

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

#### 1.1. Product identifier

Product Name PF-06928316

Product Code(s) PZ03551

Synonyms ABRYSVO; PF-06928316 RSV Vaccine; Lyophilized RSV 847A and 847B Bivalent Drug

Product; RSV Bivalent Vaccine

Trade Name: Not applicable 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

Pfizer Research and Development

445 Eastern Point Road

Groton, CT USA

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: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

2.2. Label elements

Signal word Not Classified

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

**Supplemental Hazard** Compound, not fully tested, hazards unknown.

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.

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### Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

#### 3.2 Mixtures

NonHazardous

TTOTIL IGEOLOGIC							
Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to	Specific concentration	M-Factor	M-Factor (long-term)
		Number		Regulation (EC) No.	limit (SCL)		
				1272/2008			
				ICLP1			
Mannitol	*	-	200-711-8	Not classified	Not Listed	No data	No data
(CAS #: 69-65-8)				as hazardous		available	available
Sucrose	*	-	200-334-9	Not classified	Not Listed	No data	No data
(CAS #: 57-50-1)				as hazardous		available	available
SODIUM CHLORIDE	*	-	231-598-3	Not classified	Not Listed	No data	No data
(CAS #: 7647-14-5)				as hazardous		available	available
Tris(hydroxymethyl)a	*	-	214-684-5	Not classified	Not Listed	No data	No data
minomethane				as hazardous		available	available
hydrochloride							
(CAS #: 1185-53-1)							
PF-06937100 (847B	< 1		Not Listed	Not classified	Not Listed	No data	No data
Prefusion Protein)				as hazardous		available	available
(CAS #: NOT							
ASSIGNED)							
PF-06934186 (847A	< 1		Not Listed	Not classified	Not Listed	No data	No data
Prefusion Protein)				as hazardous		available	available
(CAS #: NOT							
ASSIGNED)	*						
Tromethamine	*	-	201-064-4	Not classified	Not Listed	No data	No data
(CAS #: 77-86-1)	*			as hazardous		available	available
Polysorbate 80	*	-	500-019-9	Not classified	Not Listed	No data	No data
(CAS #: 9005-65-6)				as hazardous		available	available
PF-06928316	*		Not Listed	Not classified	Not Listed	No data	No data
(CAS #: NOT				as hazardous		available	available
ASSIGNED)							

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

**Acute Toxicity Estimate** 

Observing Language	O==11 DE0	D LL DE0	Industrial OCO 4	Indicated and LOCO. A	labalatian LOSO A
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4	Innalation LC50 - 4	Innalation LC50 - 4
			hour - dust/mist -	hour - vapor - mg/L	hour - gas - ppm
			mg/L	, ,	<b>3</b> 11
Mannitol	13500	No data available	No data available	No data available	No data available
69-65-8					
Sucrose	29700	No data available	No data available	No data available	No data available
57-50-1					
SODIUM CHLORIDE	3000	10000	No data available	No data available	No data available
7647-14-5					

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Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4 hour - vapor - mg/L	
Tromethamine 77-86-1	5900	5000	No data available	No data available	No data available
Polysorbate 80 9005-65-6	34.5 mL/kg	No data available	No data available	No data available	No data available

Additional information \* 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

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

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

### Section 6: ACCIDENTAL RELEASE MEASURES

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#### 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

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**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 Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or

leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust

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generation.

**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

Restrict access to work area. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Additional controls (based on risk assessment) should be implemented where open handling is required. Use enclosed manufacturing processing strategies. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

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

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Storage Temperature as lyophilized cake: 2-8C. Storage Temperature as reconstitued

solution 15-30C. Keep away from heat, sparks, and flames.

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.

Mannitol

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

Sucrose

 ACGIH TLV
 10 mg/m³

 Bulgaria
 10.0 mg/m³

 Estonia
 10 mg/m³

 France
 10 mg/m³

 Ireland
 10 mg/m³

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STEL: 20 mg/m3

Latvia 5 mg/m<sup>3</sup> Spain 10 mg/m<sup>3</sup> **OSHA PEL** 15 mg/m<sup>3</sup> 5 mg/m<sup>3</sup>

> (vacated) TWA: 15 mg/m3 total dust (vacated) TWA: 5 mg/m<sup>3</sup> respirable fraction

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United Kingdom TWA: 10 mg/m<sup>3</sup>

STEL: 20 mg/m3

**SODIUM CHLORIDE** 

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Latvia 5 mg/m<sup>3</sup> MAC: 5 mg/m<sup>3</sup> Russia

(OEB) Statement:

Pfizer Occupational Exposure Band The Vaccines Occupational Exposure Band (V-OEB) is a classification that has been assigned to biotechnology-based vaccines and antigen components. Risk assessments should be performed to assess potential exposures and determine appropriate controls.

**SODIUM CHLORIDE** 

Pfizer Occupational Exposure

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

Band (OEB):

PF-06937100 (847B Prefusion Protein)

Pfizer Occupational Exposure **V-OEB** 

Band (OEB):

PF-06934186 (847A Prefusion Protein)

Pfizer Occupational Exposure V-OFB

Band (OEB):

**Tromethamine** 

Pfizer Occupational Exposure

Band (OEB):

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

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Pfizer Occupational Exposure

Band (OEB):

V-OEB

8.2. Exposure controls

**Engineering controls** Release prevention and exposure protection measures should be established for any

> activities involving this material, as determined by a risk assessment conducted using appropriate Occupational Hygiene Risk Assessment tools. The containment level required for the activity should be based on the conclusions of the risk assessment. Where warranted, engineering controls, such as biosafety cabinets, should be applied as the

primary means to control exposures.

No information available. **Environmental exposure controls** 

Refer to applicable national standards and regulations in the selection and use of personal Personal protective equipment

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 as minimum protection (goggles recommended). (Eve protection must

meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double Hand protection

recommended). (Protective gloves must meet the standards in accordance with EN374,

ASTM F1001 or international equivalent.).

Skin and body protection Wear impervious disposable protective clothing when handling this compound. Full body

protection is recommended (scale dependent). (Protective clothing must meet the standards

in accordance with EN13982, ANSI 103 or international equivalent.).

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#### Respiratory protection

If operating and handling conditions result in airborne exposure, wear an appropriate respirator with a protection factor sufficient to control exposures (e.g. particulate cartridge with a full face respirator, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

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**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 solid Color White

No information available. Odor No information available **Odor threshold** 

Molecular formula Mixture Molecular weight Mixture

**Property** <u>Values</u> 7.4 pН Melting point / freezing point 66

Boiling point / boiling range

No information available Flash point **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 No information available **Particle Size Distribution Explosive properties** No information available

#### Partition Coefficient: (Method, pH, Endpoint, Value)

**Tromethamine** 

Predicted 7.4 Log D -4.668

#### 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

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### 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 No data available.

#### Section 11: TOXICOLOGICAL INFORMATION

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

General Information: The following information is available for the individual ingredients. Toxicological properties

of the formulation have not been investigated.

**Short term** In the event of accidental injection, an allergic reaction may occur. If an allergic reaction

occurs, the worker should be removed to the nearest emergency room and the appropriate

therapy instituted.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this

compound may include: injection site pain, tiredness, headache, muscle pain, gestational

hypertension, preeclampsia.

Acute toxicity Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Skin corrosion/irritation
Respiratory or skin sensitization

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.

STOT - single exposure
STOT - repeated exposure
Reproductive toxicity
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
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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

**Sucrose** 

Rat Oral LD 50 29,700 mg/kg

**SODIUM CHLORIDE** 

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup> Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

**Tromethamine** 

Rat Oral LD50 5900 mg/kg

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Rat Dermal LD 50 > 5000 mg/kg

Polysorbate 80

Rat Intravenous LD 50 1790 mg/kg Mouse Oral LD 50 25 g/kg

Chemical name Oral LD50		Dermal LD50	Inhalation LC50	
Mannitol = 13500 mg/kg ( Rat )		-	-	
Sucrose	= 29700 mg/kg ( Rat )	-	-	
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg ( Rabbit )	> 42 mg/L (Rat)1 h	
Tromethamine	= 5900 mg/kg (Rat)	> 5000 mg/kg (Rat)	-	
Polysorbate 80	= 34.5mL/kg ( Rat )	-	-	

**Acute Toxicity Comments:** 

A greater than symbol (>) indicates that the toxicity endpoint being tested was not

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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

**Tromethamine** 

Eye Irritation Rabbit Slight Skin Irritation Rabbit Slight

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

**Tromethamine** 

Bacterial Mutagenicity (Ames) E. coli Negative

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

OSHA.

\* Data below is for PF-07203723 ( Lyophilized RSV 847A (PF-06934186) and 847B (PF-06937100) Bivalent Vaccine Drug Product).

\*\* Data below is for PF-07052944 ( Lyophilized RSV 847A (PF-06934186) and 847B (PF-06937100) Bivalent Vaccine Drug Product).

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

\*\* 31 Day(s) Rat Intramuscular 240 ug/dose NOAEL None identified \*\* 38 Day(s) 240 ug/dose Rat NOAEL None identified Intramuscular Repeated Dose Toxicity Comments: PF-07052944 = 847A [RSV A] and 847B [RSV B]) in Tris, NaCl, Polysorbate 80, sucrose

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

\* Fertility & Embryonic Rabbit Intramuscular Not Specified NOAEL No effects at **Development - Females** maximum dose

**Reproductive & Development** 

\* PF-07203723 = 847A [RSV A] and 847B [RSV B] in Tris, NaCl, Polysorbate 80, sucrose,

**Toxicity Comments:** mannitol

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No information available. **Endocrine disrupting properties** 

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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

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

**Tromethamine** 

Daphnia magna (Water Flea) OECD EC50 48 hours > 980 mg/L

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 48 Hours 473 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

**Tromethamine** 

Activated sludge OECD EC50 > 1000 mg/L

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** 

Partition Coefficient: (Method, pH, Endpoint, Value)

**Tromethamine** 

Predicted 7.4 Log D -4.668

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
Tris(hydroxymethyl)aminomethane hydrochloride	The substance is not PBT / vPvB PBT assessment does
	not apply
Tromethamine	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

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#### 13.1. Waste treatment methods

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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:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
Not applicable
Not applicable
Not applicable

### Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### Mannitol

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

Sucrose

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 200-334-9
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

Tris(hydroxymethyl)aminomethane hydrochloride

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present EINECS 214-684-5 AICS Present

PF-06937100 (847B Prefusion Protein)

CERCLA/SARA Section 313 de minimus %

California Proposition 65

EINECS

Not Listed
Not Listed
Not Listed

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PF-06934186 (847A Prefusion Protein)

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

**Tromethamine** 

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **TSCA** Present 201-064-4 **EINECS AICS** Present Schedule 4

Standard for Uniform Scheduling of Medicines and

Poisons (SUSMP)

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Polysorbate 80

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

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

#### **France**

Occupational Illnesses (R-463-3, France)

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

#### **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)

i lant protection products directive (51/414/EEO)			
Chemical name	Plant protection products directive (91/414/EEC)		
Sucrose - 57-50-1	Plant protection agent		
SODIUM CHLORIDE - 7647-14-5	Plant protection agent		

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

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### **Section 16: OTHER INFORMATION**

#### Key or legend to abbreviations and acronyms used in the safety data sheet

**Data Sources:** Pfizer proprietary drug development information.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the

Company/Undertaking.

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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.