MATERIAL SAFETY DATA SHEET

Product Name: Pentazocine Lactate Injection, USP (Talwin® Injection)

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 (02) 8014 4880

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

Product Name
Pentazocine Lactate Injection, USP (Talwin® Injection)

Synonyms
1, 2, 3, 4, 5, 6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocin-8-ol lactate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Pentazocine Lactate

Chemical Formula
C_{19}H_{27}NO \cdot C_3H_6O_3

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include acetone sodium bisulfite, sodium chloride, and methylparaben (as a preservative). Lactic acid or sodium hydroxide may be added to adjust the pH.

<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>Pentazocine Lactate</td>
<td>3</td>
<td>17146-95-1</td>
<td>OD5400000</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>Pentazocine Lactate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Pentazocine Lactate Injection, USP (Talwin® Injection) is a solution containing pentazocine lactate, a synthetic benzomorphone opiate-like drug used for relief of pain. In the workplace, this product should be considered potentially severely irritating to the eyes and respiratory tract, and potentially irritating to the skin. This product also contains a sulfite which may induce allergic reactions in persons sensitive to sulfites. In the US, pentazocine is a Schedule IV controlled substance; this material has some potential to produce psychological and physical dependence. Based on clinical use, possible target organs include the central nervous system and cardiovascular system.

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. In clinical use, adverse effects may include nausea, dizziness or lightheadedness, vomiting, euphoria. Infrequently, respiratory depression, and
dyspnea. In addition, circulatory depression, shock, hypertension; dizziness, lightheadedness, hallucinations, sedation, euphoria, headache, confusion, disorientation have been reported. Ulceration (sloughing) and severe sclerosis of the skin and subcutaneous tissues (and, rarely, underlying muscle) have been reported after multiple doses. Other reported dermatologic reactions include diaphoresis, sting on injection, flushed skin including plethora, dermatitis including pruritus.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to this material; pre-existing central nervous system or cardiovascular system ailments; pre-existing sulfite sensitivity.

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 for this aqueous product.

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>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentazocine Lactate</td>
<td>Not Applicable</td>
<td>mg/m3 ppm µg/m3 Note</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A N/A N/A</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) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. 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

Appearance/Physical State: Liquid
Color: Clear, colorless to pale yellow
Odor: NA
Odor Threshold:
pH: 4 to 5
Melting point/Freezing point:
Initial Boiling Point/Boiling Point Range:
Evaporation Rate:
Flammability (solid, gas):
Upper/Lower Flammability or Explosive Limits:
Vapor Pressure:
Vapor Density:
Specific Gravity:
Solubility:
Soluble in acidic aqueous solutions
Partition coefficient: n-octanol/water:
Auto-ignition temperature:
Decomposition temperature:
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) and nitrogen oxides (NOx).

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>Pentazocine</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1110</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>305</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Pentazocine</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>21</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19.8</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent contact with skin may produce irritation.

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

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. Multi-dose vials of this product contain acetone sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Reproductive Effects
Pentazocine did not increase congenital malformations when tested in rats or rabbits. A study in hamsters found maternal administration of opioids, including pentazocine, to be associated with congenital abnormalities in the offspring. However, the most clearly demonstrated adverse fetal effects of pentazocine administration to the mother include a neonatal withdrawal syndrome and behavioral abnormalities. The withdrawal syndrome has been well-documented in humans and consists of jitteriness, irritability, hypertonia,
Product Name: Pentazocine Lactate Injection, USP (Talwin® Injection)

vomiting, and diarrhea.

Mutagenicity No information was located regarding the mutagenic potential of pentazocine lactate.

Carcinogenicity No long-term studies in animals to test for carcinogenesis have been performed with the components of pentazocine.

Target Organ Effects Based on clinical use, possible target organs include the central nervous system and cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity Not determined for product.

Persistence/Biodegradability Not determined for product.

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

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>
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<tbody>
<tr>
<td>Pentazocine Lactate</td>
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<table>
<thead>
<tr>
<th>RCRA Status</th>
<th>Not Listed</th>
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</thead>
<tbody>
<tr>
<td>U.S. OSHA</td>
<td>Target Organ Toxin</td>
</tr>
<tr>
<td>Classification</td>
<td>Possible Irritant</td>
</tr>
<tr>
<td><strong>GHS Classification</strong></td>
<td><em>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.</em></td>
</tr>
<tr>
<td>Hazard Class</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Hazard Category</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Signal Word</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Symbol</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Prevention</td>
<td>P260 - Do not breathe dust/fume/gas/mist/vapors/spray.</td>
</tr>
<tr>
<td>Hazard Statement</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Response:</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

**EU Classification**

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

**Classification(s):** Not Applicable

**Symbol:** Not Applicable

**Indication of Danger:** Not Applicable

**Risk Phrases:** Not Applicable

**Safety Phrases:** S23 - Do not breathe vapors. S24 - Avoid contact with skin. S25 - Avoid contact with 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
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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: 11/03/2011
Obsolete Date: 10/21/2008

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