MATERIAL SAFETY DATA SHEET

Product Name: Dipyridamole 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 Dipyridamole Injection

Synonyms 2,6 bis-(diethanolamino)-4,8-dipiperidino-pyrimido-(5,4-d) pyrimidine.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Dipyridamole

Chemical Formula C_{24}H_{40}N_{8}O_{4}

Preparation Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at < 1% include tartaric acid. Hydrochloride acid is 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>Poly(ethylene glycol)</td>
<td>5</td>
<td>25322-68-3</td>
<td>TQ4100000/PEG6000; TQ3675000/PEG400</td>
</tr>
<tr>
<td>Dipyridamole</td>
<td>0.5</td>
<td>58-32-2</td>
<td>KK7450000</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>Dipyridamole</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Poly(ethylene glycol)</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview Dipyridamole Injection is a solution containing dipyridamole, a non-nitrate coronary vasodilator. Clinically, it is used in combination therapy to prevent post-operative thromboembolic complications, and for myocardial imaging. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the 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 exposures. In clinical use, adverse effects may include chest pain/angina pectoris, electrocardiographic changes (most commonly ST-T changes), headache, and dizziness. Abdominal distress (nausea, vomiting, diarrhea), peripheral vasodilation (flushing), pruritus, rash and hypotension may also occur.
## Product Name: Dipyridamole Injection

### Medical Conditions Aggravated by Exposure
- Pre-existing hypersensitivity to this material; pre-existing cardiovascular ailments.

### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye contact</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Skin contact</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td><strong>Ingestion</strong></td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
</tbody>
</table>

### 5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flammability</strong></td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td><strong>Fire &amp; Explosion Hazard</strong></td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td><strong>Extinguishing media</strong></td>
<td>As with any fire, use extinguishing media appropriate for primary cause of fire.</td>
</tr>
<tr>
<td><strong>Special Fire Fighting Procedures</strong></td>
<td>No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.</td>
</tr>
</tbody>
</table>

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spill Cleanup and Disposal</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

### 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Handling</strong></td>
<td>No special handling required under conditions of normal product use.</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Special Precautions</strong></td>
<td>No special precautions required for hazard control.</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<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>Dipyridamole</td>
<td>Hospira EEL</td>
<td></td>
<td>300</td>
<td></td>
<td>8-hr TWA</td>
</tr>
<tr>
<td>Poly(ethylene glycol)</td>
<td>AIHA WEEL</td>
<td>10</td>
<td>N/A</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) 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

<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>Pale yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>2.2 to 3.2</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 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>
Product Name: Dipyridamole Injection

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>Dipyridamole</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>8400</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2150</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4250</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Dipyridamole</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>195</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>85</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Polyethylene Glycol 6000</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>50,000</td>
<td>mg/kg</td>
<td>Rat, Guinea Pig</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.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, polyethylene glycol 6000 was a mild eye irritant in a study in animals. Inadvertent contact of this product with eyes may produce irritation and redness.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
There was no evidence of impaired fertility when dipyridamole was administered to male and female rats at oral doses up to 500 mg/kg/day. A significant reduction in number of corpora lutea with consequent reduction in implantations and live fetuses was, however, observed at 1250 mg/kg/day. Reproduction studies performed in mice and rats at daily oral doses of up to 125 mg/kg and in rabbits at daily oral doses of up to 20 mg/kg have revealed no evidence of impaired embryonic development due to dipyridamole.

Mutagenicity
Mutagenicity tests of dipyridamole with bacterial and mammalian cell systems were negative.
Product Name: Dipyridamole Injection

Carcinogenicity

In long-term feeding studies in which dipyridamole was administered in the diet at dosages up to 75 mg/kg/day in mice and rats, there was no evidence of drug related carcinogenesis.

Target Organ Effects

Based on clinical use, possible target organs include the 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>
</tr>
</thead>
<tbody>
<tr>
<td>Dipyridamole</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Poly(ethylene glycol)</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

Possible Irritant

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:
Product Name: Dipyridamole Injection

Hazard Class                  Not Applicable
Hazard Category               Not Applicable
Signal Word                  Not Applicable
Symbol                       Not Applicable
Prevention                   P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
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 Dipyridamole.

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
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