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

#### 1.1. Product identifier

Pfizer-BioNTech COVID-19 Vaccine **Product Name** 

PF00092 Product Code(s) **Form** nanoform

Comirnaty; PF-07302048 containing PF-07305885 (BNT162b2); CorVAC Containing **Synonyms** 

PF-07305885 (BNT162b2); CoVVAC Containing PF-07305885 (BNT162b2); COVID Vaccine Containing PF-07305885 (BNT162b2); COVID-19 Vaccine Containing

PF-07305885 (BNT162b2)

Not applicable **Trade Name:** PF-07302048 **Compound Number** 

Item Code H000022941: H000023057:H000024547: H000024742

**Chemical Family:** Lipid Nanoparticles containing PF-07305885 (BNT162b2) and Lipids

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

Pharmaceutical product **Recommended Use** 

#### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc Pfizer Ireland Pharmaceuticals 235 East 42nd Street

**OSG** Building

New York, New York 10017 Ringaskiddy, Co. Cork.

Ireland

+353 21 4378701

### 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

Not classified as hazardous

2.2. Label elements

1-800-879-3477

Not classified Signal word

**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).

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

which require the inclusion of all known hazards of the product or its ingredients regardless

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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

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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)
Sucrose	< 10		200-334-9	No data	Not Listed	No data	No data
57-50-1				available		available	available
SODIUM CHLORIDE 7647-14-5	< 10		231-598-3	No data available	Not Listed	No data available	No data available
Potassium phosphate 7778-77-0	< 1		231-913-4	No data available	Not Listed	No data available	No data available
POTASSIUM CHLORIDE 7447-40-7	< 1		231-211-8	No data available	Not Listed	No data available	No data available
NonHazardous		T		T	1		T
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
ALC-0315 2036272-55-4	< 2		Not Listed	No data available	Not Listed	No data available	No data available
PF-07305885 -	<1		Not Listed	No data available	Not Listed	No data available	No data available
PF-07302048 -	< 1		Not Listed	No data available	Not Listed	No data available	No data available
PEGA / ALC-0159 -	< 1		Not Listed	No data available	Not Listed	No data available	No data available
Disodium phosphate dihydrate 10028-24-7	< 1		Not Listed	No data available	Not Listed	No data available	No data available
Cholesterol 57-88-5	< 1		200-353-2	No data available	Not Listed	No data available	No data available
1,2-Distearoyl-sn-glyc ero-3-phosphocholine 816-94-4	< 1		212-440-2	No data available	Not Listed	No data available	No data available

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

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#### **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
Sucrose 57-50-1	29700	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
Potassium phosphate 7778-77-0	3200	No data available	No data available	No data available	No data available
POTASSIUM CHLORIDE 7447-40-7	2600	No data available	No data available	No data available	No data available
Cholesterol 57-88-5	No data available	2000	No data available	No data available	No data available

Additional information - Not Assigned

\* Proprietary

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

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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

No data available

effects

#### 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.

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#### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

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

**Hazardous combustion products** 

Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

chemical

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

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

Prevent further leakage or spillage if safe to do so. **Methods for containment** 

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.

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevention of secondary hazards

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. No open handling permitted. Minimize generating airborne mists and vapors. If solvent based liquid, ground and bond all bulk transfer equipment. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. 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. 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

Store at < -70 °C in properly labeled containers. Keep away from heat, sparks, and flames. **Storage Conditions** 

7.3. Specific end use(s)

Specific use(s) Vaccine.

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### Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters

#### **Exposure Limits**

Refer to available public information for specific member state Occupational Exposure Limits.

**Sucrose** 

**ACGIH TLV** 10 mg/m<sup>3</sup> Bulgaria 10.0 mg/m<sup>3</sup> Estonia 10 mg/m<sup>3</sup> France 10 mg/m<sup>3</sup> Ireland 10 mg/m<sup>3</sup> STEL: 20 mg/m3 5 mg/m<sup>3</sup> Latvia 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 Page 5/12

TWA: 10 mg/m<sup>3</sup> STEL: 20 mg/m<sup>3</sup>

**SODIUM CHLORIDE** 

United Kingdom

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

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

**POTASSIUM CHLORIDE** 

Bulgaria 5.0 mg/m<sup>3</sup> Latvia 5 mg/m<sup>3</sup> Russia MAC: 5 ma/m<sup>3</sup>

**Pfizer OEB Statement:** 

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

SODIUM CHLORIDE

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

Band (OEB):

ALC-0315 Pfizer Occupational Exposure

Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m3 to < 100ug/m3)

**POTASSIUM 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-07305885

Pfizer Occupational Exposure B-OEB Default (control exposure to the range of 10 μg/day to <100 μg/day) Band (OEB):

PF-07302048

Pfizer Occupational Exposure B-OEB 5 (control exposure to <10 µg/day)

Band (OEB):

8.2. Exposure controls

Engineering controls should be used as the primary means to control exposures. Use **Engineering controls** 

process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. It is recommended that all large scale operations should be fully enclosed. Air recirculation is not recommended.

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**Environmental exposure controls** No information available.

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Personal protective equipment 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. Refer to applicable national standards and regulations in the

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selection and use of personal protective equipment (PPE).

**Eye/face protection** Wear safety glasses as minimum protection (goggles recommended). (Eye protection

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

equivalent.).

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

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). Wear impervious protective clothing when handling this compound. (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 Biotherapeutic Occupational Exposure

Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (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 Liquid Color milky white

Odor No information available.
Odor threshold No information available

Molecular formula Mixture
Molecular weight Mixture

<u>Property</u> <u>Values</u>

pH 7.4

Melting point / freezing point No data available

Boiling point / boiling range

Flash point

Evaporation rate

No information available

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 pressureNo data availableVapor densityNo data availableRelative densityNo data availableWater solubilityNo data availableSolubility(ies)No data availablePartition coefficientNo data availableAutoignition temperatureNo data available

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Decomposition temperatureNo data availableKinematic viscosityNo data availableDynamic viscosityNo data availableParticle characteristics

Particle SizeNo information availableParticle Size DistributionNo information availableExplosive propertiesNo information available

#### 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. As a precautionary measure, keep

away from heat sources and electrostatic discharge.

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: Toxicological properties have not been thoroughly investigated. The following information is

available for the individual ingredients.

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

to this compound may include: injection site pain, muscle pain, headache, fever, chills, tiredness, joint pain, abnormal redness of skin (erythema), and sleep disturbances. Serious

allergic reactions, including anaphylaxis, have been reported.

Acute Toxicity: (Species, Route, End Point, Dose)

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

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Mouse Oral LD 50 4 g/kg Rabbit Dermal LD 50 > 10 g/kg

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Rat Oral LD50 2600 mg/kg

Potassium phosphate

Rat Oral LD50 3200 mg/kg

Rabbit Dermal LC50 > 4640 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Sucrose	= 29700 mg/kg (Rat)	-	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg ( Rabbit )	> 42 g/m³ (Rat) 1 h
Potassium phosphate	= 3200 mg/kg ( Rat )	-	-
POTASSIUM CHLORIDE	= 2600 mg/kg ( Rat )	-	-
Cholesterol		> 2000 mg/kg (Rat)	-

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE Skin irritation Rabbit Mild Eye irritation Rabbit Mild

**POTASSIUM CHLORIDE** 

Eye Irritation Rabbit Mild

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

PF-07302048

4 Week(s) Rat Intramuscular \*10 μg LOAEL Skin, Blood forming organs, Blood, Skeletal muscle, Lymphoid tissue, Spleen Repeated Dose Toxicity Comments: PF-07302048: \* Doses were administered once a week.

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s)) PF-07305885

Fertility & Embryonic Development - Females Rat Intramuscular 30 µg NOAEL No effects at maximum dose, Not teratogenic

Potassium phosphate

Reproductive & Fertility Rat No route specified 282 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus Reproductive & Fertility Mouse No route specified 320 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

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

Potassium phosphate

Bacterial Mutagenicity (Ames) Salmonella Negative

See below Carcinogenicity

Cholesterol

IARC

Group 3 (Not Classifiable)

**Data for the Drug Product** 

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

Fertility & Embryonic Rat Intramuscular N/A Not specified No effects at **Development - Females** maximum dose

#### 11.2. Information on other hazards

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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

Aquatic 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

<u>Bioaccumulation</u> 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
Potassium phosphate	The substance is not PBT / vPvB PBT assessment does
	not apply
POTASSIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does
	not apply
Cholesterol	The substance is not PBT / vPvB

#### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

12.7. Other adverse effects

No information available.

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### 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.

### 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 Sucrose	Present
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
ALC-0315	N
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65 EINECS	Not Listed Not Listed
Potassium phosphate	NOI LISIEG
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-913-4
AICS	Present
POTASSIUM CHLORIDE	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present

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231-211-8 **EINECS AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 4 Poisons (SUSMP) PF-07305885 CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed PF-07302048 CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed Not Listed **EINECS** PEGA / ALC-0159 CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Not Listed **EINECS** Disodium phosphate dihydrate CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5 Poisons (SUSMP) Cholesterol CERCLA/SARA Section 313 de minimus % Not Listed Not Listed **California Proposition 65 TSCA** Present **EINECS** 200-353-2 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 4 Poisons (SUSMP) 1,2-Distearoyl-sn-glycero-3-phosphocholine Not Listed CERCLA/SARA Section 313 de minimus % **California Proposition 65** Not Listed **EINECS** 212-440-2

#### **France**

Occupational Illnesses (R-463-3, France)

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Chemical na	me	French RG number	Title
SODIUM CHLO	RIDE	RG 78	-
7647-14-5	5		
POTASSIUM CH	LORIDE	RG 67	-
7447-40-7	7		

#### **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

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Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
Sucrose - 57-50-1	Plant protection agent
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

**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 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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