



# SAFETY DATA SHEET

Revision date 22-Apr-2022

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

### 1.1. Product identifier

**Product Name** Bleomycin for Injection, USP (Hospira Inc.)  
**Product Code(s)** PZ03076  
**Trade Name:** Bleomycin for Injection, USP  
**Chemical Family:** Not determined

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

**Recommended Use** Pharmaceutical product used as Antineoplastic Antibacterial

### 1.3. 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

**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

**Germ cell mutagenicity** Category 1B  
**Carcinogenicity** Category 2  
**Reproductive toxicity** Category 1B

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H340 - May cause genetic defects  
H351 - Suspected of causing cancer  
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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## 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.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

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)
Bleomycin Sulfate (CAS #: 9041-93-4)	100		232-925-2	Muta 1B (H340)2 (H351)1B (H360D)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ SULPHURIC ACID ... % (CAS #: 7664-93-9)	**		231-639-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 5%<=C<15% Skin Corr. 1A :: C>=15% Skin Irrit. 2 :: 5%<=C<15%	No data available	No data available

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

#### Acute Toxicity Estimate

No information available

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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
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ SULPHURIC ACID ... % 7664-93-9	2140	No data available	0.375	No data available	No data available

## Additional information

\*\* to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

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

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 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** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

### 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

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## 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**

Restrict access to work area. Minimize dust generation and accumulation. Avoid breathing dust. 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.

**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 as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Sodium hydroxide**

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	2 mg/m <sup>3</sup>
	STEL 4 mg/m <sup>3</sup>
Bulgaria	2.0 mg/m <sup>3</sup>
Czech Republic	1 mg/m <sup>3</sup>
	Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	1 mg/m <sup>3</sup>

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Finland	STEL: 2 mg/m <sup>3</sup>
France	Ceiling: 2 mg/m <sup>3</sup>
Hungary	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Ireland	STEL: 2 mg/m <sup>3</sup>
Ceiling Limit Value	STEL: 2 mg/m <sup>3</sup>
Latvia	2 mg/m <sup>3</sup>
Poland	0.5 mg/m <sup>3</sup>
	STEL: 1 mg/m <sup>3</sup>
Romania	0.5 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Slovakia	STEL: 3 mg/m <sup>3</sup>
Spain	2 mg/m <sup>3</sup>
Switzerland	STEL: 2 mg/m <sup>3</sup>
	2 mg/m <sup>3</sup>
OSHA PEL	STEL: 2 mg/m <sup>3</sup>
	2 mg/m <sup>3</sup>
United Kingdom	(vacated) Ceiling: 2 mg/m <sup>3</sup>
<b>+ SULPHURIC ACID ... %</b>	STEL: 2 mg/m <sup>3</sup>
ACGIH TLV	
Austria	0.2 mg/m <sup>3</sup>
	0.1 mg/m <sup>3</sup>
Bulgaria	STEL 0.2 mg/m <sup>3</sup>
Czech Republic	0.05 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	0.05 mg/m <sup>3</sup>
European Union	0.05 mg/m <sup>3</sup>
Finland	TWA: 0.05 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
France	STEL: 0.1 mg/m <sup>3</sup>
Germany	0.05 mg/m <sup>3</sup>
	0.1 mg/m <sup>3</sup>
Germany	Ceiling / Peak: 0.1 mg/m <sup>3</sup>
Hungary	0.1 mg/m <sup>3</sup>
Ireland	0.05 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
Italy	0.05 ppm
Ceiling Limit Value	STEL: 0.15 ppm
Latvia	0.05 mg/m <sup>3</sup>
Netherlands	1 mg/m <sup>3</sup>
Poland	0.05 mg/m <sup>3</sup>
Romania	0.05 mg/m <sup>3</sup>
Russia	0.05 mg/m <sup>3</sup>
	MAC: 1 mg/m <sup>3</sup>
	Skin
Slovakia	0.05 mg/m <sup>3</sup>
Spain	0.05 mg/m <sup>3</sup>
Switzerland	0.1 mg/m <sup>3</sup>
	STEL: 0.2 mg/m <sup>3</sup>
OSHA PEL	1 mg/m <sup>3</sup>
	(vacated) TWA: 1 mg/m <sup>3</sup>
United Kingdom	TWA: 0.05 mg/m <sup>3</sup>
	STEL: 0.15 mg/m <sup>3</sup>

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based

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upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## 8.2. Exposure controls

<b>Engineering controls</b>	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. It is recommended that all operations be fully enclosed and no air recirculated.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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).
<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	Impervious disposable gloves (e.g. Nitrile, etc.) (double 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.).
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)
<b>General hygiene considerations</b>	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>	Lyophilized powder in vial
<b>Color</b>	Cream
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	C55 H84 N17 O21 S3
<b>Molecular weight</b>	1415.56

<u>Property</u>	<u>Values</u>
<b>pH</b>	4.5-6.0
<b>Melting point / freezing point</b>	70-71
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available

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Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble
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

#### Oxidizing properties

None

### 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 Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

## Section 11: TOXICOLOGICAL INFORMATION

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

Short term	Effects of ingestion are not known. Avoid swallowing this material.
Long Term:	Animal studies have shown a potential to cause adverse effects on the fetus.
Known Clinical Effects:	Adverse effects associated with therapeutic use include pulmonary toxicity, beginning with cough and progressing to pulmonary fibrosis. Effects on blood and blood-forming organs have also occurred.
Acute toxicity	Based on available data, the classification criteria are not met.

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**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.

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

### Bleomycin Sulfate

Rat Para-periosteal LD50 240 mg/kg  
Rat Subcutaneous LC50 86 mg/kg  
Mouse Intravenous LD50 210 mg/kg  
Mouse Intraperitoneal LD50 210 mg/kg  
Mouse Oral LD50 > 2000 mg/kg

### Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ SULPHURIC ACID ... %	= 2140 mg/kg ( Rat )	-	= 0.375 mg/L ( Rat ) 4 h

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

### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

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

### Bleomycin Sulfate

Embryo / Fetal Development Rat Intraperitoneal 1.5 mg/kg/day LOAEL Fetotoxicity, Teratogenic  
Embryo / Fetal Development Rabbit Intravenous 15.6 mg/kg LOAEL Fetotoxicity  
Reproductive & Fertility Rabbit Intravenous 1.2 mg/kg/day LOEL Not Teratogenic, Embryotoxicity

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

### Bleomycin Sulfate

*In Vivo* Chromosome Aberration Mouse Positive  
*In Vivo* Sister Chromatid Exchange Mouse Positive  
*In Vivo* Micronucleus Mouse Positive  
Bacterial Mutagenicity (Ames) Positive  
*In Vitro* Chromosome Aberration Human Lymphocytes Positive

**Genetic Toxicity Comments:** Mutagenic effects were seen in humans taking this drug.

## Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Bleomycin Sulfate

Not specified Rat Subcutaneous 0.35 mg/kg/week LOEL Kidneys, Connective tissue

**Carcinogenicity** See below

### Bleomycin Sulfate

IARC Group 2B (Possibly Carcinogenic to Humans)

### + SULPHURIC ACID ... %

IARC Group 1 (Carcinogenic to Humans)  
NTP Known Human Carcinogen

## 11.2. Information on other hazards

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## 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

### 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.

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ SULPHURIC ACID ... %	The substance is not PBT / vPvB PBT assessment does not apply

### 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.

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## 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

Bleomycin Sulfate

CERCLA/SARA Section 313 de minimus % Not Listed  
California Proposition 65 Not Listed  
EINECS 232-925-2  
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) Schedule 4

Sodium hydroxide

CERCLA/SARA Section 313 de minimus % Not Listed  
Hazardous Substances RQs 1000 lb  
California Proposition 65 Not Listed  
TSCA Present  
EINECS 215-185-5  
AICS Present  
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) Schedule 5  
Schedule 6

+ SULPHURIC ACID ... %

CERCLA/SARA Section 313 de minimus % 1.0 %  
Hazardous Substances RQs 1000 lb  
California Proposition 65 carcinogen 3/14/2003  
TSCA Present  
EINECS 231-639-5  
AICS Present  
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) Schedule 6

### 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)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ SULPHURIC ACID ... % - 7664-93-9	Use restricted. See item 75.	

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## 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

#### **Full text of H-Statements referred to under section 3**

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects Carcinogenicity-Cat.2; H351 - Suspected of causing cancer Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

<b>Data Sources:</b>	Pfizer proprietary drug development information. Publicly available toxicity information.
<b>Reason for revision</b>	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.
<b>Revision date</b>	22-Apr-2022
<b>Prepared By</b>	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.**