SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Vinblastine Sulfate Injection (Hospira, Inc.)

Product Code(s) PZ03451
Trade Name: Vinblastine Sulfate njection, 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

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 Australia Pty Ltd
11 Lexia Place
Mulgrave VIC 3170
Australia

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

GHS - Classification

Germ cell mutagenicity Category 2 - (H341)
Reproductive toxicity Category 1A - (H360)

2.2. Label elements

Signal word Danger

Hazard statements H360 - May damage fertility or the unborn child
H341 - Suspected of causing genetic defects

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

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)
Vinblastine Sulfate 143-67-9	0.1		205-606-0	Acute Tox.4 (H302) Eye Dam.1 (H318) Muta.2 (H341) Repr.1A (H360)	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 ::	No data available	No data available

					5%<=C<15%		

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
SODIUM CHLORIDE 7647-14-5	*		231-598-3	No data available	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
Vinblastine Sulfate 143-67-9	305	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
Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

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 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

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 the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge to.

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 breathing vapor or mist. 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.

Vinblastine Sulfate
Pfizer OEL TWA-8 Hr: 1 µg/m³

SODIUM CHLORIDE

Latvia	5 mg/m³
Russia	MAC: 5 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m³
ACGIH TLV	Ceiling: 2 mg/m³
Austria	2 mg/m³
	STEL 4 mg/m³
Bulgaria	2.0 mg/m³
Czech Republic	1 mg/m³
	Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³
Estonia	1 mg/m³
	STEL: 2 mg/m³
Finland	Ceiling: 2 mg/m³
France	2 mg/m³
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
Spain	STEL: 2 mg/m³
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
Bulgaria	0.05 mg/m³
Czech Republic	1 mg/m³

	0.05 mg/m³
	Ceiling: 2 mg/m³
Denmark	0.05 mg/m³
Estonia	0.5 mg/m³
European Union	TWA: 0.05 mg/m³
Finland	0.05 mg/m³
	STEL: 0.1 mg/m³
France	0.05 mg/m³
Germany	0.1 mg/m³
	Ceiling / Peak: 0.1 mg/m³
Germany	0.1 mg/m³
Hungary	0.05 mg/m³
Ireland	0.05 ppm
	STEL: 0.15 ppm
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
Russia	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

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

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

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. It is recommended that all operations be fully enclosed and no air recirculated.

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.).
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.).
Respiratory protection	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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Clear, colorless
Odor	Odorless.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	3.5-5.0
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	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

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: May cause eye irritation (based on components)
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. May cause blood and reproductive system effects.
Known Clinical Effects: Adverse effects associated with therapeutic use include bone marrow suppression, gastrointestinal bleeding, inflammation of the mouth (stomatitis), nausea, vomiting, shortness of breath (dyspnea), nervous system/brain toxicity (neurotoxicity), weakness, headache, depression, numbness, sensory/motor nerve injury (peripheral neuropathy), loss of hair, cardiac toxicity, increase in blood pressure (hypertension), decreased sperm count.

Acute Toxicity: (Species, Route, End Point, Dose)
SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m^3
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg
+ Sulfuric acid
Rat Oral LD50 2140 mg/kg
Sodium hydroxide
Mouse IP LD50 40 mg/kg
Vinblastine Sulfate
Rat Oral LD50 305 mg/kg
Mouse Oral LD50 423 mg/kg
Rat IV LD50 37 mg/kg
Mouse IV LD50 9.5 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 g/m^3 (Rat) 1 h

Vinblastine Sulfate	= 305 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)
SODIUM CHLORIDE
Skin irritation Rabbit Mild
Eye irritation Rabbit Mild
+ Sulfuric acid
Eye Irritation Rabbit Severe
Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe
Vinblastine Sulfate
Eye Irritation Not specified Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Vinblastine Sulfate
Embryo / Fetal Development Rat Intraperitoneal 0.12 mg/day LOAEL Teratogenic, Fetotoxicity
Embryo / Fetal Development Hamster Intravenous 0.25 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Mouse Intraperitoneal 0.25 mg/kg LOAEL Teratogenic
Reproductive Effects Therapeutic use of antineoplastic agents may cause decreased sperm production and abnormal menstrual cycles in women.

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Vinblastine Sulfate
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Micronucleus Positive
Dominant Lethal Assay Mouse Negative
In Vivo Micronucleus Mouse Positive aneugenic

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Vinblastine Sulfate
6 Month(s) Mouse Intravenous Maximally Tolerated Dose None identified
6 Month(s) Rat Intravenous Maximally Tolerated Dose None identified
Carcinogenicity See below
Vinblastine 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 .

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
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, ADG or IMDG regulations.

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

SODIUM CHLORIDE
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 231-598-3
- **AICS** Present

Vinblastine Sulfate
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** developmental toxicity 7/1/1990
- **EINECS** 205-606-0

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

+ Sulfuric 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

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

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

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
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed. Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage. Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage. Reproductive toxicity-Cat.1A; H360 - May damage fertility or the unborn child.

Data Sources: Pfizer proprietary drug development information. 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 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date 07-Apr-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.