SAFETY DATA SHEET

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

Product Identifier

Material Name: LIPOSYN III (Intravenous Fat Emulsion) (Hospira, Inc.)
Trade Name: LIPOSYN
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as electrolyte replacement

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
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
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

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
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM HYDROXIDE</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314) **</td>
<td></td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed *</td>
<td></td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed *</td>
<td></td>
</tr>
<tr>
<td>Egg Phosphatide</td>
<td>97281-44-2</td>
<td>306-544-8</td>
<td>Not Listed *</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary

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 skin irritation persists, call a physician.

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: Move to fresh air. If discomfort persists, get medical attention.

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 phosphorous

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all fire fighting 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. Clean up 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.

**Incompatible Materials:**
None known

**Specific end use(s):**
Pharmaceutical product used for electrolyte replacement

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified. Refer to available public information for specific member state Occupational Exposure Limits.

**SODIUM HYDROXIDE**

**ACGIH Ceiling Threshold Limit:** 2 mg/m³

**Australia PEAK:** 2 mg/m³

**Austria OEL - MAKs:** 2 mg/m³

**Bulgaria OEL - TWA:** 2.0 mg/m³

**Czech Republic OEL - TWA:** 1 mg/m³

**Estonia OEL - TWA:** 1 mg/m³

**France OEL - TWA:** 2 mg/m³

**Greece OEL - TWA:** 2 mg/m³

**Hungary OEL - TWA:** 2 mg/m³

**Japan - OELs - Ceilings:** 2 mg/m³

**Latvia OEL - TWA:** 0.5 mg/m³

**OSHA - Final PELs - TWAs:** 2 mg/m³

**Poland OEL - TWA:** 0.5 mg/m³

**Slovakia OEL - TWA:** 2 mg/m³

**Slovenia OEL - TWA:** 2 mg/m³

**Sweden OEL - TWA:** 1 mg/m³

**Switzerland OEL - TWAs:** 2 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Glycerin, USP

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>20 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>200 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>50 mg/m³</td>
</tr>
</tbody>
</table>

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.

Personal Protective Equipment:

- 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Emulsion</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Off-white</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>Soluble</td>
</tr>
<tr>
<td>pH:</td>
<td>6.0-9.0</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partition Coefficient:</td>
<td>(Method, pH, Endpoint, Value)</td>
</tr>
<tr>
<td>Egg Phosphatide:</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

SODIUM HYDROXIDE
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Glycerin, USP

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
Specific Gravity: 0.995
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: None
Conditions to Avoid: None known
Incompatible Materials: None known
Hazardous Decomposition Products: Thermal decomposition products include Oxides of phosphorus

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the active ingredient(s).

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

Glycerin, USP

Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1 hr > 570 mg/m³
Rat Dermal LD 50 > 21.9 g/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)

Glycerin, USP

Eye Irritation Rabbit Mild
11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

- Glycerin, USP
  - *Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 50 mg/L
  - *Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

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.

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
15. REGULATORY INFORMATION

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

Egg Phosphatide
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: 306-544-8

SODIUM HYDROXIDE
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 1000 lb 454 kg
- **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 5 Schedule 6
- **EU EINECS/ELINCS List**: 215-185-5

Glycerin, USP
- **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 V - Exemptions from the obligations of Register**: Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bio accumulative, and toxic or very persistent and very bio accumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
- **EU EINECS/ELINCS List**: 200-289-5

16. OTHER INFORMATION

**Data Sources**: Publicly available toxicity information.

**Reasons for Revision**: New data sheet.
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet