SAFETY DATA SHEET

Product Name: AQUASOL A® Parenteral

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
224 212-2000

Product Name
AQUASOL A® Parenteral

Synonyms
Aquasol A - Vitamin A Palmitate Injection, Solution

2. HAZARD(S) IDENTIFICATION

Emergency Overview
AQUASOL A® Parenteral is a solution containing 50,000 USP units of vitamin A per milliliter as retinol (15 mg/ml) in the form of vitamin A palmitate. Vitamin A is a fat-soluble vitamin essential for normal growth and development and vision. Clinically, this product is used for the treatment of vitamin A deficiency. In the workplace, this product should be considered a potent compound, potentially irritating to the eyes and respiratory tract, and a potent occupational reproductive hazard. Based on clinical use, possible target organs include the skin, eyes, nervous system, and liver.

U.S. OSHA GHS Classification

Physical Hazards

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Classified</td>
<td>Not Classified</td>
</tr>
</tbody>
</table>

Health Hazards

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Damage / Irritation</td>
<td>2B</td>
</tr>
<tr>
<td>Toxic to Reproduction</td>
<td>2</td>
</tr>
<tr>
<td>STOT - RE</td>
<td>2</td>
</tr>
</tbody>
</table>

Label Element(s)

Pictogram

Signal Word
Danger

Hazard Statement(s)
Causes eye irritation
May damage fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Prevention
Do not breathe vapor or spray
Wash hands thoroughly after handling
Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection

Response
If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.
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.
Product Name: AQUASOL A® Parenteral

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Active Ingredient Name</th>
<th>Vitamin A Palmitate</th>
<th>Polysorbate 80</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Formula</td>
<td>C_{36}H_{60}O_{2}</td>
<td>C_{60}H_{124}O_{26}</td>
</tr>
</tbody>
</table>

<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>Vitamin A Palmitate</td>
<td>1.5</td>
<td>79-81-2</td>
<td>VH6860000</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>12</td>
<td>9005-65-6</td>
<td>WG2932500</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include 0.5% chlorobutanol which is added as a preservative. Citric acid and sodium hydroxide are used for pH adjustment.

### 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 from this aqueous product.

**Extinguishing Media**
As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

**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 control 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 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 are required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A Palmitate</td>
<td>8 hr TWA: Not</td>
<td>8 hr TWA: Not</td>
<td>8 hr TWA: Not</td>
<td>8 hr TWA: Not</td>
</tr>
<tr>
<td></td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>8 hr TWA: Not</td>
<td>8 hr TWA: Not</td>
<td>8 hr TWA: Not</td>
<td>8 hr TWA: Not</td>
</tr>
<tr>
<td></td>
<td>established</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
</tbody>
</table>

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

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 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>A light yellow to amber odorless liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>NA</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>Flash Point</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 (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Relative Density</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility</td>
<td>NA</td>
</tr>
<tr>
<td>Log 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>
<tr>
<td>Viscosity</td>
<td>NA</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity  Not determined
Chemical Stability  Stable under standard use and storage conditions. Vitamin A is light sensitive and exposure to light should be minimized.
Hazardous Reactions  Not determined
Conditions to Avoid  Not determined
Incompatibilities  Not determined
Hazardous Decomposition  Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx).

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:  - not determined for the product formulation. Information for ingredients is provided below:

<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>Vitamin A Palmitate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>6060</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7910</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>25,000</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>37,260</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
</tbody>
</table>

LD50: Dosage that produces 50% mortality.

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  Not anticipated from normal handling of this product. In clinical use, the toxicity depends on the dosage, size, and duration of administration. For adults, acute toxicity is manifested after a single dose of about 25,000 Units/kg body weight, or about 2 million Units (about 525 mg) for a 70 kg adult. A single oral dose of 1,500,000 - 2,000,000 IU may produce headache, nausea, vomiting, and irritability. However, more prolonged exposure to lower dosages may also produce hyper-vitaminosis A, a disorder characterized by skeletal effects, hepatotoxicity and jaundice, leukopenia, skin effects including drying and cracking, fatigue, malaise, lethargy, psychiatric changes (depression or schizophrenia), anorexia, nausea and vomiting, and mild fever. For adults, chronic toxicity is manifested after a dosage of about 4,000 Units/kg body weight for 6 to 15 months (e.g. about 1 million Units daily (about 300 mg) for three days; about 500,000 Units (about 150 mg) daily for two months; or about 50,000 Units (about 16 mg) daily for longer than 18 months). Finally, several reports have indicated that maternal ingestion of 25,000 IU or more per day before and during pregnancy may produce birth defects.

Aspiration Hazard  Not anticipated from normal handling of this product.
Dermal Irritation/Corrosion  Not anticipated from normal handling of this product.
Ocular Irritation/Corrosion  Not anticipated from normal handling of this product. However, inadvertent contact of this product formulation with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization  Not anticipated from normal handling of this product.
Reproductive Effects  Not anticipated from normal handling of this product. The use of vitamin A in excess of the recommended dietary allowance may cause fetal harm when given to a pregnant woman. Animal reproduction studies have shown fetal abnormalities affecting the nervous system, eye, palate, and the urogenital tract. FDA Pregnancy Category X.
11. TOXICOLOGICAL INFORMATION: continued

Mutagenicity
Vitamin A palmitate was reported to be negative in Ames assay for mutagenicity and positive in an in vitro sister chromatid exchange assay for genotoxicity. By analogy, vitamin A aldehyde (Retinal) was negative in the Ames Assay.

Carcinogenicity
Long-term studies in animals to evaluate carcinogenic potential have not been conducted.

Carcinogen Lists
- IARC: Not listed
- NTP: Not listed
- OSHA: Not listed

Specific Target Organ Toxicity
- Single Exposure: NA
- Repeat Exposure: Based on clinical use, possible target organs include the skin, eyes, nervous system, and liver.

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

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

ICAO/IATA STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

IMDG STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

Notes: DOT - US Department of Transportation Regulations
Product Name: AQUASOL A® Parenteral

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Regulations</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>US TSCA Status</td>
<td>Exempt</td>
</tr>
<tr>
<td>US CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>


GHS/CLP 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.

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Prevention

Do not breathe vapor or spray
Wash hands thoroughly after handling
Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.
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.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

<table>
<thead>
<tr>
<th>Classification(s)</th>
<th>Symbol</th>
<th>Indication of Danger</th>
<th>Risk Phrases</th>
<th>Safety Phrases</th>
</tr>
</thead>
</table>
| NA                | NA     | NA                   | S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection. |
# 16. OTHER INFORMATION

Notes:

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

MSDS Coordinator: Hospira GEHS
Date Prepared: 17 October 2012
Date Revised: June 02, 2014

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