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); 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 9NU
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>EC No</th>
<th>CAS No</th>
<th>Weight-%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
<th>REACH Registration Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>231-791-2</td>
<td>7732-18-5</td>
<td>*</td>
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<tr>
<td>Sucrose</td>
<td>200-334-9</td>
<td>57-50-1</td>
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<tr>
<td>SODIUM CHLORIDE</td>
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<tr>
<td>POTASSIUM CHLORIDE</td>
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<td>7447-40-7</td>
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<td>PF-07305885</td>
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<td>NOT ASSIGNED</td>
<td>&lt; 1</td>
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<tr>
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<td>Not Listed</td>
<td>NOT ASSIGNED</td>
<td>&lt; 1</td>
<td>Not Listed</td>
<td></td>
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<tr>
<td>PEGA / ALC-0159</td>
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<td>&lt; 1</td>
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<tr>
<td>Disodium phosphate dihydrate</td>
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<tr>
<td>Cholesterol</td>
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<td>57-88-5</td>
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</tr>
<tr>
<td>1,2-Distearoyl-sn-glycero-3-phosphocholine</td>
<td>212-440-2</td>
<td>816-94-4</td>
<td>&lt; 1</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

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
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.

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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/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
  - (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 Band (OEB): 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>milky white</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Odor</td>
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<tr>
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</tr>
<tr>
<td>Melting point / freezing point</td>
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</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
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</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
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</tr>
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</table>
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)

Sucreose
Rat Oral LD 50 29,700 mg/kg

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3 g/kg
Mouse Oral LD50 4 g/kg
Rabbit Dermal LD50 > 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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>&gt; 90 mL/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sucrose</td>
<td>= 29700 mg/kg (Rat)</td>
<td>-</td>
<td>&gt; 42 g/m³ (Rat) 1 h</td>
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<td>= 3 g/kg (Rat)</td>
<td>-</td>
<td>&gt; 42 g/m³ (Rat) 1 h</td>
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<tr>
<td>Potassium phosphate</td>
<td>= 3200 mg/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>POTASSIUM CHLORIDE</td>
<td>= 2600 mg/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**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)

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**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
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.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>PBT and vPvB assessment</th>
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<tr>
<td>SODIUM CHLORIDE</td>
<td>The substance is not PBT / vPvB PBT assessment does not apply</td>
</tr>
<tr>
<td>Potassium phosphate</td>
<td>The substance is not PBT / vPvB PBT assessment does not apply</td>
</tr>
<tr>
<td>POTASSIUM CHLORIDE</td>
<td>The substance is not PBT / vPvB PBT assessment does not apply</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>The substance is not PBT / vPvB</td>
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</table>

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 Poisons (SUSMP)
Schedule 5
Poisons (SUSMP)

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA Section 313 de minimus %</th>
<th>California Proposition 65</th>
<th>TSCA</th>
<th>EINECS</th>
<th>AICS</th>
<th>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</th>
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<tbody>
<tr>
<td>Cholesterol</td>
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<td>200-353-2</td>
<td>Present</td>
<td>Schedule 4</td>
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1,2-Distearoyl-sn-glycero-3-phosphocholine

<table>
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<tr>
<th>Substance</th>
<th>CERCLA/SARA Section 313 de minimus %</th>
<th>California Proposition 65</th>
<th>EINECS</th>
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<tbody>
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<td></td>
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<td>Not Listed</td>
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</tr>
</tbody>
</table>

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

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.