SAFETY DATA SHEET

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
Synonyms 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
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
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

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 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

NonHazardous

Chemical name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	*	Not Listed	
Sucrose	200-334-9	57-50-1	< 10	Not Listed	
SODIUM CHLORIDE	231-598-3	7647-14-5	< 10	Not Listed	
ALC-0315	Not Listed	NOT ASSIGNED	< 2	Not Listed	
Potassium phosphate	231-913-4	7778-77-0	< 1	Not Listed	
POTASSIUM CHLORIDE	231-211-8	7447-40-7	< 1	Not Listed	
PF-07305885	Not Listed	NOT ASSIGNED	<1	Not Listed	
PF-07302048	Not Listed	NOT ASSIGNED	< 1	Not Listed	
PEGA / ALC-0159	Not Listed	NOT ASSIGNED	< 1	Not Listed	
Disodium phosphate dihydrate	Not Listed	10028-24-7	< 1	Not Listed	
Cholesterol	200-353-2	57-88-5	< 1	Not Listed	
1,2-Distearoyl-sn-glycero-3-phosphocholine	212-440-2	816-94-4	< 1	Not Listed	

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

Additional information * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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.

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. 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

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

7.3. Specific end use(s)

Specific use(s) Vaccine.

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/m³
Bulgaria	10.0 mg/m³
Estonia	10 mg/m³
France	10 mg/m³
Ireland	10 mg/m³ STEL: 20 mg/m³
Latvia	5 mg/m³
Spain	10 mg/m³
OSHA PEL	15 mg/m³ 5 mg/m³ (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction
United Kingdom	TWA: 10 mg/m³ STEL: 20 mg/m³
SODIUM CHLORIDE	
Latvia	5 mg/m³
Russia	MAC: 5 mg/m³
Potassium phosphate	
Russia	MAC: 10 mg/m³
POTASSIUM CHLORIDE	
Bulgaria	5.0 mg/m³
Latvia	5 mg/m³
Russia	MAC: 5 mg/m³

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	
Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)
POTASSIUM CHLORIDE	
Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)
PF-07305885	
Pfizer Occupational Exposure Band (OEB):	B-OEB Default (control exposure to the range of 10 µg/day to <100 µg/day)
PF-07302048	
Pfizer Occupational Exposure	B-OEB 5 (control exposure to <10 µg/day)

Band (OEB):

8.2. Exposure controls

Engineering controls	Engineering controls should be used as the primary means to control exposures. Use 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.
Environmental exposure controls	No information available.
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 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
Molecular formula	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available

Property	**Values**
pH	7.4
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available

Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2. Other information

Liquid Density	No data available
Bulk density	No data 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 toxicological effects

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: muscle pain, abnormal redness of skin (erythema), fever, and sleep disturbances.

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^3

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 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)	-	> 42 g/m³ (Rat) 1 h
Potassium phosphate	= 3200 mg/kg (Rat)	-	-
POTASSIUM CHLORIDE	= 2600 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))
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

Carcinogenicity See below
Cholesterol
IARC Group 3 (Not Classifiable)

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 No information available.

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. Other adverse effects

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 waste water 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	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

ALC-0315

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

Potassium phosphate

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
EINECS	231-211-8
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

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
EINECS	Not Listed

PEGA / ALC-0159

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

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
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-353-2
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

1,2-Distearoyl-sn-glycero-3-phosphocholine

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	212-440-2

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.

Revision date 16-Nov-2020

Prepared By Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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