



# SAFETY DATA SHEET

Revision date 20-Aug-2025

Version 1.02

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

### 1.1. Product identifier

**Product Name** Pfizer-BioNTech Covid-19 vaccine Tris-Sucrose Omicron LP.8.1 Variant

**Product Code(s)** PF01329

**Form** nanoform

**Synonyms** Pfizer-BioNTech Covid-19 vaccine for ages 5 through 11: 5 to 11, Ready to use, Blue Cap; Pfizer-BioNTech Covid-19 vaccine for ages 6m through 4: Dilute to use, Yellow Cap; Pfizer-BioNTech Covid-19 vaccine for ages 12 and older: Refrigerated Single Dose Prefilled Syringe; PF-07302048 containing PF-08152264 (BNT162b2); Covid19 Tris Formulation; PF-07302048 containing PF-08152264 (BNT162b2); CorVAC Containing PF-08152264 (BNT162b2); CoVVAC Containing PF-08152264 (BNT162b2); COVID Vaccine Containing PF-08152264 (BNT162b2); COVID-19 Vaccine Containing PF-08152264 (BNT162b2)

**Trade Name:** Comirnaty

**Chemical Family:** Lipid Nanoparticles containing PF-08152264 (BNT162b2)

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours): +1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

#### OSHA Classification

##### Hazards not otherwise classified (HNOC)

Not applicable

##### Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

### 2.2. Label elements

**Signal word** Not classified

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**Hazard statements** Not classified in accordance with international standards for workplace safety.

## Unknown acute toxicity

- 0.5 - 1.0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
- 0.5 - 1.0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
- 0.5 - 1.0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

## Unknown aquatic toxicity

Contains 0.5 - 1.0 % of components with unknown hazards to the aquatic environment.

## 2.3. Other hazards

**Other hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**PBT & vPvB** The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

**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

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Sucrose (CAS #: 57-50-1)	< 10	-	200-334-9	Not classified	Not classified	No data available	No data available
ALC-0315 (CAS #: 2036272-55-4)	< 2	-	Not Listed	Not classified	Not classified	No data available	No data available
Tromethamine (CAS #: 77-86-1)	*	-	201-064-4	Not classified	Not classified	No data available	No data available
Tris(hydroxymethyl)aminomethane hydrochloride (CAS #: 1185-53-1)	*	-	214-684-5	Not classified	Not classified	No data available	No data available
PF-08152264 (CAS #: -)	0.5 - 1.0		Not Listed	Not classified	Not classified	No data available	No data available
Cholesterol	< 1	-	200-353-2	Not classified	Not classified	No data	No data

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(CAS #: 57-88-5)						available	available
ALC-0159 (CAS #: 1849616-42-7)	< 1	-	Not Listed	Not classified	Not classified	No data available	No data available
1,2-Distearoyl-sn-glycero-3-phosphocholine (CAS #: 816-94-4)	< 1	-	212-440-2	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
Tromethamine 77-86-1	5900	5000	No data available	No data available	No data available
Cholesterol 57-88-5	>2000	>2000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

- Not Assigned

\* Proprietary

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

<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.
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## 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.

#### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### 5.3. Advice for firefighters

Special protective equipment and precautions 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)

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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. Handle in accordance with good industrial hygiene and safety practice.

## General hygiene considerations

### 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	TWA: 10 mg/m <sup>3</sup>
Bulgaria	TWA: 10.0 mg/m <sup>3</sup> ; dust, inhalable fraction
Estonia	TWA: 10 mg/m <sup>3</sup> ;
France	10 mg/m <sup>3</sup>
Ireland	TWA: 10 mg/m <sup>3</sup> ;
	STEL: 20 mg/m <sup>3</sup> ;
Latvia	TWA: 5 mg/m <sup>3</sup> ; dust
Spain	TWA-(VLA-ED): 10 mg/m <sup>3</sup> ;
OSHA PEL	TWA: 15 mg/m <sup>3</sup> total dust
	TWA: 5 mg/m <sup>3</sup> respirable fraction
	(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> ;

#### 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.

#### ALC-0315

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

#### 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>)

#### ALC-0159

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

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## PF-08152264

Pfizer Occupational Exposure V-OEB  
Band (OEB):

## PF-07302048

Pfizer Occupational Exposure V-OEB  
Band (OEB):

### Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Tris(hydroxymethyl)aminomethane hydrochloride 1185-53-1	-	216.6 mg/kg bw/day [4] [6]	152.8 mg/m <sup>3</sup> [4] [6]
Tromethamine 77-86-1	-	166.7 mg/kg bw/day [4] [6]	117.5 mg/m <sup>3</sup> [4] [6]
Cholesterol 57-88-5	-	18 mg/kg bw/day [4] [6]	132 mg/m <sup>3</sup> [4] [6]

### Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Tris(hydroxymethyl)aminomethane hydrochloride 1185-53-1	10.8 mg/kg bw/day [4] [6]	-	37.7 mg/m <sup>3</sup> [4] [6]
Tromethamine 77-86-1	8.3 mg/kg bw/day [4] [6]	-	29 mg/m <sup>3</sup> [4] [6]
Cholesterol 57-88-5	10.7 mg/kg bw/day [4] [6]	-	39 mg/m <sup>3</sup> [4] [6]

### Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Tromethamine 77-86-1	-	-	300 mg/L	-	-

## 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.

### 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).

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<b>Eye/face protection</b>	Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
<b>Hand protection</b>	Wear impervious 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.).
<b>Skin and body protection</b>	Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
<b>Respiratory protection</b>	If operating and handling conditions result in airborne exposure, wear an appropriate respirator with a protection factor sufficient to control exposures (e.g. particulate cartridge with a full face respirator, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
<b>Thermal hazards</b>	No information available.
<b>Environmental exposure controls</b>	No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Liquid
<b>Color</b>	White milky
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Property</b>	<b>Values</b>
<b>Melting point / freezing point</b>	No data available
<b>Boiling point or initial boiling point and boiling range</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower and upper explosion limit/flammability limit</b>	
Lower explosion limit	No data available
Upper explosion limit	No data available
<b>Flash point</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	
SADT (°C)	No data available
<b>pH</b>	No data available
pH (as aqueous solution)	No data available
<b>Kinematic viscosity</b>	No data available
Dynamic viscosity	No data available
<b>Solubility</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Density and/or relative density</b>	No data available
Bulk density	No data available
Liquid Density	No data available
<b>Vapor density</b>	No data available
<b>Particle characteristics</b>	
Particle Size	No information available
Particle Size Distribution	No information available

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

### Tromethamine

Predicted 7.4 Log D -4.668

### Cholesterol

Measured Log P >6.5

## 9.2. Other information

### Molecular formula

Mixture

### Molecular weight

Mixture

### 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 information available.

### 10.2. Chemical stability

#### Stability

Stable under normal conditions.

#### Explosion data

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information 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**

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.



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**Respiratory or skin sensitization** Based on available data, the classification criteria are not met.  
**STOT - single exposure** Based on available data, the classification criteria are not met.  
**STOT - repeated exposure** Based on available data, the classification criteria are not met.  
**Reproductive toxicity** Based on available data, the classification criteria are not met.  
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.  
**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Aspiration hazard** Based on available data, the classification criteria are not met.

## **Acute Toxicity: (Species, Route, End Point, Dose)**

### **Sucrose**

Rat Oral LD 50 29,700 mg/kg

### **Tromethamine**

Rat Oral LD50 5900 mg/kg

Rat Dermal LD 50 > 5000 mg/kg

### **Cholesterol**

Rat Oral LD50 > 2000 mg/kg

Rat Dermal LD50 > 2000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Sucrose	= 29700 mg/kg ( Rat )	-	-
Tromethamine	= 5900 mg/kg ( Rat )	> 5000 mg/kg ( Rat )	-
Cholesterol	>2000 mg/kg (Rat)	> 2000 mg/kg ( Rat )	-

## **Unknown acute toxicity**

0.5 - 1.0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

0.5 - 1.0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

0.5 - 1.0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

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

### **Tromethamine**

Eye Irritation Rabbit Slight

Skin Irritation Rabbit Slight

### **Cholesterol**

Skin irritation Epidermal Non-irritating

Eye irritation Rabbit Non-irritating

Skin Sensitization - LLNA Mouse Negative

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

### **Cholesterol**

24 Week(s) Mouse Oral, in feed 1 % LOAEL Liver

### **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.

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

### **Tromethamine**

Bacterial Mutagenicity (Ames) *E. coli* Negative

### **Cholesterol**

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

## **Carcinogenicity**

See below

### **Cholesterol**

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## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 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.

**Unknown aquatic toxicity** Contains 0.5 - 1.0 % of components with unknown hazards to the aquatic environment.

### 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

##### Cholesterol

Measured Log P >6.5

### 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
Tromethamine	Not PBT/vPvB PBT assessment does not apply
Tris(hydroxymethyl)aminomethane hydrochloride	Not PBT/vPvB PBT assessment does not apply
Cholesterol	Not PBT/vPvB

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## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable

## Section 15: REGULATORY INFORMATION

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

Water

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

Sucrose

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present

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<b>EINECS</b>	200-334-9
<b>AICS</b>	Present
ALC-0315	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Tromethamine	
<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
Tris(hydroxymethyl)aminomethane hydrochloride	
<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
PF-08152264	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Cholesterol	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-353-2
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4
ALC-0159	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
1,2-Distearoyl-sn-glycero-3-phosphocholine	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	212-440-2

## National regulations

### Germany

**Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

**TRGS 905**

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material** Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20** Not applicable

**Major Accidents Ordinance SR 814.012** Not applicable

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## 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 (EU) 2024/590

Not applicable.

### EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sucrose 57-50-1	Plant protection agent

### Explosives Precursors Marketing and Use (2019/1148)

Not applicable

#### Legend:

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

**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

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

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TCSI** - Taiwan Chemical Substance Inventory

### 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** 20-Aug-2025

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## Prepared By

Pfizer Global Environment, Health, and Safety

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