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

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

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 Ireland Pharmaceuticals
OSG Building
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

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 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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Weight-%</th>
<th>REACH Registration Number</th>
<th>EC No</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
<th>Specific concentration limit (SCL)</th>
<th>M-Factor (long-term)</th>
<th>M-Factor (long-term)</th>
</tr>
</thead>
<tbody>
<tr>
<td>POTASSIUM CHLORIDE 7447-40-7</td>
<td>&lt; 1</td>
<td>231-211-8</td>
<td>Acute Tox 5 (H303)</td>
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<tr>
<td><strong>Hazardous</strong></td>
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<tr>
<td>Water 7732-18-5</td>
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<td>No data available</td>
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</tr>
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<td>No data available</td>
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<td>PF-07302048 -</td>
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<td>Not Listed</td>
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*Full text of H- and EUH-phrases: see section 16*
Acute Toxicity Estimate

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50 - 4 hour - dust/mist - mg/L</th>
<th>Inhalation LC50 - 4 hour - vapor - mg/L</th>
<th>Inhalation LC50 - 4 hour - gas - ppm</th>
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<tbody>
<tr>
<td>Water 7732-18-5</td>
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</table>

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

Inhalation
Remove to fresh air. Seek immediate medical attention/advice.

Eye contact
Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion
Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects
For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians
None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media
Dry chemical, CO2, alcohol-resistant foam or water spray.
5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical
Fine particles (such as 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.

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
Latvia
STEL: 20 mg/m³
Spain
5 mg/m³
OSHA PEL
15 mg/m³
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 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):
ALC-0315
OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

POSSUM CHLORIDE
Pfizer Occupational Exposure Band (OEB):
PF-07305885
V-OEB

PF-07302048
V-OEB

ALC-0159
OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls
Release prevention and exposure protection measures should be established for any
activities involving this material, as determined by a risk assessment conducted using appropriate Occupational Hygiene Risk Assessment tools. The containment level required for the activity should be based on the conclusions of the risk assessment. Where warranted, engineering controls, such as biosafety cabinets, should be applied as the primary means to control exposures.

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 gloves, (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection
Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

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

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

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<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
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<td>Physical state</td>
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<td>milky white</td>
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<tr>
<td>Odor</td>
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<tr>
<td>Odor threshold</td>
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</tr>
<tr>
<td>Molecular formula</td>
<td>Mixture</td>
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<tr>
<td>Molecular weight</td>
<td>Mixture</td>
</tr>
<tr>
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</tr>
<tr>
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<tr>
<td>Boiling point / boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
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</tr>
<tr>
<td>Flammability Limit in Air</td>
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<tr>
<td>- Upper flammability limit:</td>
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</tr>
<tr>
<td>- Lower flammability limit:</td>
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<tr>
<td>Water solubility</td>
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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 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.

Short term
In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects:
Based on clinical trials in humans, possible adverse effects following 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/m³  
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 LD 50  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>
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<td>-</td>
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<tr>
<td>Sucrose</td>
<td>= 29700 mg/kg (Rat)</td>
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<td>-</td>
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<td>&gt; 10000 mg/kg (Rabbit)</td>
<td>&gt; 42 mg/L (Rat) 1 h</td>
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<td>Potassium phosphate</td>
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<tr>
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<td>-</td>
</tr>
<tr>
<td>Cholesterol</td>
<td></td>
<td>&gt; 2000 mg/kg (Rat)</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))**

**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

**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

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

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

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.

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**

**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

**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

**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

**ALC-0159**
- CERCLA/SARA Section 313 de minimus %: Not Listed
- California Proposition 65: Not Listed
- EINECS: Not Listed

**1,2-Distearoyl-sn-glycero-3-phosphocholine**
- CERCLA/SARA Section 313 de minimus %: Not Listed
- California Proposition 65: Not Listed
- EINECS: 212-440-2

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>French RG number</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM CHLORIDE</td>
<td>RG 78</td>
<td>-</td>
</tr>
<tr>
<td>7647-14-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POTASSIUM CHLORIDE</td>
<td>RG 67</td>
<td>-</td>
</tr>
<tr>
<td>7447-40-7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Plant protection products directive (91/414/EEC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose - 57-50-1</td>
<td>Plant protection agent</td>
</tr>
<tr>
<td>SODIUM CHLORIDE - 7647-14-5</td>
<td>Plant protection agent</td>
</tr>
</tbody>
</table>

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 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 16 - Other Information.

Revision date 07-Dec-2021

Prepared By Pfizer Global Environment, Health, and Safety

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