



# SAFETY DATA SHEET

Revision date 06-Dec-2021

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

### 1.1. Product identifier

**Product Name** Vincristine Sulfate Injection, USP (Hospira, Inc.)  
**Product Code(s)** PZ03149  
**Trade Name:** Not applicable  
**Chemical Family:** Mixture

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

**Recommended Use** Pharmaceutical product used as Antineoplastic

### 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

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887  
**E-mail address** pfizer-MSDS@pfizer.com

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

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

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H341 - Suspected of causing genetic defects  
H360D - May damage the unborn child

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## Precautionary Statements

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations  
P308 + P313 - IF exposed or concerned: Get medical attention/advice



## 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)
Vincristine Sulfate 2068-78-2	0.1		218-190-0	Repr.1B (H360D) Muta.2 (H341)	Not Listed	No data available	No data available
Sodium hydroxide 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
+ Sulfuric acid 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

#### NonHazardous

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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 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
Mannitol 69-65-8	*		200-711-8	No data available	Not Listed	No data available	No data available

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

## Acute Toxicity Estimate

No information available

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
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Sulfuric acid 7664-93-9	2140	No data available	0.375	No data available	No data available

## Additional information

\* Proprietary

\*\* to adjust pH

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>	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

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**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** Not applicable.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### **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** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**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**

Avoid generating airborne dust. Avoid contact with eyes, skin and clothing. 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.

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## 7.3. Specific end use(s)

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

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

#### Vincristine Sulfate

Pfizer OEL TWA-8 Hr: 0.2 µg/m<sup>3</sup>

#### Mannitol

Russia MAC: 10 mg/m<sup>3</sup>

#### 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>

STEL: 2 mg/m<sup>3</sup>

Finland Ceiling: 2 mg/m<sup>3</sup>

France 2 mg/m<sup>3</sup>

Hungary 1 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

Ireland STEL: 2 mg/m<sup>3</sup>

Ceiling Limit Value 2 mg/m<sup>3</sup>

Latvia 0.5 mg/m<sup>3</sup>

Poland STEL: 1 mg/m<sup>3</sup>

0.5 mg/m<sup>3</sup>

Romania 1 mg/m<sup>3</sup>

STEL: 3 mg/m<sup>3</sup>

Slovakia 2 mg/m<sup>3</sup>

Spain STEL: 2 mg/m<sup>3</sup>

Switzerland 2 mg/m<sup>3</sup>

STEL: 2 mg/m<sup>3</sup>

OSHA PEL 2 mg/m<sup>3</sup>

(vacated) Ceiling: 2 mg/m<sup>3</sup>

United Kingdom STEL: 2 mg/m<sup>3</sup>

#### + Sulfuric acid

ACGIH TLV 0.2 mg/m<sup>3</sup>

Austria 0.1 mg/m<sup>3</sup>

STEL 0.2 mg/m<sup>3</sup>

Bulgaria 0.05 mg/m<sup>3</sup>

Czech Republic 1 mg/m<sup>3</sup>

0.05 mg/m<sup>3</sup>

Ceiling: 2 mg/m<sup>3</sup>

Denmark 0.05 mg/m<sup>3</sup>

Estonia 0.05 mg/m<sup>3</sup>

European Union TWA: 0.05 mg/m<sup>3</sup>

Finland 0.05 mg/m<sup>3</sup>

STEL: 0.1 mg/m<sup>3</sup>

France 0.05 mg/m<sup>3</sup>

Germany 0.1 mg/m<sup>3</sup>

Ceiling / Peak: 0.1 mg/m<sup>3</sup>

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Germany	0.1 mg/m <sup>3</sup>
Hungary	0.05 mg/m <sup>3</sup>
Ireland	0.05 ppm
	STEL: 0.15 ppm
Italy	0.05 mg/m <sup>3</sup>
Ceiling Limit Value	1 mg/m <sup>3</sup>
Latvia	0.05 mg/m <sup>3</sup>
Netherlands	0.05 mg/m <sup>3</sup>
Poland	0.05 mg/m <sup>3</sup>
Romania	0.05 mg/m <sup>3</sup>
Russia	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>

## 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.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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.
<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 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, 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** Aqueous liquid suspension

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<b>Color</b>	Clear, colorless
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture

<u>Property</u>	<u>Values</u>
<b>pH</b>	No data available
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	100
<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
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	1.03
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	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

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**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:** The information included in this section describes the potential hazards of the individual ingredients  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.  
**Known Clinical Effects:** Central nervous system effects such as dizziness, headache, insomnia, irritability and weakness have also been reported. Effects on blood and blood-forming organs have also occurred.

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

##### Mannitol

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

##### Vincristine Sulfate

Rat Para-periosteal LD 50 1.9 mg/kg  
Rat Para-periosteal LD 50 1 mg/kg  
Rat Oral LD 50 > 5 mg/kg  
Mouse Intraperitoneal LD 50 3 mg/kg  
Mouse Intravenous LD 50 1.7 mg/kg

##### Sodium hydroxide

Mouse IP LD50 40 mg/kg

##### + Sulfuric acid

Rat Oral LD50 2140 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Mannitol	= 13500 mg/kg ( Rat )	-	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Sulfuric acid	= 2140 mg/kg ( Rat )	-	= 0.375 mg/L ( Rat ) 4 h

**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)

##### Vincristine Sulfate

Skin irritation Rabbit Mild

##### Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

##### + Sulfuric acid

Eye Irritation Rabbit Severe

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Vincristine Sulfate

6 Week(s) Dog Intravenous 0.02 mg/kg/week LOAEL Central nervous system

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



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## Vincristine Sulfate

Embryo / Fetal Development Rat Intraperitoneal 0.05 mg/kg LOAEL Teratogenic  
Embryo / Fetal Development Hamster Intravenous 0.1 mg/kg LOAEL Teratogenic  
Embryo / Fetal Development Mouse Intraperitoneal 0.2 mg/kg LOAEL Teratogenic

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

### Vincristine Sulfate

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Micronucleus Mouse Positive  
Cytogenetics *In Vitro* Human Lymphocytes Equivocal  
Chromosome Aberration Rodent Negative  
Mammalian Cell Mutagenicity Mouse Lymphoma Positive

**Carcinogenicity** See below

### Vincristine Sulfate

IARC Group 3 (Not Classifiable)

### + Sulfuric acid

IARC Group 1 (Carcinogenic to Humans)

## 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.

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does

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	not apply
+ Sulfuric 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.

## 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.

## 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

Mannitol

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-711-8
<b>AICS</b>	Present

Vincristine Sulfate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	developmental toxicity 7/1/1990
<b>EINECS</b>	218-190-0
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

Sodium hydroxide

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
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<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
+ Sulfuric acid	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	carcinogen 3/14/2003
<b>TSCA</b>	Present
<b>EINECS</b>	231-639-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	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.	
+ Sulfuric acid - 7664-93-9	Use restricted. See item 75.	

### 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

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child. Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects. Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage.

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

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date** 06-Dec-2021

**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.**