MATERIAL SAFETY DATA SHEET

Product Name: Bacteriostatic Water 1.1% for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Bacteriostatic Water 1.1% for Injection, USP

Synonyms
NA

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Benzyl Alcohol

Chemical Formula
C₇H₈O

Preparation
Non-hazardous ingredients include Water for Injection.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.1</td>
<td>100-51-6</td>
<td>DN3150000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
1.1% Bacteriostatic Water for Injection, USP is an aqueous solution containing benzyl alcohol. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Possible target organs include the central nervous system, gastrointestinal system, respiratory system, and eyes.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. Inhalation of product aerosols or inadvertent splashes to the eyes may produce irritation. In clinical use, concentrations of benzyl alcohol normally used for preservation are generally not associated with serious adverse effects in patients. However, over-exposure to benzyl alcohol by ingestion or inhalation may cause nausea, vomiting, diarrhea, headache, and vertigo. As with many alcohols, serious over-exposure may produce central nervous system and respiratory depression.

Medical Conditions
Pre-existing hypersensitivity to benzyl alcohol; pre-existing central nervous system,
4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated from this aqueous product. However, when heated, this product may produce combustible vapors.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
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.

7. HANDLING AND STORAGE

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

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

Special Precautions
No special precautions required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>AIHA WEEL</td>
<td>N/A</td>
<td>10</td>
<td>N/A</td>
<td>8-hr TWA</td>
</tr>
</tbody>
</table>

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) and an organic vapor cartridge is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

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.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear, colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>4.5 - 7.0</td>
</tr>
<tr>
<td>Melting point/Freezing point</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or</td>
<td>NA</td>
</tr>
<tr>
<td>Explosive Limits</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>NA</td>
</tr>
</tbody>
</table>
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10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined

Conditions to avoid
Not determined

Incompatibilities
Not determined

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx).

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1660, 1230</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1360, 1580</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1040, 1940</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2500</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>53</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>324</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>2000</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LC50/8hr</td>
<td>Inhalation</td>
<td>&gt;500</td>
<td>mg/m^3</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1000</td>
<td>ppm</td>
<td></td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product. However, inadvertent inhalation of product aerosol/vapors may produce irritation with coughing.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. Pure benzyl alcohol was considered moderately irritating in a skin irritation study in animals.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. Rarely, systemic hypersensitivity reactions to benzyl alcohol have been reported during clinical use. In a skin patch study in volunteers exposed to 5 to 10 percent benzyl alcohol in petrolatum for 24-48 hours, about 1 percent of the volunteers gave a positive reaction.

Reproductive Effects
In a short term in vivo bioassay, fifty pregnant CD-1 mice were given 750 mg/kg/day benzyl alcohol in water by gavage on days 6-13 of gestation, and were allowed to deliver. A decrease in birth weights and weight gain, but no
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malformations, were noted in the pups. Maternal toxicity (death, 19/50) was noted at this dosage.

**Mutagenicity**

Benzyl alcohol was negative in the Ames Assay for mutagenicity. Further, benzyl alcohol was generally negative or equivocal for genotoxicity in an additional battery of tests. However, benzyl alcohol was considered positive in the chromosome aberration test in Chinese hamster ovary (CHO) cells in the presence of a metabolic activating system.

**Carcinogenicity**

The results of 2 year gavage studies indicate that there was no evidence of carcinogenic activity in male or female F344/N rats dosed with 200 or 400 mg/kg of benzyl alcohol. Similarly, there was no evidence of carcinogenic activity of benzyl alcohol in male or female B6C3F1 mice dosed with 100 or 200 mg/kg/day for 2 years.

**Target Organ Effects**

During occupational use, possible target organs include the central nervous system, gastrointestinal system, respiratory system, and eyes. In clinical use, pre-mature infants over-exposed to benzyl alcohol may exhibit a gasping syndrome characterized by respiratory distress and apneic spells.

12. ECOLOGICAL INFORMATION

**Aquatic Toxicity**

Not determined for the product. Information for ingredients is provided below:

- LC50(96 hr) = 460 mg/L in Pimephales promelas for benzyl alcohol
- LC50 = 640 mg/L in Leuciscus idus for benzyl alcohol
- EC50(24 hr) = 400 mg/L in Daphnia magna for benzyl alcohol
- EC50 = 95 mg/L in Chlorella pyrenoidosa for benzyl alcohol

**Persistence/Biodegradability**

Not determined for the product. Information for ingredients is provided below:

- Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.

**Bioaccumulation**

Not determined for product.

**Mobility in Soil**

Not determined for product.

13. DISPOSAL CONSIDERATIONS

**Waste Disposal**

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

**Container Handling and Disposal**

Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

**ADR/ADG/ DOT STATUS:** Not regulated

**IMDG STATUS:** Not regulated
Product Name: Bacteriostatic Water 1.1% for Injection, USP

ICAO/IATA STATUS: Not regulated

Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status: Not Listed

U.S. OSHA Classification: Target Organ Toxin

GHS Classification: *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class: Not Applicable

Hazard Category: Not Applicable

Signal Word: Not Applicable

Symbol: Not Applicable


Hazard Statement: Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Benzyl Alcohol.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.
16. OTHER INFORMATION:

Notes:
- ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
- CAS: Chemical Abstracts Service Number
- CERCLA: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
- DOT: US Department of Transportation Regulations
- EEL: Employee Exposure Limit
- IATA: International Air Transport Association
- LD50: Dosage producing 50% mortality
- NA: Not applicable/Not available
- NE: Not established
- NIOSH: National Institute for Occupational Safety and Health
- OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
- Prop 65: California Proposition 65
- RCRA: US EPA, Resource Conservation and Recovery Act
- RTECS: Registry of Toxic Effects of Chemical Substances
- SARA: Superfund Amendments and Reauthorization Act
- STEL: 15-minute Short Term Exposure Limit
- TSCA: Toxic Substance Control Act
- TWA: 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/17/2012
Obsolete Date: 09/02/2011

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