



# SAFETY DATA SHEET

Revision date 07-Dec-2021

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

### 1.1. Product identifier

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

**Product Code(s)** PF00092

**Form** nanoform

**Synonyms** Comirnaty; PF-07302048 containing PF-07305885 (BNT162b2); CorVAC Containing PF-07305885 (BNT162b2) ; CoVVAC Containing PF-07305885 (BNT162b2); COVID Vaccine Containing PF-07305885 (BNT162b2); COVID-19 Vaccine Containing PF-07305885 (BNT162b2)

**Trade Name:** Not applicable

**Compound Number** PF-07302048

**Item Code** H000022941: H000023057,H000024547: H000024742, H000027229, H000027228

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

### 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 Inc  
66 Hudson Boulevard East  
New York, New York 10001  
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

### 2.2. Label elements

**Signal word** Not classified

**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).

**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

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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)
POTASSIUM CHLORIDE (CAS #: 7447-40-7)	< 1		231-211-8	Acute Tox 5 (H303)	Not Listed	No data available	No data available

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 (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Sucrose (CAS #: 57-50-1)	< 10	-	200-334-9	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	< 10	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
ALC-0315 (CAS #: 2036272-55-4)	< 2	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Potassium phosphate (CAS #: 7778-77-0)	< 1	-	231-913-4	Not classified as hazardous	Not Listed	No data available	No data available
PF-07305885 (CAS #: -)	< 1	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
PF-07302048 (CAS #: -)	< 1	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Disodium phosphate dihydrate (CAS #: 10028-24-7)	< 1		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Cholesterol (CAS #: 57-88-5)	< 1	-	200-353-2	Not classified as hazardous	Not Listed	No data available	No data available
ALC-0159 (CAS #: 1849616-42-7)	< 1	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
1,2-Distearoyl-sn-glycero-3-phosphocholine (CAS #: 816-94-4)	< 1	-	212-440-2	Not classified as hazardous	Not Listed	No data available	No data available

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## 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
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	0.83	No data available	No data available
POTASSIUM CHLORIDE 7447-40-7	3020	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 a trade secret.

## **Section 4: FIRST AID MEASURES**

### **4.1. Description of first aid measures**

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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**

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**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 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**

### **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 spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

### **6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### **7.1. Precautions for safe handling**

#### **Advice on safe handling**

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** Store as directed by product packaging.

### **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/m <sup>3</sup>
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/m <sup>3</sup> total dust
	(vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction
United Kingdom	TWA: 10 mg/m <sup>3</sup>
	STEL: 20 mg/m <sup>3</sup>

#### SODIUM CHLORIDE

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

#### Potassium phosphate

Russia	MAC: 10 mg/m <sup>3</sup>
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#### POTASSIUM CHLORIDE

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

**Pfizer Occupational Exposure Band (OEB) Statement:** 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. 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/m <sup>3</sup> to 3000ug/m <sup>3</sup> )
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#### ALC-0315

Pfizer Occupational Exposure Band (OEB):	OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m <sup>3</sup> to < 100ug/m <sup>3</sup> )
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#### POTASSIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m <sup>3</sup> to 3000ug/m <sup>3</sup> )
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#### PF-07305885

Pfizer Occupational Exposure Band (OEB):	V-OEB
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#### PF-07302048

Pfizer Occupational Exposure Band (OEB):	V-OEB
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#### ALC-0159

Pfizer Occupational Exposure Band (OEB):	OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m <sup>3</sup> to < 100ug/m <sup>3</sup> )
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### 8.2. Exposure controls

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<b>Engineering controls</b>	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.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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 selection and use of personal protective equipment (PPE).
<b>Eye/face protection</b>	Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
<b>Hand protection</b>	Wear impervious gloves, (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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.).
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Liquid
<b>Color</b>	milky white
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	7.4
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available

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<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No 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**

<b>General Information:</b>	Toxicological properties have not been thoroughly investigated. The following information is available for the individual ingredients.
<b>Short term</b>	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.
<b>Known Clinical Effects:</b>	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.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.

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**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.  
**Skin corrosion/irritation** Based on available data, the classification criteria are not met.  
**Respiratory or skin sensitization** Based on available data, the classification criteria are not met.  
**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.  
**Reproductive toxicity** Based on available data, the classification criteria are not met.  
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.  
**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)

### 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

### POTASSIUM CHLORIDE

Rat Oral LD50 3020 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 mg/L ( Rat ) 1 h
Potassium phosphate	= 3200 mg/kg ( Rat )	-	> 0.83 mg/L ( Rat ) 4 h
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-07305885

17 Day(s) Rat Intramuscular \* 30 µg RNA/Dose NOAEL None identified

### 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 RNA/Dose 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



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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

**Carcinogenicity** See below

### 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 Development - Females	Rat	Intramuscular	N/A	Not specified	No effects at maximum dose
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## 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

### 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

**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**

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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.

## 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.**

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

**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

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

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

Sucrose

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
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<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-334-9
<b>AICS</b>	Present
SODIUM CHLORIDE	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present
ALC-0315	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Potassium phosphate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-913-4
<b>AICS</b>	Present
POTASSIUM CHLORIDE	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-211-8
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4
PF-07305885	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
PF-07302048	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Disodium phosphate dihydrate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
Cholesterol	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-353-2
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4
ALC-0159	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
1,2-Distearoyl-sn-glycero-3-phosphocholine	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	212-440-2

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## France

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

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-
POTASSIUM CHLORIDE 7447-40-7	RG 67	-

## 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)
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

#### Full text of H-Statements referred to under section 3

Acute toxicity, oral-Cat.5; H303 - May be harmful if swallowed

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reason for revision** Updated Section 11 - Toxicology Information.

**Revision date** 07-Dec-2021

**Prepared By** Pfizer Global Environment, Health, and Safety

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**is no known information at this time.**