MATERIAL SAFETY DATA SHEET

Product Name: Aquasol E Drops

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
Aquasol E Drops

Synonyms
Vitamin E Acetate; 2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecy)-, acetate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Vitamin E (dl-alpha tocopherol acetate)

Chemical Formula
C_{31}H_{52}O_{3}

Preparation
Non-hazardous ingredients include Water for Injection and sorbitol. Hazardous ingredients present at less than 1% include sodium saccharin, anise oil, and butterscotch flavor. Sodium hydroxide 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>Propylene Glycol</td>
<td>≤20</td>
<td>57-55-6</td>
<td>TY2000000</td>
</tr>
<tr>
<td>Vitamin E (dl-alpha tocopherol acetate)</td>
<td>≤5</td>
<td>7695-91-2</td>
<td>GA8747000</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>≤25</td>
<td>9005-65-6</td>
<td>WG2932500</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>Polysorbate 80</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Vitamin E (dl-alpha tocopherol acetate)</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview

Aquasol E Drops is a liquid formulation containing 15 IU/0.3 ml of Vitamin E as dl-alpha tocopherol acetate. Vitamin E is a general term applied to a large number of natural or synthetic compounds, the most important of which are the tocopherols. Vitamin E is a fat-soluble vitamin that prevents the oxidation of polyunsaturated fatty acids. Clinically, Vitamin E is used in the treatment and prevention of vitamin E deficiency. In the workplace, this product should be considered potentially irritating to the skin, eyes and respiratory tract. Based on clinical use, possible target organs include the skin, eyes, liver and blood.

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.
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Signs and Symptoms
None known from occupational exposures. The recommended daily allowance (RDA) of vitamin E is 15 mg/day for healthy adults. In clinical use, Vitamin E is generally well tolerated. Large doses may cause diarrhea, abdominal pain, and other gastrointestinal disturbances, and have also been reported to cause blurred vision, dizziness, fatigue and weakness when taken in large doses. Contact dermatitis has occurred after topical application. Large doses of vitamin E have been reported to increase bleeding tendency in vitamin-K deficient patients such as those taking oral anticoagulants.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to Vitamin E or other components in this formulation; pre-existing liver or blood ailments.

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
Not anticipated from 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.

Special Fire Fighting Procedures
No special provisions required beyond normal fire fighting 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 any 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 requirements for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary
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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>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene Glycol</td>
<td>AIHA WEEL</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Vitamin E (dl-alpha tocopherol acetate)</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Not Applicable</td>
<td>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 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>Appearance/Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Clear Pale Yellow</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>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>
</tbody>
</table>
Product Name: Aquasol E Drops

Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined

Chemical Stability Stable under standard use and storage conditions. Vitamin E is light sensitive and exposure to light should be minimized.

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), nitrogen oxides (NOx), and sodium oxides (NaX).

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>d-Alpha-tocopherol acetate (58-95-7)</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt; 16,000</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>5000</td>
<td></td>
<td>Mouse</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></td>
<td>Rat</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>10,400-</td>
<td>mg/kg</td>
<td>Rat, Mouse, Rabbit, Dog, Guinea Pig</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>29,536</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6423-6800</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>6630-8000</td>
<td></td>
<td>Mouse</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>20,800</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>

Aspiration Hazard None anticipated from normal handling of the intact product.

Dermal Irritation/Corrosion None anticipated from normal handling of the intact product.

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

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

Reproductive Effects In animals, the frequency of malformations was no greater than expected among the offspring of rats or mice treated with vitamin E during pregnancy using doses hundreds to thousands of times the human RDA. In one study, an increased frequency of cleft palate was observed in the offspring of mice given 500-1000 times the human RDA of vitamin E. In another study, fetal resorptions were more common among pregnant rats fed diets containing 5-
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15% vitamin E. Decreased fertility and decreased numbers of viable fetuses when pregnancy occurred were observed in female mice that were chronically treated with more than 500 times the human RDA of vitamin E.

Mutagenicity
No in vivo or in vitro genotoxicity studies were found. Co-incubation with vitamin E has been reported to reduce the mutagenic effect of chemicals such as malonaldehyde and β-propiolactone in some Ames test studies.

Carcinogenicity
No carcinogenicity studies have been identified in laboratory animals, however, some limited chronic studies exist which suggest that vitamin E is non-carcinogenic. Sodium saccharin, a minor component of this product formulation, is listed by IARC as Group 3 – unclassifiable as to the carcinogenicity in humans.

Target Organ Effects
Based on clinical use, possible target organs include the skin, eyes, liver and blood.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

LC50(96 hr) = 51,600 mg/L in rainbow trout for propylene glycol
LC50(48 hr) = 34,400 - 43,500 mg/L in Daphnia magna for propylene glycol
EC50(14 day) = 19,000 mg/L in algae for propylene glycol

Persistence/Biodegradability
Not determined for product.

Propylene glycol was reported to be 100% biodegradable after 24-hours in activated 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.

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
Product Name: Aquasol E Drops

Transport Comments: None Established

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>Polysorbate 80</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
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<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 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:

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 Vitamin E (dl-alpha tocopherol acetate)

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: 09/01/2011
Obsolete Date: 11/16/2010

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