

## SECTION 1: IDENTIFICATION

### 1.1. (a) Product Identifier

**Product Form:** Solution

**Product Name:** Dicyclomine Hydrochloride Injection, USP

**Product Code:** NDC 14789-010-02

### 1.2. (b) Other means of identification: None

(c) Intended Use of the Product substance/mixture: An antispasmodic and anticholinergic (antimuscarinic) agent indicated for the treatment of functional bowel/irritable bowel syndrome.

### 1.3. (d) Name, Address, and Telephone of the Responsible Party Company

Nexus Pharmaceuticals, Inc.

400 Knightsbridge Parkway

Lincolnshire, IL

60069

USA

1-847-996-3790

[www.nexuspharma.net](http://www.nexuspharma.net)

### 1.4. (e) Emergency Telephone Number, Hazardous Materials or Dangerous Goods Incident, Spill, Leak, Fire, Exposure, or Accident:

Call CHEMTREC 24 Hours: 1-800-424-9300 / 1-703-527-3887

Customer Service Team email: [CHEMTREC@chemtrec.com](mailto:CHEMTREC@chemtrec.com)

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. (a) Classification of the Substance or Mixture:

**Classification (GHS-US)**

Not classified

### 2.2. (b) Label Elements GHS-US Labeling: No labeling applicable.

### 2.3 (c) Other Hazards: Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.4 (d) Unknown Acute Toxicity (GHS-US): No data available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances: Not applicable

### 3.2. Mixtures:

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

## Dicyclomine Hydrochloride Injection, USP

### SECTION 4: FIRST AID MEASURES

**4.1. (a) Description of First Aid Measures:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a Poison center or seek medical advice.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical advice.

**First-aid Measures After Eye Contact:** Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting.

**First-aid Measures After Inhalation:** When symptoms occur go into open air and ventilate suspected area. Seek medical attention.

**4.2. (b) Most important symptoms and effects, both acute and delayed Symptoms/Injuries:** See product insert.

**4.3. (c) Indication of immediate medical attention and special treatment needed:** Notes to Physician Treat symptomatically.

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. (a) Extinguishing Media

**Suitable Extinguishing Media:** Water spray, dry chemical, foam, carbon dioxide.

**Unsuitable Extinguishing Media:** A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

**(b) Special Hazards Arising from the Substance or Mixture:** Reactivity: Hazardous reactions will not occur under normal conditions.

**5.2. (c) Special protective equipment and precautions for fire-fighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

**Firefighting Instructions:** Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

**6.1. (a) Personal Precautions, Protective Equipment and Emergency Procedures General Measures:** Avoid all unnecessary exposure. Do not breathe vapor or mist.

**For Non-emergency Personnel Protective Equipment:** Use appropriate personal protection equipment (PPE). Refer to section 8.2.

**Emergency Procedures:** Evacuate the area and alert emergency team.

**For Emergency Responders Protective Equipment:** Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

**Environmental Precautions:** Ventilate area.

#### 6.2. (b) Methods and Material for Containment and Cleaning Up Methods:

Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads, or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

**6.3. (c) Reference to Other Sections:** See heading 8, Exposure Controls and Personal Protection.

## SECTION 7: HANDLING AND STORAGE

**7.1. (a) Precautions for Safe Handling Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

**7.2. (b) Conditions for Safe Storage, Including Any Incompatibilities Technical Measures:**

**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

**Specific end use(s):** Pharmaceutical

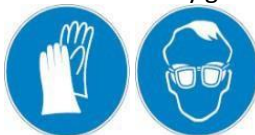
**(c) Incompatible Products:** Strong bases. Strong oxidizers.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1. (a) Exposure Limit:** Not applicable.

**8.2. (b) Appropriate 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.

**8.3. (c) Personal Protective Equipment:** Gloves. Safety glasses.



**Hand Protection:** Wear chemically resistant protective gloves.

**Eye/Face Protection:** Chemical goggles or safety glasses.

**Skin and Body Protection:** Wear suitable protective clothing. Wash contaminated clothing before reuse.

**Respiratory Protection:** In case of inadequate ventilation wear respiratory protection.

**Other Information:** When using, do not eat, drink, or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**9.1. Information on Basic Physical and Chemical Properties**

|   |   |
|---|---|
| <b>(a) Appearance (physical state. Color, etc.),</b>    | : Liquid, clear, colorless to slight yellow |
| <b>(b) Odor</b>   | : No odor                                   |
| <b>(c) Odor Threshold</b>                               | : None                                      |
| <b>(d) pH</b>   | : 3.5 – 6.5                                 |
| <b>(e) Melting Point/freezing point</b>                 | : Not applicable                            |
| <b>(f) Initial boiling point and boiling range</b>      | : Not applicable                            |
| <b>(g) Flash Point</b>                                  | : No data available                         |
| <b>(h) Evaporation rate</b>                             | : Not applicable                            |
| <b>(i) Flammability (solid, gas)</b>                    | : Not applicable                            |
| <b>(j) Upper/lower flammability or explosive limits</b> | : Not available                             |
| <b>(k) Vapor Pressure</b>                               | : No data available                         |
| <b>(l) Vapor Density</b>                                | : No data available                         |
| <b>(m) Relative Density</b>                             | : No data available                         |
| <b>(n) Solubility (ies)</b>                             | : Not applicable                            |
| <b>(o) Partition Coefficient: N-Octanol/Water</b>       | : Not applicable                            |
| <b>(p) Auto-ignition temperature</b>                    | : Not available                             |
| <b>(q) Decomposition temperature</b>                    | : No data available                         |
| <b>(r) Viscosity</b>                                    | : Not applicable                            |
| <b>Other Information</b>                                | : No additional information available       |

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. (a) Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. (b) Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. (c) Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. (d) Conditions to Avoid:** Exposure to or contact with extreme temperatures, incompatible chemicals.
- 10.5. (e) Incompatible Materials:** Strong acids, strong bases, compounds that are incompatible with water.
- 10.6. (f) Hazardous Decomposition Products:** Under normal storage and use, hazardous decomposition products should not be produced.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

**(a) Likely Route of entry:** Skin, eyes or inhalation of mists or sprays.

**(b) Symptoms related to the chemical, and toxicological characteristics:**

**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

**(c) Delayed and immediate effects and chronic effects from short- and long-term exposure:** Not applicable.

**(d) Acute Toxicity:** Not classified.

| Component   | Type             | Route | Species | Dosage     |
|---|------------------|-------|---------|------------|
| 1,1'-Bicyclohexyl]-1-carboxylic acid, 2-(diethylamino) ethyl ester, hydrochloride | LD <sub>50</sub> | Oral  | Rat     | 1290 mg/kg |

**(e) Hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA:** Not regulated

**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.

## SECTION 12: ECOLOGICAL INFORMATION

- 12.1. (a) Ecotoxicity:** Not classified.
- 12.2. (b) Persistence and Degradability:** Not established.
- 12.3. (c) Bio accumulative Potential:** Not established
- 12.4. (d) Mobility in Soil:** No additional information available
- 12.5. (e) Other Adverse Effects:** Not Applicable.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**(a) Sewage Disposal Recommendations:** Do not empty into drains; dispose of this material and its container in a safe way.

**(b) Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, and international regulations.

## SECTION 14: TRANSPORT INFORMATION

- 14.1. In Accordance with DOT:** Not regulated for transport
- (a) **UN Number:** Not applicable
  - (b) **UN Proper Shipping Name:** Not applicable.
  - (c) **Transportation Hazardous Class (es):** Not applicable.
  - (d) **Packing group:** Not applicable.
  - (e) **Environmental Hazards (e.g., Marine pollutant):** Not applicable
  - (f) **Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable.
  - (g) **Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises:** Not applicable.

**In Accordance with DOT:** Not regulated for transport

**In Accordance with IMDG:** Not regulated for transport

**In Accordance with IATA:** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1 US Federal Regulations

|   |                                 |
|---|---------------------------------|
| Dicyclomine Hydrochloride Injection USP, 10 mg/mL   |                                 |
| SARA Section 311/312 Hazard Classes   | Immediate (acute) health hazard |
| Water (7732-18-5)   |                                 |
| 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) |                                 |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory                   |                                 |

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

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**16.1. Other Information:** This document has been prepared in accordance with the SDS requirements of the OSHA Hazard

Communication Standard 29 CFR 1910.1200.

### GHS Full Text Phrases:

|                                       |  |
|---------------------------------------|--|
| Acute Tox. 4 (Dermal)                 | Acute toxicity (dermal) Category 4                               |
| Acute Tox. 4 (Inhalation: dust, mist) | Acute toxicity (inhalation: dust, mist) Category 4               |
| Acute Tox. 4 (Oral)                   | Acute toxicity (oral) Category 4                                 |
| Aquatic Chronic 3                     | Hazardous to the aquatic environment - Chronic Hazard Category 3 |
| Comb. Dust                            | Combustible Dust   |
| Eye Irrit. 2A                         | Serious eye damage/eye irritation Category 2A                    |
| Skin Irrit. 2                         | Skin corrosion/irritation Category 2                             |
| STOT SE 3                             | Specific target organ toxicity (single exposure) Category 3      |
| Comb. Dust                            | May form combustible dust concentrations in air                  |
| H302                                  | Harmful if swallowed   |
| H312                                  | Harmful in contact with skin                                     |
| H315                                  | Causes skin irritation   |
| H319                                  | Causes serious eye irritation                                    |
| H332                                  | Harmful if inhaled   |
| H335                                  | May cause respiratory irritation                                 |
| H412                                  | Harmful to aquatic life with long lasting effects                |

**16.2. Key or legend to abbreviations and acronyms used in the safety data sheet**

## SECTION 16 CONTINUED: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

|            |   |
|------------|---|
| 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   |
| 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   |

## SECTION 16 CONTINUED: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

|       |  |
|-------|--|
| UN    | United Nations                                   |
| USP   | United States Pharmacopeia                       |
| WEEL  | Workplace Environmental Exposure Level (AIHA)    |
| WHMIS | Workplace Hazardous Materials Information System |

Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Refer to Nexus Pharmaceuticals, Inc prescribing information for further information at:

<https://www.nexuspharma.net/products/>

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