# SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Product Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Material Name:</strong> GELFOAM(R) Sterile Powder</td>
</tr>
<tr>
<td><strong>Trade Name:</strong> GELFOAM(R)</td>
</tr>
<tr>
<td><strong>Synonyms:</strong> Absorbable gelatin powder from absorbable gelatin sponge, USP</td>
</tr>
<tr>
<td><strong>Chemical Family:</strong> Not applicable</td>
</tr>
</tbody>
</table>

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

| Intended Use: | Medical device |

**Details of the Supplier of the Safety Data Sheet**

<table>
<thead>
<tr>
<th>Pfizer Global Supply</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Inc</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, NY 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-800-879-3477</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300</td>
<td>Emergency telephone number: +00 44 (0)1304 616161</td>
</tr>
<tr>
<td>Contact E-Mail: <a href="mailto:pfizer-MSDS@pfizer.com">pfizer-MSDS@pfizer.com</a></td>
<td>International CHEMTREC (24 hours): +1-703-527-3887</td>
</tr>
</tbody>
</table>

**2. HAZARDS IDENTIFICATION**

**Classification of the Substance or Mixture**

| GHS - Classification | Not classified as hazardous |

**US OSHA Specific - Classification**

| Physical Hazard: | Combustible Dust |

**EU Classification:**

| EU Indication of danger: Not classified |

**Label Elements**

| Signal Word: | Warning |
| Hazard Statements: | May form combustible dust concentrations in air |

**Other Hazards**

<table>
<thead>
<tr>
<th>Australian Hazard Classification (NOHSC):</th>
</tr>
</thead>
</table>

**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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</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.

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:**
Consult a physician if necessary

**Inhalation:**
Due to the nature of this material first aid is not normally required. If discomfort occurs, get medical attention.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:**
No data available

**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:**
Extinguish fires with CO2, extinguishing powder, foam, or water.

**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.

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

**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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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**
No special handling requirements for normal use of this material. Avoid generating airborne dust.

**Conditions for Safe Storage, Including any Incompatibilities**
- **Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
- **Specific end use(s):** Medical device

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters
No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

**Exposure Controls**
- **Engineering Controls:** General room ventilation is adequate unless the process generates dust, mist or fumes.
- **Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
  - Hands: Wear impervious gloves.
  - Eyes: Not required under normal conditions of use.
  - Skin: Wear protective clothing when working with large quantities.
  - Respiratory protection: Under normal conditions of use, respiratory protection is not expected to be necessary. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Solid</td>
<td></td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td></td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Gelatin</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Water for injection</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>
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Material Name: GELFOAM(R) Sterile Powder
Revision date: 10-Mar-2015

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: This product is composed of non-hazardous ingredients.

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

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.

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

Canada - WHMIS: Classifications
WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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:
EU EINECS/ELINCS List 231-791-2

Gelatin
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 232-554-6
16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage.

Revision date: 10-Mar-2015

Prepared by: Product Stewardship Hazard Communication

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