



Version 2

Page 1/12

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) Trade Name: Chemical Family: PZ03149 Not applicable 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 Pfizer Ireland Pharmaceuticals OSG Building Ringaskiddy, Co. Cork. Ireland +353 21 4378701

E-mail address

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: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

pfizer-MSDS@pfizer.com

Germ cell mutagenicity Reproductive toxicity	Category 2 - (H341) Category 1B - (H360D)
<u>2.2. Label elements</u> Signal word	Danger
Hazard statements	H341 - Suspected of causing genetic defects H360D - May damage the unborn child
Precautionary Statements	P201 - Obtain special instructions before use

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

- 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

Note:

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

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.	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Vincristine Sulfate (CAS #: 2068-78-2)	0.1		218-190-0	1272/2008 [CLP] Repr.1B (H360D)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Muta.2 (H341) 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 (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
NonHazardous							-
Chemical name	Weight-%	REACH Registration	EC No	Classification according to	Specific concentration	M-Factor	M-Factor (long-term)

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

		Number		Regulation (EC) No. 1272/2008 [CLP]	limit (SCL)		
Water	*	-	231-791-2	Not classified	Not Listed	No data	No data
(CAS #: 7732-18-5)				as hazardous		available	available
Mannitol	*	-	200-711-8	Not classified	Not Listed	No data	No data
(CAS #: 69-65-8)				as hazardous		available	available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4 hour - vapor - mg/L	
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

+ Substance with a Union workplace exposure limit

- * 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

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.		
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.		
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.		
Ingestion	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 an	d effects, both acute and delayed		
Most important symptoms and	For information on potential signs and symptoms of exposure, See Section 2 - Hazards		

effects Identification and/or Section 11 - Toxicological Information.

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

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

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	e substance or mixture				
Specific hazards arising from the chemical	Fine particles (such as mists) may fuel fires/explosions.				
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 REI	_EASE MEASURES				
6.1. Personal precautions, protectiv	ve 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 conta	ainment and cleaning up				
Methods for containment Methods for cleaning up	Prevent further leakage or spillage if safe to do so. 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 S	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.

7.3. Specific end use(s)

Ceiling / Peak: 0.1 mg/m³

0.1 mg/m³

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/m³ Mannitol Russia MAC: 10 mg/m³ Sodium hydroxide ACGIH OEL (Ceiling) 2 mg/m³ ACGIH TLV Ceiling: 2 mg/m³ Austria 2 mg/m³ STEL 4 mg/m³ 2.0 mg/m³ Bulgaria **Czech Republic** 1 mg/m³ Ceiling: 2 mg/m³ Ceiling: 2 mg/m³ Denmark 1 mg/m^3 Estonia STEL: 2 mg/m³ Finland Ceiling: 2 mg/m³ 2 mg/m³ France Hungary 1 mg/m³ STEL: 2 mg/m³ Ireland STEL: 2 mg/m³ **Ceiling Limit Value** 2 mg/m³ Latvia 0.5 mg/m³ Poland STEL: 1 mg/m3 0.5 mg/m³ Romania 1 mg/m³ STEL: 3 mg/m³ Slovakia 2 mg/m³ STEL: 2 mg/m³ Spain Switzerland 2 mg/m³ STEL: 2 mg/m³ OSHA PEL 2 mg/m³ (vacated) Ceiling: 2 mg/m³ United Kingdom STEL: 2 mg/m³ + Sulfuric acid ACGIH TLV 0.2 mg/m³ Austria 0.1 mg/m³ STEL 0.2 mg/m3 0.05 mg/m³ Bulgaria 1 mg/m^3 **Czech Republic** 0.05 mg/m³ Ceiling: 2 mg/m³ Denmark 0.05 mg/m³ 0.05 mg/m³ Estonia TWA: 0.05 mg/m³ **European Union** Finland 0.05 mg/m³ STEL: 0.1 mg/m³ France 0.05 ma/m³ Germany 0.1 mg/m³

Germany

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

Hungary Ireland Italy Ceiling Limit Value Latvia Netherlands Poland Romania Russia Slovakia Spain Switzerland OSHA PEL United Kingdom	0.05 mg/m ³ 0.05 ppm STEL: 0.15 ppm 0.05 mg/m ³ 1 mg/m ³ 0.05 mg/m ³ 0.05 mg/m ³ 0.05 mg/m ³ 0.05 mg/m ³ MAC: 1 mg/m ³ Skin 0.05 mg/m ³ 0.15 mg/m ³ 0.1 mg/m ³ STEL: 0.2 mg/m ³ 1 mg/m ³ (vacated) TWA: 1 mg/m ³ TWA: 0.05 mg/m ³ STEL: 0.15 mg/m ³			
8.2. Exposure controls				
Engineering controls	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.			
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	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.).			
Hand protection	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.).			
	the standards in accordance with EN374, ASTM F1001 of International equivalent.).			
Skin and body protection	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.).			

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
Color	Clear, colorless

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023 Page 7/12 Version 2

Odor Odor threshold Molecular formula Molecular weight

Property

pH Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air Upper flammability limit:

Lower flammability limit:

Vapor pressure Vapor density Relative density Water solubility Solubility(ies) Partition coefficient Autoignition temperature Decomposition temperature Kinematic viscosity Dynamic viscosity Particle characteristics Particle Size Particle Size Particle Size Distribution Explosive properties

No information available. No information available Mixture Mixture

Values

No data available No data available 100 No information available No data available No data available

No data available

No data available

No data available No data available 1.03 No data available No data available

No information available No information available No information available

<u>9.2. Other information</u> 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 reaction	ons_		
Possibility of hazardous reactions	No information available.		
10.4. Conditions to avoid			
Conditions to avoid	Fine particles (such as mists) may fuel fires/explosions.		
<u>10.5. Incompatible materials</u> Incompatible materials	As a precautionary measure, keep away from strong oxidizers.		

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

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	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	Classification is based on mixture calculation methods based on component data.
Germ cell mutagenicity	Classification is based on mixture calculation methods based on component data.
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)

<u>Mannitol</u>

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 mo/kg

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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 Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

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

<u>Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))</u> <u>Vincristine Sulfate</u>

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 SulfateNegativeBacterial Mutagenicity (Ames)Salmonella, E. coliNegativeIn VivoMicronucleusMousePositiveCytogeneticsIn VitroHuman LymphocytesEquivocalChromosome AberrationRodentNegativeMammalian Cell MutagenicityMouseLymphomaPositiveNoteNegative

Carcinogenicity Vincristine Sulfate	See below
IARC	Group 3 (Not Classifiable)
+ Sulfuric acid IARC NTP	Group 1 (Carcinogenic to Humans) Known Human Carcinogen

11.2. Information on other hazards11.2.1. Endocrine disrupting propertiesEndocrine disrupting propertiesNo 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

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

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

Water

CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA Not Listed Not Listed Present

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

EINECS AICS	231-791-2 Present
Mannitol	riesent
CERCLA/SARA Section 313 de minimus % California Proposition 65	Not Listed Not Listed
TSCA	Present
EINECS	200-711-8
AICS	Present
Vincristine Sulfate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	developmental toxicity 7/1/1990
EINECS	218-190-0
Standard for Uniform Scheduling of Medicines and	Schedule 4
Poisons (SUSMP)	
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	Schedule 5
Poisons (SUSMP)	Schedule 6
+ Sulfuric acid	4.0.00
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 contains one or more substance(s) 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

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.) Revision date 28-Mar-2023

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.

Data Sources:	Publicly available toxicity 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 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.
Revision date	28-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.