



Revision date 28-Mar-2023 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) 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

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

Germ cell mutagenicity Reproductive toxicityCategory 2 - (H341)

Category 1B - (H360D)

2.2. Label elements

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

Revision date 28-Mar-2023 Version 2

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

Page 2/12

P308 + P313 - IF exposed or concerned: Get medical attention/advice



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.

concentration

(long-term)

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

Registration

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 (CAS #: 2068-78-2)	0.1		218-190-0	Repr.1B (H360D) Muta.2 (H341)	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
+ 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	144 1 1 4 0 4	DE4011		l o	1 0 111		
Chemical name	Weight-%	REACH	EC No	Classification	Specific	M-Factor	M-Factor

according to

Page 3/12

Version 2

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 - 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

- + Substance with a Union workplace exposure limit
- * 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 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 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

^{**} to adjust pH

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 substance or mixture

Specific hazards arising from the

Fine particles (such as mists) may fuel fires/explosions.

chemical

fire-fighters

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

5.3. Advice for firefighters

Special protective equipment for

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Page 4/12

Version 2

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.

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.

7.3. Specific end use(s)

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

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/m^3

Ceiling: 2 mg/m³ Ceiling: 2 mg/m³ Denmark 1 mg/m³ 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/m³ 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 Ceiling / Peak: 0.1 mg/m³

0.1 mg/m³

Germany

Revision date 28-Mar-2023 Version 2

 Hungary
 0.05 mg/m³

 Ireland
 0.05 ppm

 STEL: 0.15 ppm

Product Name Vincristine Sulfate Injection, USP (Hospira, Inc.)

 Italy
 0.05 mg/m³

 Ceiling Limit Value
 1 mg/m³

 Latvia
 0.05 mg/m³

 Netherlands
 0.05 mg/m³

 Poland
 0.05 mg/m³

 Romania
 0.05 mg/m³

0.05 mg/m³ MAC: 1 mg/m³

Skin

 Slovakia
 0.05 mg/m³

 Spain
 0.05 mg/m³

 Switzerland
 0.1 mg/m³

STEL: 0.2 mg/m³

OSHA PEL 1 mg/m³

(vacated) TWA: 1 mg/m³

United Kingdom

TWA: 0.05 mg/m³

STEL: 0.15 mg/m³

8.2. Exposure controls

Skin and body protection

Russia

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.

Page 6 / 12

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.).

and standards in association with Error 1, 7 to 110 from mornalisma equivalently.

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.).

Respiratory protectionUnder 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

Color Clear, colorless

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

No information available. Odor Odor threshold No information available

Molecular formula Mixture Mixture Molecular weight

Values Property

рΗ Melting point / freezing point No data available

Boiling point / boiling range 100

No information available Flash point **Evaporation rate** No data available Flammability (solid, gas)

Flammability Limit in Air

Upper flammability limit:

Lower flammability limit: No data available

Vapor pressure Vapor density No data available

Relative density

No data available Water solubility 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 Particle Size Distribution No information available No information available **Explosive properties**

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 mists) may fuel fires/explosions.

10.5. Incompatible materials

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

PZ03149

Page 7/12 Version 2

No data available

No data available

No data available

No data available

1.03

No information available

Page 8/12 Version 2

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
Respiratory or skin sensitization
STOT - single exposure
STOT - repeated exposure
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.

Reproductive toxicity

Classification is based on mixture calculation methods based on component data.

Classification is based on mixture calculation methods based on component data.

CarcinogenicityAspiration hazard
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.

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

Page 9/12

Version 2

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

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

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)
NTP Known Human Carcinogen

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

<u>Bioaccumulation</u> No information available.

12.4. Mobility in soil

Page 10 / 12 Version 2

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

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	The substance is not PBT / vPvB PBT assessment does		
	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.

Not applicable

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):

Not applicable
Not applicable
Not applicable

Special precautions for user:

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 % Not Listed California Proposition 65 Not Listed TSCA Present

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

231-791-2 **EINECS AICS** Present

Mannitol

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

Vincristine Sulfate

CERCLA/SARA Section 313 de minimus % Not Listed

developmental toxicity 7/1/1990 **California Proposition 65**

218-190-0 **EINECS** Standard for Uniform Scheduling of Medicines and Schedule 4

Poisons (SUSMP)

Sodium hydroxide

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

Poisons (SUSMP) + Sulfuric acid

CERCLA/SARA Section 313 de minimus % 1.0 %

1000 lb **Hazardous Substances RQs**

California Proposition 65 carcinogen 3/14/2003

TSCA Present **EINECS** 231-639-5 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 6

Poisons (SUSMP)

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	Substance subject to authorization per
	Annex XVII	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

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

Page 11 / 12 Version 2

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

Revision date 28-Mar-2023 Version 2

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.

Page 12 / 12

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.