

SAFETY DATA SHEET

Chloroprocaine Hydrochloride Injection, USP**hikma.**

Section 1. Identification

GHS product identifier	: Chloroprocaine Hydrochloride Injection, USP
Chemical name	: Benzoic acid, 4-amino-2-chloro-2-(diethylamino) ethyl ester, monohydrochloride
Product code	: Not available.
Other means of identification	: Nesacaine
Product type	: Regulated prescription drug.
Container information	: 20 ml vials.

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

Identified uses	: Anesthetic Infiltration, Peripheral and Central nerve block including lumbar and caudal epidural blocks. Not to be used for Subarachnoid administration.
------------------------	---

Supplier's details	: Hikma Pharmaceuticals USA Inc. 246 Industrial Way West Eatontown, New Jersey (NJ) 07724
---------------------------	---

Emergency telephone number (with hours of operation)	: CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887 24/7
---	--

Section 2. Hazards identification

OSHA/HCS status	: While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
------------------------	--

Classification of the substance or mixture	: Not classified.
---	-------------------

GHS label elements

Signal word	: No signal word.
Hazard statements	: No known significant effects or critical hazards.

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statements

Prevention	: Not applicable.
Response	: Not applicable.

Section 2. Hazards identification

Storage	: Not applicable.
Disposal	: Not applicable.
Hazards not otherwise classified	: None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Chemical name	: Benzoic acid, 4-amino-2-chloro-2-(diethylamino) ethyl ester, monohydrochloride
Other means of identification	: Nesacaine

Ingredient name	%	CAS number
2-Diethylaminoethyl 4-amino-2-chlorobenzoate hydrochloride	≥3 - <5	3858-89-7

Active pharmaceutical ingredient	%	CAS number
2-Diethylaminoethyl 4-amino-2-chlorobenzoate hydrochloride	≥3 - <5	3858-89-7

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

See Package Insert for further information.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Skin contact	: Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
Ingestion	: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.

Section 4. First aid measures

Ingestion : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Section 6. Accidental release measures

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
2-Diethylaminoethyl 4-amino-2-chlorobenzoate hydrochloride	None.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Section 8. Exposure controls/personal protection

Skin protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Liquid.
- Color** : Not available.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 2.7 to 4
- Melting point** : Not available.
- Boiling point** : 100°C (212°F)
- Flash point** : Not available.
- Evaporation rate** : Approximates water.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Approximate to water.
- Vapor density** : 0.6 [Air = 1]
- Relative density** : 1
- Solubility** : Not available.
- Solubility in water** : Soluble
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.
- Flow time (ISO 2431)** : Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: Incompatible with water-reactive chemicals. Strong oxidizers.
Hazardous decomposition products	: Decomposition products of Chloroprocaine may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and carbon dioxide.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure	: Dermal contact. Eye contact. Inhalation. Ingestion.
---	---

Potential acute health effects

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

Section 11. Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects	: No known significant effects or critical hazards.
Potential delayed effects	: No known significant effects or critical hazards.

Long term exposure

Potential immediate effects	: No known significant effects or critical hazards.
Potential delayed effects	: No known significant effects or critical hazards.

Potential chronic health effects

General	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	3333.3 mg/kg

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (K_{oc})	: Not available.
---	------------------

Other adverse effects	: No known significant effects or critical hazards.
-----------------------	---

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

FDA : Chloroprocaine Hydrochloride Injection, USP is an approved prescription medication.
U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

Section 15. Regulatory information

DEA List I Chemicals : Not listed
(Precursor Chemicals)

DEA List II Chemicals : Not listed
(Essential Chemicals)

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
2-Diethylaminoethyl 4-amino-2-chlorobenzoate hydrochloride	No.	No.	No.	Yes.	No.

SARA 313

There is no data available.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
Not classified.	

History

Revision date mm/dd/yyyy : 11/15/2018

Version : 2

Prepared by : KMK Regulatory Services Inc.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.