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

1.1. Product identifier

Product Name Hetastarch in Lactated Electrolyte Injection (Hospira, Inc.)

Product Code(s) PZ03177
Trade Name: HEXTEND
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product

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: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

Signal word Not classified

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Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which

EC No (EU

Index No)

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.

Specific

concentration

limit (SCL)

M-Factor

M-Factor

(long-term)

Classification

according to

Regulation

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

REACH

registration

number

3.1 Substances

Chemical name

Substances Not applicable

Weight-%

3.2 Mixtures

Hazardous

				(EC) No. 1272/2008 [CLP]			
Calcium chloride USP (CAS #: 10035-04-8)	<0.1		Not Listed	Eye Irrit. 2 (H319)	Not classified	No data available	No data available
POTASSIUM CHLORIDE (CAS #: 7447-40-7)	*		231-211-8	Acute Tox 5 (H303)	Not classified	No data available	No data available
NonHazardous				T			
Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Hydroxyethyl starch (CAS #: 9005-27-0)	6		Not Listed	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available
Sodium lactate (CAS #: 72-17-3)	*		200-772-0	Not classified	Not classified	No data available	No data available
Dextrose	*		Not Listed	Not classified	Not classified	No data	No data

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available

available

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(CAS #: available available 14431-43-7)

Magnesium chloride * Not Listed Not classified Not classified No data No data

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

Acute Toxicity Estimate

hexahydrate

(CAS #: 7791-18-6)

Chemical name	Oral LD50 mg/kg		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
Hydroxyethyl starch 9005-27-0	50000	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Sodium lactate 72-17-3	No data available	2000	7.94	No data available	No data available
Calcium chloride USP 10035-04-8	1000	No data available	No data available	No data available	No data available
POTASSIUM CHLORIDE 7447-40-7	3020	No data available	No data available	No data available	No data available
Magnesium chloride hexahydrate 7791-18-6	8100	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

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. Non-hazardous ingredients provided for completeness.

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.

^{*} Proprietary

^{**} to adjust pH

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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

None. Note to physicians

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 dust and mists) may fuel fires/explosions.

chemical

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

Explosion data

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions 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

Personnel involved in clean-up should wear appropriate personal protective equipment (see Personal precautions

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be **Environmental precautions**

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 if it is safe to do so. Absorb spills with non-combustible

absorbent material and transfer into a labeled container for disposal.

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

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7.1. Precautions for safe handling

Advice on safe handling Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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.

Handle in accordance with good industrial hygiene and safety practice. **General hygiene considerations**

7.2. Conditions for safe storage, including any incompatibilities

Store as directed by product packaging. **Storage Conditions**

7.3. Specific end use(s)

Specific use(s) Pharmaceutical 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.

Hydroxyethyl starch

MAC: 10 mg/m³ Russia

SODIUM CHLORIDE

Latvia TWA: 5 mg/m³; Russia MAC: 5 mg/m³

POTASSIUM CHLORIDE

TWA: 5.0 mg/m³; Bulgaria Latvia TWA: 5 mg/m³; MAC: 5 mg/m³ Russia

Magnesium chloride hexahydrate

MAC: 2 mg/m3 Russia

Pfizer Occupational Exposure Band

(OEB) Statement: The purpose of the Occupational Exposure Band (OEB) classification system is to separate

> substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based 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 OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Band (OEB):

POTASSIUM CHLORIDE

Pfizer Occupational Exposure

Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

8.2. Exposure controls

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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.

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 gloves (e.g. Nitrile, etc.) are 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 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.).

Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance Liquid solution

Physical state Liquid

ColorNo information availableOdorNo information available.

Odor threshold No information available

Property Values

Melting point / freezing point

No data available

Boiling point or initial boiling point and boiling range

No data available

Flammability (solid, gas)

No data available
No data available

Lower and upper explosion limit/flammability limit

Lower explosion limit
Upper explosion limit
No data available
No data available
No data available

Autoignition temperature No data available Decomposition temperature

SADT (°C)

No data available

No data available

pH (as aqueous solution)

Kinematic viscosity

Dynamic viscosity

No data available

No data available

No data available

No data available

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Vapor pressure No data available Density and/or relative density No data available No data available **Bulk density** No data available **Liquid Density** Vapor density No data available

Particle Size No information available **Particle Size Distribution** No information available

9.2. Other information

Particle characteristics

Mixture Molecular formula Molecular weight Mixture

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

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information 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 No data available.

Section 11: TOXICOLOGICAL INFORMATION

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

The information included in this section describes the potential hazards of the individual **General Information:**

ingredients

Known Clinical Effects: Serious allergic reactions, including anaphylaxis, have been reported. Adverse effects

associated with therapeutic use include effects on cardiovascular system, blood clotting irregularities, bleeding, decreased red blood cell count (anemia), vomiting, headache,

flu-like syndrome, swelling, muscle pain.

Based on available data, the classification criteria are not met. **Acute toxicity** Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met. Skin corrosion/irritation

Respiratory or skin sensitization Based on available data, the classification criteria are not met.

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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. Based on available data, the classification criteria are not met. Reproductive toxicity Based on available data, the classification criteria are not met. Germ cell mutagenicity 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)

Hydroxyethyl starch

Rat Oral LD50 > 50 g/kg

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

Sodium lactate

Rat Oral LD50 > 90 mL/kg

Calcium chloride USP

Rat Oral LD50 2301 mg/kg

Mouse Oral LD50 1940 mg/kg

Rabbit Dermal LD50 > 5000 mg/kg

POTASSIUM CHLORIDE

Rat Oral LD50 3020 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Hydroxyethyl starch	> 50 g/kg (Rat)	-	-
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
Sodium lactate		> 2000 mg/kg (Rabbit)	> 7.94 mg/L (Rat) 4 h
POTASSIUM CHLORIDE	= 2600 mg/kg (Rat)	-	-
Magnesium chloride hexahvdrate	= 8100 mg/kg (Rat)	-	-

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

Sodium lactate

Eye Irritation Rabbit Mild

Calcium chloride USP

Eye Irritation Rabbit Moderate

POTASSIUM CHLORIDE

Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ) Magnesium chloride hexahydrate

13 Week(s) Mouse Oral 273 g/kg LOEL Kidney, Ureter, Bladder

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

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Hydroxyethyl starch

Embryo / Fetal Development Mouse Intravenous 60 mL/kg NOAEL Not teratogenic Embryo / Fetal Development Rabbit Intravenous 75 mL/kg NOAEL Not Teratogenic Embryo / Fetal Development Mouse Rat Intraperitoneal 50 g/kg NOAEL Not Teratogenic

None of the components of this formulation are listed as a carcinogen by IARC, NTP or Carcinogenicity

OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

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

Aguatic Toxicity: (Species, Method, End Point, Duration, Result)

POTASSIUM CHLORIDE

Gambusia affinis (Mosquitofish) LC50 96 hours 920 mg/L

Lepomis macrochirus (Bluegill Sunfish) LC50 96 hours 2010 mg/L

Daphnia Magna (Water Flea) EC50 48 hours 825 mg/L

Scenedesmus subspicatus (Green Alga) EC50 72 hours 2500 mg/L

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	Not PBT/vPvB PBT assessment does not apply
Sodium lactate	Not PBT/vPvB
POTASSIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply

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12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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 Not applicable Packing group: **Environmental Hazard(s):** 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 % Not Listed **California Proposition 65** Not Listed **TSCA** Present **EINECS** 231-791-2 **AICS** Present

Hydroxyethyl starch

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

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Not Listed

AICS	Present
CODUIN OUI ODIDE	

SODIUM CHLORIDE

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

Sodium lactate

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **TSCA** Present 200-772-0 **EINECS** AICS Present Schedule 5

Standard for Uniform Scheduling of Medicines and

Poisons (SUSMP)

Dextrose

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed **AICS** Present

Calcium chloride USP

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Not Listed **EINECS** Present **AICS**

POTASSIUM CHLORIDE

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **TSCA** Present **EINECS** 231-211-8 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 4

Poisons (SUSMP)

Magnesium chloride hexahydrate

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed **AICS** Present

National regulations

France

Occupational Illnesses (R-463-3, France)

Occupational limesses (N-405-5, 1 lance)		
	Chemical name	French RG number
	SODIUM CHLORIDE	RG 78
	7647-14-5	
	POTASSIUM CHLORIDE	RG 67
	7447-40-7	

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

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Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable **Storage of Hazardous Material** Not applicable WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable Not applicable Major Accidents Ordinance SR 814.012

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 (EU) 2024/590

Not applicable.

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE	Plant protection agent
7647-14-5	

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE	Product-type 1: Human hygiene
7647-14-5	

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

H319 - Causes serious eye irritation H303 - May be harmful if swallowed.

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Data Sources: Safety data sheets for individual ingredients. 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.

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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.