method of recycling. Discard precautions: Operators should pay attention to their own safety protection and wear appropriate protective equipment. Never let water from washing equipment go down the drain. Refer to the relevant national and local laws and regulations before disposal.

Part 14 Transport Information

Transporting Label



Marine Pollutant	No
UN Number	2811
UN Proper Shipping Name	TOXIC SOLID, ORGANIC, N.O.S. (2-(diethylamino) ethyl 4-aminobenzoate hydrochloride)
Transport Hazard Class	6.1
Transport Subsidiary Hazard Class	/
Packaging Group	III

Part 15 Regulatory Information

>International Chemical Inventory

Component	EINECS	KECI	MOE	TSCA	NZIoC	PICCS	AICS	DSL
2-(diethylamino)ethyl 4-aminobenzoate hydrochloride	✓	✓	✗	✓	✓	✓	✗	✓

【EINECS】 European Inventory of Existing Commercial Chemical Substances.

【KECI】 Korean Existing Chemicals List.

【MOE】 K-reach CMR substance list.

【TSCA】 United States Toxic Substances Control Act Inventory.

- 【NZIoC】 New Zealand Inventory of Chemicals
 【PICCS】 Philippine Inventory of Chemicals and Chemical Substances.
 【AICS】 Australian Inventory of Chemical Substances
 【DSL】 Canada Domestic Substances List

>Chemical Management Directory of China

Component	A	B	C	D	E	F	G	H
2-(diethylamino)ethyl 4-aminobenzoate hydrochloride	✓	×	×	×	×	×	×	✓

- 【A】 A list of existing chemicals in China
 【B】 List of hazardous chemicals under key supervision Catalogue of hazardous chemicals (2015)
 【C】 China strictly restricts the import and export of toxic chemicals
 【D】 Prohibited import and export of substances
 【E】 List of hazardous chemicals under key supervision
 【F】 Precursor chemicals
 【G】 Non-medicinal narcotic drugs and psychotropic drugs
 【H】 An inventory of chemicals available in Taiwan

"✓" Indicates that the substance included in the regulations

"×" That no date or included in the regulations

Part 16 Additional Information

Creation Date 2023-08-29

Revision Date _____

Reason for Revision _____

Disclaimer

The format of this safety specification conforms to GHS(the tenth revised edition) requires that the data come from international authoritative database and data submitted by enterprises, and other information is based on the center's current knowledge This document is for users' reference only due to the diversity of information sources and the limitations of the center's knowledge. Users of safety technical specifications should make a judgment on the rationality of relevant information according to the purpose of use. We shall not be liable for any damage caused by the operation, storage, use or disposal of the product.

End of the report

Notice

1. The report is invalid without the "special seal for inspection and testing" or the official seal of the unit.
2. The report is invalid without the signature of the approver.
3. The report is invalid if the appraisal conclusion was altered without permission.
4. The duplicate report is invalid without re-stamping the "special seal for inspection and testing" or the official seal of the unit.
5. If the entrusting party has any objection to the appraisal result, it shall, within 15 days from the date of receipt of the report, request the performing inspection party to reinspect, and the appraisal party shall give a reply within five days. Unless there is no retained sample or the submitted sample fails to meet the requirements of the standard, it shall not be accepted beyond the time limit.
6. If the reinspection results are in conformity with the original appraisal results, the entrusting party shall pay the appraisal party a reinspection fee as stipulated. If the reinspection results confirm that the original appraisal results are wrong, the inspection party shall not charge the reinspection fee.
7. If the entrusting party still has any objection to the reinspection result and both parties have no solution through negotiation, the entrusting party shall sign a written agreement with the appraising party and entrust an arbitration institution for arbitration.
8. The report shall not be used for advertising without the consent of the laboratory.
9. The result of this report is only responsible for the sample, this report does not bear the economic responsibility.

Name of the entity: Chongqing Customs Technical Center/National Key Laboratory of Hazardous Chemicals Testing (Chongqing)

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