



# SAFETY DATA SHEET

Revision date 15-Jan-2025

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

### 1.1. Product identifier

|                  |  |
|------------------|--|
| Product Name     | RSVpreF Vaccine  |
| Product Code(s)  | PZ03551  |
| Synonyms         | PF-06928316 RSV Vaccine; Lyophilized RSV 847A and 847B Bivalent Drug Product; RSV Bivalent Vaccine |
| Trade Name:      | ABRYSVO  |
| Chemical Family: | Not determined   |

### 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 Research and Development<br>445 Eastern Point Road<br>Groton, CT USA<br>1-800-879-3477 | Pfizer Ireland Pharmaceuticals<br>OSG Building<br>Ringaskiddy, Co. Cork.<br>Ireland<br>+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 according to Regulation (EC) 1272/2008 and/or other applicable regulations.

### 2.2. Label elements

|                     |   |
|---------------------|---|
| Signal word         | Not Classified  |
| Hazard statements   | Not classified in accordance with international standards for workplace safety. |
| Supplemental Hazard | Compound, not fully tested, hazards unknown.                                    |

### 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. |
|-------|---|

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## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

NonHazardous

| Chemical name  | Weight-% | REACH<br>Registration<br>Number | EC No      | Classification<br>according to<br>Regulation<br>(EC) No.<br>1272/2008<br>[CLP] | Specific<br>concentration<br>limit (SCL) | M-Factor             | M-Factor<br>(long-term) |
|--|----------|---------------------------------|------------|--|--|----------------------|-------------------------|
| Mannitol<br>(CAS #: 69-65-8)   | *        | -                               | 200-711-8  | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |
| Sucrose<br>(CAS #: 57-50-1)  | *        | -                               | 200-334-9  | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |
| SODIUM CHLORIDE<br>(CAS #: 7647-14-5)                                  | *        | -                               | 231-598-3  | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |
| Tris(hydroxymethyl)aminomethane<br>hydrochloride<br>(CAS #: 1185-53-1) | *        | -                               | 214-684-5  | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |
| PF-06937100 (847B<br>Prefusion Protein)<br>(CAS #: NOT<br>ASSIGNED)    | < 1      |                                 | Not Listed | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |
| PF-06934186 (847A<br>Prefusion Protein)<br>(CAS #: NOT<br>ASSIGNED)    | < 1      |                                 | Not Listed | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |
| Tromethamine<br>(CAS #: 77-86-1)                                       | *        | -                               | 201-064-4  | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |
| Polysorbate 80<br>(CAS #: 9005-65-6)                                   | *        | -                               | 500-019-9  | Not classified<br>as hazardous   | Not Listed                               | No data<br>available | No data<br>available    |

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

#### Acute Toxicity Estimate

| Chemical name                | Oral LD50 | Dermal LD50       | Inhalation LC50 - 4<br>hour - dust/mist -<br>mg/L | Inhalation LC50 - 4<br>hour - vapor - mg/L | Inhalation LC50 - 4<br>hour - gas - ppm |
|------------------------------|-----------|-------------------|---|--|---|
| Mannitol<br>69-65-8          | 13500     | No data available | No data available                                 | No data available                          | No data available                       |
| Sucrose<br>57-50-1           | 29700     | No data available | No data available                                 | No data available                          | No data available                       |
| SODIUM CHLORIDE<br>7647-14-5 | 3550      | 10000             | No data available                                 | No data available                          | No data available                       |

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| 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 |
|--------------------------|------------|-------------------|---|---|--------------------------------------|
| Tromethamine 77-86-1     | 5900       | 5000              | No data available                           | No data available                       | No data available                    |
| Polysorbate 80 9005-65-6 | 34.5 mL/kg | No data available | No data available                           | No data available                       | No data available                    |

## Additional information

\* Proprietary

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

|  |  |
|--|--|
| <b>Most important symptoms and effects</b> | 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

|                           |       |
|---------------------------|-------|
| <b>Note to physicians</b> | None. |
|---------------------------|-------|

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

|                                     |   |
|-------------------------------------|---|
| <b>Suitable Extinguishing Media</b> | Dry chemical, CO2, alcohol-resistant foam or water spray. |
|-------------------------------------|---|

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

|   |  |
|---|--|
| <b>Specific hazards arising from the chemical</b> | Fine particles (such as dust and mists) may fuel fires/explosions. |
| <b>Hazardous combustion products</b>              | Formation of toxic gases is possible during heating or fire.       |

### 5.3. Advice for firefighters

|   |  |
|---|--|
| <b>Special protective equipment for fire-fighters</b> | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. |
|---|--|

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## 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 the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. 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** Storage Temperature as lyophilized cake: 2-8C. Storage Temperature as reconstituted solution 15-30C. Keep away from heat, sparks, and flames.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

**Mannitol**  
Russia  
**Sucrose**

MAC: 10 mg/m<sup>3</sup>

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|                        |  |
|------------------------|--|
| 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>                             |
| <b>SODIUM CHLORIDE</b> |  |
| 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.

## 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>)

## PF-06934186 (847A Prefusion Protein)

Pfizer Occupational Exposure Band (OEB): V-OEB

## PF-06937100 (847B Prefusion Protein)

Pfizer Occupational Exposure Band (OEB): V-OEB

## Tromethamine

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

## PF-06928316

Pfizer Occupational Exposure Band (OEB): V-OEB

## 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

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). 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.

### 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

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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). (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

|                   |                           |
|-------------------|---------------------------|
| Physical state    | solid                     |
| Color             | White                     |
| Odor              | No information available. |
| Odor threshold    | No information available  |
| Molecular formula | Mixture                   |
| Molecular weight  | Mixture                   |

#### Property

#### Values

|                                |                          |
|--------------------------------|--------------------------|
| pH                             | 7.4                      |
| Melting point / freezing point | 66                       |
| Boiling point / boiling range  |                          |
| Flash point                    | No information 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               | Soluble                  |
| Solubility(ies)                | No data available        |
| Partition coefficient          | No data available        |
| Autoignition temperature       | No data available        |
| Decomposition temperature      | No data available        |
| Kinematic viscosity            | No data available        |
| Dynamic viscosity              | No data available        |
| Particle characteristics       |                          |
| Particle Size                  | No information available |
| Particle Size Distribution     | No information available |
| Explosive properties           | No information available |

### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Tromethamine

Predicted 7.4 Log D -4.668

### 9.2. Other information

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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 dust and mists) may fuel fires/explosions.

### **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:** The following information is available for the individual ingredients. Toxicological properties of the formulation have not been investigated.

**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 exposure to this compound may include: injection site pain, tiredness, headache, muscle pain, gestational hypertension, preeclampsia, joint pain, nausea.

**Acute toxicity** Based on available data, the classification criteria are not met.

**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)**

#### **Mannitol**

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/kg

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## **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

## **Tromethamine**

Rat Oral LD50 5900 mg/kg

Rat Dermal LD 50 > 5000 mg/kg

## **Polysorbate 80**

Rat Intravenous LD 50 1790 mg/kg

Mouse Oral LD 50 25 g/kg

| Chemical name   | Oral LD50             | Dermal LD50              | Inhalation LC50       |
|-----------------|-----------------------|--------------------------|-----------------------|
| Mannitol        | = 13500 mg/kg ( Rat ) | -                        | -                     |
| Sucrose         | = 29700 mg/kg ( Rat ) | -                        | -                     |
| SODIUM CHLORIDE | = 3550 mg/kg ( Rat )  | > 10000 mg/kg ( Rabbit ) | > 42 mg/L ( Rat ) 1 h |
| Tromethamine    | = 5900 mg/kg ( Rat )  | > 5000 mg/kg ( Rat )     | -                     |
| Polysorbate 80  | = 34.5mL/kg ( Rat )   | -                        | -                     |

## **Acute Toxicity Comments:**

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

### **SODIUM CHLORIDE**

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

### **Tromethamine**

Eye Irritation Rabbit Slight

Skin Irritation Rabbit Slight

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

### **Tromethamine**

Bacterial Mutagenicity (Ames) *E. coli* Negative

## **Carcinogenicity**

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

\* Data below is for PF-07203723 ( Lyophilized RSV 847A (PF-06934186) and 847B (PF-06937100) Bivalent Vaccine Drug Product).

\*\* Data below is for PF-07052944 ( Lyophilized RSV 847A (PF-06934186) and 847B (PF-06937100) Bivalent Vaccine Drug Product).

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

|              |     |               |             |       |                 |
|--------------|-----|---------------|-------------|-------|-----------------|
| ** 31 Day(s) | Rat | Intramuscular | 240 ug/dose | NOAEL | None identified |
| ** 38 Day(s) | Rat | Intramuscular | 240 ug/dose | NOAEL | None identified |



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**Repeated Dose Toxicity Comments:** PF-07052944 = 847A [RSV A] and 847B [RSV B] in Tris, NaCl, Polysorbate 80, sucrose  
**Reproduction & Development Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

\* Fertility & Embryonic Development - Females      Rabbit      Intramuscular      Not Specified      NOAEL      No effects at maximum dose

**Reproductive & Development Toxicity Comments:**      \* PF-07203723 = 847A [RSV A] and 847B [RSV B] in Tris, NaCl, Polysorbate 80, sucrose, mannitol

## **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)**

##### **Tromethamine**

*Daphnia magna* (Water Flea) OECD EC50 48 hours > 980 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 48 Hours 473 mg/L

#### **Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

##### **Tromethamine**

Activated sludge OECD EC50 > 1000 mg/L

### **12.2. Persistence and degradability**

**Persistence and degradability**      No information available.

### **12.3. Bioaccumulative potential**

#### **Bioaccumulation**

#### **Partition Coefficient: (Method, pH, Endpoint, Value)**

##### **Tromethamine**

Predicted 7.4 Log D -4.668

### **12.4. Mobility in soil**

**Mobility in soil**      No information available.

### **12.5. Results of PBT and vPvB assessment**

#### **PBT and vPvB assessment**

| Chemical name   | PBT and vPvB assessment                                       |
|-----------------|---|
| SODIUM CHLORIDE | The substance is not PBT / vPvB PBT assessment does not apply |

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|   |   |
|---|---|
| Tris(hydroxymethyl)aminomethane hydrochloride | The substance is not PBT / vPvB PBT assessment does not apply |
| Tromethamine                                  | The substance is not PBT / vPvB PBT assessment does not apply |

## 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

Mannitol

|   |            |
|---|------------|
| <b>CERCLA/SARA Section 313 de minimus %</b> | Not Listed |
| <b>California Proposition 65</b>            | Not Listed |
| <b>TSCA</b>                                 | Present    |
| <b>EINECS</b>                               | 200-711-8  |
| <b>AICS</b>                                 | Present    |

Sucrose

|   |            |
|---|------------|
| <b>CERCLA/SARA Section 313 de minimus %</b> | Not Listed |
| <b>California Proposition 65</b>            | Not Listed |
| <b>TSCA</b>                                 | Present    |
| <b>EINECS</b>                               | 200-334-9  |

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|   |            |
|---|------------|
| <b>AICS</b>   | Present    |
| <b>SODIUM CHLORIDE</b>  |            |
| <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    |
| <b>Tris(hydroxymethyl)aminomethane hydrochloride</b>                    |            |
| <b>CERCLA/SARA Section 313 de minimus %</b>                             | Not Listed |
| <b>California Proposition 65</b>  | Not Listed |
| <b>TSCA</b>   | Present    |
| <b>EINECS</b>   | 214-684-5  |
| <b>AICS</b>   | Present    |
| <b>PF-06937100 (847B Prefusion Protein)</b>                             |            |
| <b>CERCLA/SARA Section 313 de minimus %</b>                             | Not Listed |
| <b>California Proposition 65</b>  | Not Listed |
| <b>EINECS</b>   | Not Listed |
| <b>PF-06934186 (847A Prefusion Protein)</b>                             |            |
| <b>CERCLA/SARA Section 313 de minimus %</b>                             | Not Listed |
| <b>California Proposition 65</b>  | Not Listed |
| <b>EINECS</b>   | Not Listed |
| <b>Tromethamine</b>   |            |
| <b>CERCLA/SARA Section 313 de minimus %</b>                             | Not Listed |
| <b>California Proposition 65</b>  | Not Listed |
| <b>TSCA</b>   | Present    |
| <b>EINECS</b>   | 201-064-4  |
| <b>AICS</b>   | Present    |
| <b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b> | Schedule 4 |
| <b>Polysorbate 80</b>   |            |
| <b>CERCLA/SARA Section 313 de minimus %</b>                             | Not Listed |
| <b>California Proposition 65</b>  | Not Listed |
| <b>TSCA</b>   | Present    |
| <b>EINECS</b>   | Not Listed |
| <b>AICS</b>   | Present    |

## France

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

| Chemical name                | French RG number | Title |
|------------------------------|------------------|-------|
| SODIUM CHLORIDE<br>7647-14-5 | RG 78            | -     |

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

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## Plant protection products directive (91/414/EEC)

| Chemical name               | Plant protection products directive (91/414/EEC) |
|-----------------------------|--|
| Sucrose - 57-50-1           | Plant protection agent                           |
| SODIUM CHLORIDE - 7647-14-5 | Plant protection agent                           |

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### Key or legend to abbreviations and acronyms used in the safety data sheet

**Data Sources:** Pfizer proprietary drug development information.

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

**Revision date** 15-Jan-2025

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

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