SAFETY DATA SHEET
Midazolam Injection, USP

Section 1. Identification

GHS product identifier : Midazolam Injection, USP
Synonyms : Midazolam HCl Injection
Product code : NDC 0641-6056-01, NDC 0641-6056-10, NDC 0641-6057-01, NDC 0641-6057-25, NDC 0641-6057-10, NDC 0641-6059-01, NDC 0641-6059-10, NDC 0641-6060-01, NDC 0641-6060-10, NDC 0641-6061-01, NDC 0641-6061-25, NDC 0641-6061-10, NDC 0641-6063-01, NDC 0641-6063-25, NDC 0641-6063-10
Chemical family : Benzodiazepine
Product type : Regulated prescription drug.
Container information : 1 ml, 2 ml, 5 ml, and 10 ml vials.

Identified uses
Pharmaceutical.

Supplier's details : West-Ward Pharmaceutical Corp.
465 Industrial Way West
Eatontown NJ 07724 USA

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.
Precautionary statements
General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
Prevention : Not applicable.
Response : Not applicable.
Storage : Not applicable.
Disposal : Not applicable.
Hazards not otherwise classified : None known.
Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Other means of identification : Midazolam HCl Injection

CAS number/other identifiers

CAS number : Not applicable.
Product code : NDC 0641-6056-01, NDC 0641-6056-10, NDC 0641-6057-01, NDC 0641-6057-25, NDC 0641-6057-10, NDC 0641-6059-01, NDC 0641-6059-10, NDC 0641-6060-01, NDC 0641-6060-10, NDC 0641-6061-01, NDC 0641-6061-25, NDC 0641-6061-10, NDC 0641-6063-01, NDC 0641-6063-25, NDC 0641-6063-10

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>%</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>60 - 100</td>
<td>7732-18-5</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>0.1 - 1</td>
<td>100-51-6</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>0.1 - 1</td>
<td>7647-14-5</td>
</tr>
<tr>
<td>Midazolam hydrochloride</td>
<td>0.1 - 1</td>
<td>59467-96-8</td>
</tr>
<tr>
<td>Disodium dihydrogen ethylenediaminetetraacetate</td>
<td>0 - 0.1</td>
<td>139-33-3</td>
</tr>
</tbody>
</table>

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

There are no 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.

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.

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.

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : No specific treatment.
Section 4. First aid measures

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

Hazardous thermal decomposition products: Decomposition products may include the following materials:
- carbon dioxide
- carbon monoxide

Special protective actions for fire-fighters: No special measures are required.

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. 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

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.
Section 7. Handling and storage

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.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>AIHA WEEL (United States, 10/2011). TWA: 10 ppm 8 hours.</td>
</tr>
</tbody>
</table>

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. 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.

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:

Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state:

Liquid.

Color:

Colorless to light yellow.

Odor:

Odorless.

Odor threshold:

Not available.

pH:

2.9 to 3.7

Melting point:

Not available.
Section 9. Physical and chemical properties

- Boiling point: Not available.
- Flash point: Not available.
- Evaporation rate: Not available.
- Flammability (solid, gas): Not available.
- Lower and upper explosive (flammable) limits: Not available.
- Vapor pressure: Not available.
- Vapor density: Not available.
- Relative density: Not available.
- Solubility: Soluble in the following materials: cold water and hot water.
- Partition coefficient: n-octanol/water: Not available.
- Auto-ignition temperature: Not available.
- Decomposition temperature: Not available.
- Viscosity: 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: Reactive or incompatible with the following materials: oxidizing materials and acids.
- 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

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>LD50 Dermal</td>
<td>Rabbit</td>
<td>2000 mg/kg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>1230 mg/kg</td>
<td>-</td>
</tr>
</tbody>
</table>

Irritation/Corrosion

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Score</th>
<th>Exposure</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>Skin - Moderate irritant</td>
<td>Rabbit</td>
<td>-</td>
<td>24 hours 100 mg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Skin - Mild irritant</td>
<td>Man</td>
<td>-</td>
<td>48 hours 16 mg</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Skin - Moderate irritant</td>
<td>Pig</td>
<td>-</td>
<td>100%</td>
<td>-</td>
</tr>
</tbody>
</table>

Sensitization

There is no data available.

Carcinogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.
Section 11. Toxicological information

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

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 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

<table>
<thead>
<tr>
<th>Route</th>
<th>ATE value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>123000 mg/kg</td>
</tr>
<tr>
<td>Inhalation (vapors)</td>
<td>1100 mg/L</td>
</tr>
</tbody>
</table>
Section 12. Ecological information

Toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>Acute EC50 640 mg/L</td>
<td>Algae - Scenedesmus subspicatus</td>
<td>96 hours</td>
</tr>
<tr>
<td></td>
<td>Acute IC50 700 mg/L</td>
<td>Algae</td>
<td>72 hours</td>
</tr>
<tr>
<td></td>
<td>Acute LC50 10000 µg/l Fresh water</td>
<td>Fish - Lepomis macrochirus</td>
<td>96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Test</th>
<th>Result</th>
<th>Dose</th>
<th>Inoculum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>OECD 301C 301C Ready Biodegradability - Modified MITI Test (I)</td>
<td>92 to 96 % - 28 days</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Aquatic half-life</th>
<th>Photolysis</th>
<th>Biodegradability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>-</td>
<td>-</td>
<td>Readily</td>
</tr>
</tbody>
</table>

Bioaccumulative potential

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>LogP_{ow}</th>
<th>BCF</th>
<th>Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>0.87</td>
<td>-</td>
<td>low</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>UN number</th>
<th>DOT Classification</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>UN proper shipping name</th>
<th>DOT Classification</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>-</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transport hazard class(es)</th>
<th>DOT Classification</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Packing group</th>
<th>DOT Classification</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Section 14. Transport information

**Environmental hazards**

<table>
<thead>
<tr>
<th>Environmental hazards</th>
<th>No.</th>
<th>No.</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional information</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**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 73/78 and the IBC Code**: Not available.

AERG : Not applicable.

Section 15. Regulatory information

**U.S. Federal regulations**

| 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 |
| DEA List II Chemicals (Essential Chemicals) | Not listed |

**TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

**United States inventory (TSCA 8b)**: Not determined.

**SARA 302/304**

- **Composition/information on ingredients**: No products were found.

**SARA 304 RQ** : Not applicable.

**SARA 311/312**

- **Composition/information on ingredients**

<table>
<thead>
<tr>
<th>Name</th>
<th>%</th>
<th>Fire hazard</th>
<th>Sudden release of pressure</th>
<th>Reactive</th>
<th>Immediate (acute) health hazard</th>
<th>Delayed (chronic) health hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>0.1 - 1</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
<td>Yes.</td>
<td>No.</td>
</tr>
</tbody>
</table>

**State regulations**

**Massachusetts** : The following components are listed: Benzyl Alcohol

**New York** : None of the components are listed.

**New Jersey** : None of the components are listed.

**Pennsylvania** : The following components are listed: Benzyl Alcohol

**California Prop. 65**
Section 15. Regulatory information

**WARNING:** This product contains less than 1% of a chemical known to the State of California to cause birth defects or other reproductive harm.

<table>
<thead>
<tr>
<th>Ingredient name</th>
<th>Cancer</th>
<th>Reproductive</th>
<th>No significant risk level</th>
<th>Maximum acceptable dosage level</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine monohydrochloride</td>
<td>No.</td>
<td>Yes.</td>
<td>No.</td>
<td>No.</td>
</tr>
</tbody>
</table>

International regulations

**International lists**
- **Australia inventory (AICS):** Not determined.
- **China inventory (IECSC):** Not determined.
- **Japan inventory:** Not determined.
- **Korea inventory:** Not determined.
- **Malaysia Inventory (EHS Register):** Not determined.
- **New Zealand Inventory of Chemicals (NZIoC):** All components are listed or exempted.
- **Philippines inventory (PICCS):** Not determined.
- **Taiwan inventory (CSNN):** Not determined.

- **Chemical Weapons Convention List Schedule I Chemicals:** Not listed
- **Chemical Weapons Convention List Schedule II Chemicals:** Not listed
- **Chemical Weapons Convention List Schedule III Chemicals:** Not listed

Section 16. Other information

**History**
- **Date of issue mm/dd/yyyy:** 12/15/2013
- **Version:** 1
- **Revised Section(s):** Not applicable.
- **Prepared by:** KMK Regulatory Services Inc.

**Key to abbreviations**
- ATE = Acute Toxicity Estimate
- 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
- UN = United Nations

**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.