



SAFETY DATA SHEET

Revision date 09-Mar-2023

Version 2

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Gelfoam Sponge
Product Code(s) PZ02527
Synonyms Absorbable gelatin sponge, USP; Absorbable gelatin compressed sponge, USP
Trade Name: GELFOAM
Item Code H000006622, H000010672, H000200384, H00020084, H000015509, H000015510, H000015511
Chemical Family: Not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Medical device

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

2.2. Label elements

Signal word Not classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

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 require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SAFETY DATA SHEET

Product Name Gelfoam Sponge
Revision date 09-Mar-2023

Page 2 / 8
Version 2

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

NonHazardous

| Chemical name | Weight-% | REACH Registration Number | EC No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|-------------------------------|----------|---------------------------|-----------|---|------------------------------------|-------------------|----------------------|
| Gelatin (CAS #: 9000-70-8) | * | | 232-554-6 | Not classified as hazardous | Not Listed | No data available | No data available |
| Water (CAS #: 7732-18-5) | * | - | 231-791-2 | Not classified as hazardous | Not Listed | No data available | No data available |

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapor - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|--------------------|-----------|-------------------|---|---|--------------------------------------|
| Water 7732-18-5 | 89838.9 | No data available | No data available | No data available | No data available |

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.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

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

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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects

No data available

SAFETY DATA SHEET

Product Name Gelfoam Sponge
Revision date 09-Mar-2023

Page 3 / 8
Version 2

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

No special handling requirements for normal use of this material. Avoid generating airborne dust.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

SAFETY DATA SHEET

Product Name Gelfoam Sponge
Revision date 09-Mar-2023

Page 4 / 8
Version 2

7.3. Specific end use(s)

Specific use(s) Medical device.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Gelatin

Russia

MAC: 10 mg/m³

8.2. Exposure controls

Engineering controls General room ventilation is adequate unless the process generates dust, mist or fumes.

Environmental exposure controls No information available.

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.

Eye/face protection Not required under normal conditions of use.

Hand protection Wear impervious gloves (e.g. Nitrile, etc.) as minimum protection. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Wear protective clothing when working with large quantities. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

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. (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.)

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|--------------------------|---------------------------|
| Physical state | solid |
| Color | No information available |
| Odor | No information available. |
| Odor threshold | No information available |
| Molecular formula | Mixture |
| Molecular weight | Mixture |

Property

| Property | Values |
|---------------------------------------|--------------------------|
| pH | No data available |
| Melting point / freezing point | No data available |
| Boiling point / boiling range | |
| Flash point | No information available |

SAFETY DATA SHEET

Product Name Gelfoam Sponge
Revision date 09-Mar-2023

Page 5 / 8
Version 2

| | |
|-----------------------------------|--------------------------|
| Evaporation rate | No data available |
| Flammability (solid, gas) | No data available |
| Flammability Limit in Air | |
| Upper flammability limit: | No data available |
| Lower flammability limit: | No data available |
| Vapor pressure | No data available |
| Vapor density | No data available |
| Relative density | No data available |
| Water solubility | No data available |
| Solubility(ies) | No data available |
| Partition coefficient | No data available |
| Autoignition temperature | No data available |
| Decomposition temperature | No data available |
| Kinematic viscosity | No data available |
| Dynamic viscosity | No data available |
| Particle characteristics | |
| Particle Size | No information available |
| Particle Size Distribution | No information available |
| Explosive properties | No information available |

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: This product is composed of non-hazardous ingredients.

SAFETY DATA SHEET

Product Name Gelfoam Sponge
Revision date 09-Mar-2023

Page 6 / 8
Version 2

Acute toxicity Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Based on available data, the classification criteria are not met.
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Respiratory or skin sensitization Based on available data, the classification criteria are not met.
STOT - single exposure Based on available data, the classification criteria are not met.
STOT - repeated exposure Based on available data, the classification criteria are not met.
Reproductive toxicity Based on available data, the classification criteria are not met.
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------|--------------------|-------------|-----------------|
| Water | > 90 mL/kg (Rat) | - | - |

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

SAFETY DATA SHEET

Product Name Gelfoam Sponge
Revision date 09-Mar-2023

Page 7 / 8
Version 2

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 wastewater 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.

Section 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.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Gelatin

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 232-554-6 |
| AICS | Present |

Water

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 231-791-2 |
| AICS | Present |

France

Occupational Illnesses (R-463-3, France)

| Chemical name | French RG number | Title |
|---------------|------------------|-------|
|---------------|------------------|-------|

SAFETY DATA SHEET

Product Name Gelfoam Sponge
Revision date 09-Mar-2023

Page 8 / 8
Version 2

| | | |
|----------------------|-------|---|
| Gelatin 9000-70-8 | RG 88 | - |
|----------------------|-------|---|

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

| | |
|----------------------------|---|
| Data Sources: | Pfizer proprietary drug development information. Safety data sheets for individual ingredients. |
| Reason for revision | Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. |
| Revision date | 09-Mar-2023 |
| Prepared By | Pfizer Global Environment, Health, and Safety |

Pfizer Inc believes that the information contained in this 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.