



A  Company

SAFETY DATA SHEET

Revision date: 06-Jul-2018

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Aquasol A(R) Parenteral

Trade Name: Not established
Synonyms: Vitamin A Palmitate Injection
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
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Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	**
Chlorobutanol	57-15-8	200-317-6	Acute Tox 4(H302)	0.5
Vitamin A, Retinyl Palmitate	79-81-2	201-228-5	Repro. 1B (H360D)Chronic 4 (H413)	1.5

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Polysorbate 80	9005-65-6	500-019-9	Not Listed	12
Water for injection	7732-18-5	231-791-2	Not Listed	*
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	**

Additional Information:

* Proprietary
** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact:

Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

In the case of inhalation of aerosol/mist consult a physician if necessary

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Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of chlorine.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL - TWAs	2 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Light yellow to amber
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		

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9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Vitamin A, Retinyl Palmitate

No data available

Polysorbate 80

No data available

Water for injection

No data available

Chlorobutanol

No data available

Sodium hydroxide

No data available

Citric acid, anhydrous

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The following information is available for the individual ingredients.

Short Term: May cause eye irritation (based on components) .

Known Clinical Effects: Clinical use of this drug has caused headache, nausea, vomiting liver effects, yellowing of the skin, eyes, and mucous membranes (jaundice), skin effects, impaired mental state (psychosis), loss of appetite (anorexia).

Acute Toxicity: (Species, Route, End Point, Dose)

Vitamin A, Retinyl Palmitate

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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 > 2000 mg/kg

Polysorbate 80

Rat Intravenous LD 50 1790 mg/kg

Mouse Oral LD 50 25 g/kg

Chlorobutanol

Rat Oral LD50 510 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Vitamin A, Retinyl Palmitate

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Chlorobutanol

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Citric acid, anhydrous

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Vitamin A, Retinyl Palmitate

Embryo / Fetal Development Monkey Oral 7500 IU/kg NOAEL Teratogenic, Embryotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Chlorobutanol

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Positive

In Vitro Micronucleus Mouse Bone Marrow Negative

Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Sodium hydroxide	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
California Proposition 65	454 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
	Present

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5
Chlorobutanol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3
EU EINECS/ELINCS List	200-317-6
Polysorbate 80	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	500-019-9
Water for injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Vitamin A, Retinyl Palmitate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-228-5
Citric acid, anhydrous	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Hazardous to the aquatic environment, chronic toxicity-Cat.4; H413 - May cause long lasting harmful effects to aquatic life

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Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Revision date: 06-Jul-2018
Product Stewardship Hazard Communication
Prepared by: Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet