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
Hospira, Inc., Non-emergency	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 potential 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	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Eye Damage / Irritation	2B
	Toxic to Reproduction	2
	STOT - RE	2

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Vitamin A Palmitate	Polysorbate 80
Chemical Formula	$C_{36}H_{60}O_2$	$\sim C_{64}H_{124}O_{26}$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Vitamin A Palmitate	1.5	79-81-2	VH6860000
Polysorbate 80	12	9005-65-6	WG2932500

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

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Vitamin A Palmitate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established
Polysorbate 80	8 hr TWA: Not established	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established

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

Appearance/Physical State	A light yellow to amber odorless liquid
Odor	NA
Odor Threshold	NA
pH	NA
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Log Partition coefficient: n-octanol/water	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
Viscosity	NA

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 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 ingredients is provided below:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Vitamin A Palmitate	100	LD50	Oral	6060 7910	mg/kg mg/kg	Mouse Rat
Polysorbate 80	100	LD50	Oral	25,000 37,260	mg/kg mg/kg	Mouse Rat

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
Specific Target Organ Toxicity – 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

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

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.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

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.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	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:

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
LD_{50}	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

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

Disclaimer:

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