

## Section 1. Identification

**GHS product identifier** : Dicyclomine Hydrochloride Injection USP, 20mg/2ml (10mg/ml)  
**Product code** : NDC 31722-963-32  
**Other means of identification** : Dicyclomine Hydrochloride Injection  
**Product type** : Liquid.

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

**Product use** : Pharmaceuticals. (Finished product) - Antispasmodic and anticholinergic (antimuscarinic) agent indicated for the treatment of functional bowel/irritable bowel syndrome.

Container type: Glass vial with rubber stopper and aluminum seal.

**Area of application** : Professional applications.

**Supplier/Manufacturer** : SunGen Pharma LLC,  
303C College Road East,  
Princeton, NJ 08540  
  
Telephone (General): (609) 606-1060  
Website: sungenpharm.com

**e-mail address of person responsible for this SDS** : support@sungenpharm.com

**Emergency telephone number (with hours of operation)** : (609) 606-1028 (24 hrs)

## 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.

Percentage of the mixture consisting of ingredient(s) of unknown acute dermal toxicity: 6%

Percentage of the mixture consisting of ingredient(s) of unknown acute inhalation toxicity: 6%

### GHS label elements

**Signal word** : No signal word.

**Hazard statements** : No known significant effects or critical hazards.

### Precautionary statements

**Prevention** : Not applicable.

**Date of issue/Date of revision** : 10/22/2019 **Date of previous issue** : No previous validation **Version** : 1 1/12

## Section 2. Hazards identification

<b>Response</b>	: Not applicable.
<b>Storage</b>	: Not applicable.
<b>Disposal</b>	: Not applicable.
<b>Hazards not otherwise classified</b>	: None known.

## Section 3. Composition/information on ingredients

<b>Substance/mixture</b>	: Mixture
<b>Other means of identification</b>	: Dicyclomine Hydrochloride Injection

Ingredient name	Other names	%	CAS number
water	Purified Water	≥90	7732-18-5
sodium chloride	-	≤8.3	7647-14-5
[2-[[[1,1'-bicyclohexyl]-1-ylcarbonyl]oxy]ethyl] diethylammonium chloride	Dicyclomine hydrochloride	≤1.6	67-92-5

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 and hence require reporting in this section.**

## Section 4. First aid measures

### Description of necessary first aid measures

<b>Eye contact</b>	: 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.
<b>Inhalation</b>	: 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.
<b>Skin contact</b>	: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Ingestion</b>	: 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

<b>Eye contact</b>	: No known significant effects or critical hazards.
<b>Inhalation</b>	: No known significant effects or critical hazards.
<b>Skin contact</b>	: No known significant effects or critical hazards.
<b>Ingestion</b>	: No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

<b>Eye contact</b>	: No specific data.
<b>Inhalation</b>	: No specific data.
<b>Skin contact</b>	: No specific data.

## Section 4. First aid measures

**Ingestion** : No specific data.

### 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** : Do not use water jet.

**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  
metal oxide/oxides

**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. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Do not store above the following temperature: 30°C (86°F). Do not freeze. 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
water	None.
sodium chloride	None.
[2-[[[1,1'-bicyclohexyl]-1-ylcarbonyl]oxy]ethyl]diethylammonium chloride	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. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

### 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.

## Section 8. Exposure controls/personal protection

- 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.
- 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. [Clear.]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 3 to 6
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not applicable.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : 1.003 [Water = 1]
- Density** : 1.003 g/cm<sup>3</sup> [25°C (77°F)]
- Solubility** : Easily soluble in the following materials: cold water and hot water.
- Solubility in water** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- SADT** : 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.  
Under normal conditions of storage and use, hazardous polymerization will not occur.
- Conditions to avoid** : Do not freeze.
- Incompatible materials** : Reactive or incompatible with the following materials: oxidizing materials, reducing materials, acids and alkalis.  
Water-reactive material
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
sodium chloride	LD50 Oral	Rat	3000 mg/kg	-
[2-[[[1,1'-bicyclohexyl]-1-ylcarbonyl]oxy]ethyl] diethylammonium chloride	LD50 Oral	Rat	1290 mg/kg	-

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium chloride	Eyes - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	10 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-

#### Sensitization

Not available.

#### Mutagenicity

**Conclusion/Summary** : Not available.

#### Carcinogenicity

**Conclusion/Summary** : Not available.

#### Reproductive toxicity

**Conclusion/Summary** : Not available.

#### Teratogenicity

**Conclusion/Summary** : Not available.

#### Specific target organ toxicity (single exposure)

## Section 11. Toxicological information

Name	Category	Route of exposure	Target organs
[2-[[[1,1'-bicyclohexyl]-1-ylcarbonyl]oxy]ethyl] diethylammonium chloride	Category 3	Not applicable.	Respiratory tract irritation

### Specific target organ toxicity (repeated exposure)

Not available.

### Aspiration hazard

Not available.

**Information on the likely routes of exposure** : Not available.

### 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.

### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : No specific data.  
**Inhalation** : No specific data.  
**Skin contact** : No specific data.  
**Ingestion** : No specific data.

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

#### Short term exposure

**Potential immediate effects** : Not available.  
**Potential delayed effects** : Not available.

#### Long term exposure

**Potential immediate effects** : Not available.  
**Potential delayed effects** : Not available.

### Potential chronic health effects

Not available.

**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

## Section 11. Toxicological information

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Dicyclomine Hydrochloride Injection USP, 20mg/2ml (10mg/ml)	43000	N/A	N/A	N/A	N/A
sodium chloride	3000	N/A	N/A	N/A	N/A
[2-[[[1,1'-bicyclohexyl]-1-ylcarbonyl]oxy]ethyl] diethylammonium chloride	1290	N/A	N/A	N/A	N/A

## Section 12. Ecological information

### Toxicity

Product/ingredient name	Result	Species	Exposure
sodium chloride	Acute EC50 2430000 µg/l Fresh water	Algae - Navicula seminulum	96 hours
	Acute EC50 28.85 mg/dm3 Fresh water	Algae - Pseudokirchneriella subcapitata	72 hours
	Acute EC50 519.6 mg/l Fresh water	Crustaceans - Cypris subglobosa	48 hours
	Acute EC50 402.6 mg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute IC50 6.87 g/L Fresh water	Aquatic plants - Lemna minor	96 hours
	Acute LC50 1000000 µg/l Fresh water	Fish - Morone saxatilis - Larvae	96 hours
	Chronic LC10 781 mg/l Fresh water	Crustaceans - Hyalella azteca - Juvenile (Fledgling, Hatchling, Weanling)	3 weeks
	Chronic NOEC 6 g/L Fresh water	Aquatic plants - Lemna minor	96 hours
	Chronic NOEC 0.314 g/L Fresh water	Daphnia - Daphnia pulex	21 days
	Chronic NOEC 100 mg/l Fresh water	Fish - Gambusia holbrooki - Adult	8 weeks

**Conclusion/Summary** : Ecological information: General

### Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
water	-	-	Readily

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
water	-1.38	-	low

### Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : 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 at all times 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.

### Additional information

**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.

**Transport in bulk according to Annex II of MARPOL and the IBC Code** : Not available.

## Section 15. Regulatory information

**U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined  
**United States inventory (TSCA 8b):** All components are listed or exempted.

**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

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

## Section 15. Regulatory information

**DEA List II Chemicals (Essential Chemicals)** : Not listed

### 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	%	Classification
sodium chloride	≤8.3	EYE IRRITATION - Category 2A
[2-[[[1,1'-bicyclohexyl]-1-ylcarbonyl]oxy]ethyl]	≤1.6	ACUTE TOXICITY (oral) - Category 4
diethylammonium chloride		SKIN IRRITATION - Category 2
		EYE IRRITATION - Category 2A
		SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

### SARA 313

Not applicable.

### 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

This product does not require a Safe Harbor warning under California Prop. 65.

### International regulations

#### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

#### Montreal Protocol

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

#### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

#### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

## Section 16. Other information

### Hazardous Material Information System (U.S.A.)

Health	/	0
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

### National Fire Protection Association (U.S.A.)



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

### Procedure used to derive the classification

Classification	Justification
Not classified.	

### History

Date of issue/Date of revision	: 10/22/2019
Date of previous issue	: No previous validation
Version	: 1
Prepared by	: Sphera Solutions
Key to abbreviations	: ATE = Acute Toxicity Estimate AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) N/A = Not available

## Section 16. Other information

UN = United Nations

### References

: HCS (U.S.A.)- Hazard Communication Standard  
International transport regulations

Indicates information that has changed from previously issued version.

### 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.