



# SAFETY DATA SHEET

Revision date 09-Mar-2023

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

### 1.1. Product identifier

Product Name	GEL-FLOW NT Sterile Powder
Product Code(s)	PZ01349
Synonyms	GELFOAM; FLOSTAT NT; Absorbable gelatin powder from absorbable gelatin sponge, USP
Trade Name:	GEL-FLOW NT
Item Code	H00043305, H000400855
Chemical Family:	Not applicable

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

Recommended Use	Medical device
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### 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
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### 1.4. Emergency telephone number

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

OSHA Classification	
Physical Hazard	Combustible Dust

### 2.2. Label elements

Signal word	Warning
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Hazard statements	OSHA - May form combustible dust concentrations in air
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### 2.3. Other hazards

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

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cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 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)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Gelatin (CAS #: 9000-70-8)	*		232-554-6	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

Non-hazardous ingredients provided for completeness. 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

<b>Inhalation</b>	Due to the nature of this material first aid is not normally required. If discomfort occurs, get medical attention.
<b>Eye contact</b>	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion</b>	Consult a physician if necessary.

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

**Most important symptoms and effects** No data available

## 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, CO<sub>2</sub>, 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.

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## 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.

## 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/m<sup>3</sup>

### 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** 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. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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

<b>Physical state</b>	solid
<b>Color</b>	No information available
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture

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<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
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**

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

<b>General Information:</b>	This product is composed of non-hazardous ingredients.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	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.

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## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

## 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.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable
<b>Special precautions for user:</b>	Not applicable

## Section 15: REGULATORY INFORMATION

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

Water

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

Gelatin

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

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## France

### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
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.

**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.

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**Prepared By** Pfizer Global Environment, Health, and Safety

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