



Dicyclomine HCl Injection, USP;

20 mg/2 mL (10 mg/mL)

Safety Data Sheet (SDS)

1. IDENTIFICATION

- | | |
|---------------------------------|--|
| (a) Product Identifier: | Dicyclomine Hydrochloride Injection, USP |
| (b) Product Code: | NDC 14789-010-02 |
| Common/Trade Name: | Dicyclomine Hydrochloride Injection, USP |
| Chemical Name: | [bicyclohexyl]-1-carboxylic acid, 2-(diethylamino) ethyl ester, hydrochloride |
| Chemical Family: | Not Determined |
| (c) Product Use: | an antispasmodic and anticholinergic (antimuscarinic) agent indicated for the treatment of functional bowel/irritable bowel syndrome |
| Product Type: | Regulated Prescription Drug |
| Container Information: | Vial |
| (d) Distributor: | Nexus Pharmaceuticals, Inc., 175 E. 400 Knightsbridge Parkway, Lincolnshire, IL 60069, 847-996-3790 |
| (e) Emergency Telephone: | 800-913-2720 |

2. HAZARDS IDENTIFICATION

- | | |
|--|--|
| (a) Classification: | GHS Classification: Not classified. |
| (b) Label Elements | GHS-US Labeling: No labeling applicable |
| (c) Other Hazards | Exposure may aggravate pre-existing eye, skin, or respiratory conditions |
| (d) Unknown Acute Toxicity (GHS-US) | No data available |

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3. COMPOSITION / INFORMATION ON INGREDIENTS

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
[bicyclohexyl]-1-carboxylic acid, 2-(diethylamino) ethyl ester, hydrochloride	Dicyclomine Hydrochloride	1%	67-92-5	N/A
Sodium Chloride	Isotonicity Agent	Isotonic Solution	7440-23-5	N/A
Water for Injection	Water	q.s. to 100%	7732-18-5	N/A

4. FIRST AID MEASURES

- General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- Inhalation:** When symptoms occur go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
- Eye Exposure:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
- Skin Exposure:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.
- Ingestion:** Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Notes to Physician:** None.

5. FIRE-FIGHTING MEASURES

- (a) **Extinguishing Media** Water spray, dry chemical, foam, carbon dioxide. Do not use a heavy stream of water as it may spread fire.
- (b) **Special Hazards** Fire Hazard: Not considered flammable but may burn at high temperatures
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.



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- (b) **Hazardous Combustion Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂). Hydrogen chloride. Chlorine oxides. Halogenated compounds.
- (c) **Special Protective Equipment / Precautions:** No special provisions required beyond normal firefighting equipment. As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

6. ACCIDENTAL RELEASE MEASURES

Spill: Avoid breathing. Avoid contact with skin, eyes, or clothing. Evacuate unnecessary personnel. Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Release to Air: N/A

Release to Water: Prevent entry to sewers and public waters.

7. HANDLING AND STORAGE

General Handling: No special handling required for hazard control under conditions of normal product use.

Storage Conditions: No special storage required for hazard control. Protect from light. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

(a) **Control Parameters:** For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

(b) **Exposure Controls:**

Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Not generally required. The use of personal protective equipment may be necessary as conditions warrant. Gloves. Protective clothing. Protective goggles.



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Materials for Clothing: Chemically resistant materials and fabrics.

(c) Individual Protection Measures

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Eye Protection: Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Skin Protection: If skin contact with the product formulation is likely, the use of protective clothing and latex or nitrile gloves is recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Liquid; Colorless to Slightly Yellow

(a) Odor	N/A
(b) Odor Threshold	N/A
(d) pH	3.5 - 6.5
(e) Melting Point:	N/A
(f) Initial Boiling Point:	N/A
(g) Flash Point	N/A
(h) Evaporation Rate:	N/A
(i) Flammability	N/A
(j) Upper Lower Flammability or Explosion Limits	N/A
(k) Vapor Pressure:	N/A
(l) Vapor Density:	N/A
(m) Relative Density	N/A
(n) Solubility(ies)	N/A
(o) Partition Coefficient: n-octanol/water	N/A
(p) Auto-ignition Temperature	N/A
(q) Decomposition Temperature	N/A
(r) Viscosity	N/A

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10. STABILITY AND REACTIVITY

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|---|--|
| (a) Reactivity | Hazardous reactions will not occur under normal conditions |
| (b) Chemical Stability | Stable under standard use and storage conditions |
| (c) Possibility of Hazardous Reactions | Hazardous polymerization will not occur |
| (d) Conditions to Avoid | Direct sunlight, extremely high or low temperatures, and incompatible materials. |
| (e) Incompatible Materials | Strong acids, strong bases, strong oxidizers. Reducing agents. Water reactive materials. |
| (f) Hazardous Decomposition Products | Under normal storage and use, hazardous decomposition products should not be produced. |

11. TOXICOLOGICAL INFORMATION

(a) **Information on Toxicological Effects**

Acute Toxicity: Not classified

[1,1'-Bicyclohexyl]-1-carboxylic acid, 2-(diethylamino)ethyl ester, hydrochloride (67-92-5)

LD50 Oral Rat	1290 mg/kg
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Skin Corrosion/Irritation: Not classified

pH: 3.5 - 6.5

Serious Eye Damage/Irritation: Not classified

pH: 3.5 - 6.5

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause minor eye irritation.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: None known.

12. ECOLOGICAL INFORMATION

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	Not determined for product.



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(c)	Bioaccumulative potential	Not determined for product.
(d)	Mobility in soil	Not determined for product.
(e)	Other Adverse Effects	N/A

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions. Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

Ecology - Waste Materials: Avoid release to the environment.

14. TRANSPORT INFORMATION

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

DOT status: Not regulated
 IMDG Status: Not regulated
 ICAO/IATA Status: Not Regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Nexus usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Federal Regulations:

Dicyclomine Hydrochloride Injection USP, 10 mg/mL	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Water (7732-18-5)	



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Listed on the United States TSCA (Toxic Substances Control Act) inventory

[1,1'-Bicyclohexyl]-1-carboxylic acid, 2-(diethylamino)ethyl ester, hydrochloride (67-92-5)
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Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations Neither this product nor its chemical components appear on any US state lists.

16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.



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Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity



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RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Revision Date: February 13, 2019