



# SAFETY DATA SHEET

Revision date 14-Jun-2025

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

### 1.1. Product identifier

**Product Name** Diltiazem Hydrochloride Capsules  
**Product Code(s)** PZ00106  
**Trade Name:** Dilzem  
**Chemical Family:** Mixture

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

**Recommended Use** Pharmaceutical product used for angina high blood pressure (hypertension)

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

**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: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Acute toxicity - Oral**

Category 4 - (H302)

**Serious eye damage/eye irritation**

Category 2A - (H319)

**Reproductive toxicity**

Category 1B - (H360D)

### 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



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## Signal word

Danger

## Hazard statements

H302 - Harmful if swallowed  
H319 - Causes serious eye irritation  
H360D - May damage the unborn child

## Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 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

#### Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Diltiazem Hydrochloride (CAS #: 33286-22-5)	43.65		251-443-3	Acute Tox.4 (H302) Repr.1B (H360D)	Not classified	No data available	No data available

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Talc (non-asbestiform) (CAS #: 14807-96-6)	*	-	238-877-9	Not classified	Not classified	No data available	No data available
Fumaric acid (CAS #: 110-17-8)	10-15		203-743-0 (607-146-00-X)	Eye Irrit. 2A (H319)	Not classified	No data available	No data available
Sucrose (CAS #: 57-50-1)	*	-	200-334-9	Not classified	Not classified	No data available	No data available
Starch (CAS #: 9005-25-8)	*	-	232-679-6	Not classified	Not classified	No data available	No data available

## NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Povidone (CAS #: 9003-39-8)	*	-	Not Listed	Not classified	Not classified	No data available	No data available
Methacrylic acid copolymer (CAS #: 25086-15-1)	*		Not Listed	Not classified	Not classified	No data available	No data available
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Ammonio methacrylate copolymer (CAS #: 33434-24-1)	*		Not Listed	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate No information available

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
Diltiazem Hydrochloride 33286-22-5	560	271	No data available	No data available	No data available
Fumaric acid 110-17-8	9300	20000	1.306	No data available	No data available
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
Povidone 9003-39-8	100000	No data available	No data available	No data available	No data available
Water 7732-18-5	89838.9	No data available	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

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR

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1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	If symptoms persist, call a physician.
Skin contact	Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.
Ingestion	Get medical attention. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

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

Note to physicians	None.
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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

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

Specific hazards arising from the chemical	Not applicable.
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.
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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

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**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 contaminated surface 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** Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use only with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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 as directed by product packaging.

### **7.3. Specific end use(s)**

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

#### **Diltiazem Hydrochloride**

Pfizer OEL TWA-8 Hr: 70 µg/m<sup>3</sup>

#### **Talc (non-asbestiform)**

ACGIH TLV

Austria  
Bulgaria

Czech Republic  
Denmark

Finland

TWA: 2 mg/m<sup>3</sup> particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter  
TWA-TMW: 2 mg/m<sup>3</sup>; respirable fraction  
TWA: 1.0 fiber/cm<sup>3</sup>; respirable fraction, fibers  
TWA: 6.0 mg/m<sup>3</sup>; inhalable fraction  
TWA: 3.0 mg/m<sup>3</sup>; respirable fraction  
2.0 mg/m<sup>3</sup>  
TWA: 0.003 fiber/cm<sup>3</sup>;  
STEL: 0.006 fiber/cm<sup>3</sup>;  
TWA: 0.5 fiber/cm<sup>3</sup>;  
TWA: 2 mg/m<sup>3</sup>; inhalable dust

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Germany TRGS	TWA: 1 mg/m <sup>3</sup> ; respirable dust TWA-AGW; 1.25 mg/m <sup>3</sup> (exposure factor 2); respirable fraction TWA-AGW; 10 mg/m <sup>3</sup> (exposure factor 2); inhalable fraction
Hungary	TWA-AK: 2 mg/m <sup>3</sup> ; respirable concentration
Ireland	TWA: 10 mg/m <sup>3</sup> ; total inhalable dust TWA: 0.8 mg/m <sup>3</sup> ; respirable dust STEL: 30 mg/m <sup>3</sup> (calculated); respirable dust STEL: 2.4 mg/m <sup>3</sup> (calculated);
Netherlands	TWA: 0.25 mg/m <sup>3</sup> ; respirable
Poland	TWA-NDS: 4 mg/m <sup>3</sup> ; inhalable fraction TWA-NDS: 1 mg/m <sup>3</sup> ; respirable fraction
Romania	TWA: 2 mg/m <sup>3</sup> ; dust, respirable fraction
Slovakia	Ceiling: 10 mg/m <sup>3</sup> ; solid aerosol
Spain	TWA-(VLA-ED): 2 mg/m <sup>3</sup> ; respirable fraction
Switzerland	TWA-MAK: 3 mg/m <sup>3</sup> ; respirable dust TWA-MAK: 10 mg/m <sup>3</sup> ; fume, respirable dust
OSHA PEL	TWA: 20 mppcf if 1% Quartz or more, use Quartz limit (vacated) TWA: 2 mg/m <sup>3</sup> respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more, use Quartz limit TWA: 1 mg/m <sup>3</sup> ; respirable dust STEL: 3 mg/m <sup>3</sup> ; respirable dust
United Kingdom	
<b>Fumaric acid</b>	
Russia	MAC: 5 mg/m <sup>3</sup>
<b>Sucrose</b>	
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> ;
Latvia	STEL: 20 mg/m <sup>3</sup> ;
Spain	TWA: 5 mg/m <sup>3</sup> ; dust
OSHA PEL	TWA-(VLA-ED): 10 mg/m <sup>3</sup> ;
	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 TWA: 10 mg/m <sup>3</sup> ;
United Kingdom	STEL: 20 mg/m <sup>3</sup> ;
<b>Povidone</b>	
Russia	MAC: 10 mg/m <sup>3</sup>
<b>Methacrylic acid copolymer</b>	
Switzerland	S
<b>Starch</b>	
ACGIH TLV	TWA: 10 mg/m <sup>3</sup>
Bulgaria	TWA: 10.0 mg/m <sup>3</sup> ; dust, inhalable fraction
Czech Republic	4.0 mg/m <sup>3</sup>
Ireland	TWA: 10 mg/m <sup>3</sup> ; total inhalable dust TWA: 4 mg/m <sup>3</sup> ; respirable dust STEL: 30 mg/m <sup>3</sup> (calculated); respirable dust STEL: 12 mg/m <sup>3</sup> (calculated); MAC: 10 mg/m <sup>3</sup>
Russia	TWA-(VLA-ED): 10 mg/m <sup>3</sup> ;
Spain	TWA-MAK: 3 mg/m <sup>3</sup> ; respirable dust
Switzerland	TWA: 15 mg/m <sup>3</sup> total dust
OSHA PEL	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

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United Kingdom

TWA: 10 mg/m<sup>3</sup>; total inhalable  
TWA: 4 mg/m<sup>3</sup>; respirable  
STEL: 30 mg/m<sup>3</sup>; total inhalable  
STEL: 12 mg/m<sup>3</sup>; respirable

## 8.2. Exposure controls

### Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

### 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 or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

### Hand protection

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

### Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (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 Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

### Thermal hazards

No information available.

### Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

#### Appearance

Capsule

#### Physical state

Solid

#### Color

No information available

#### Odor

No information available.

#### Odor threshold

No information available

#### Property

#### Values

#### Melting point / freezing point

No data available

#### Boiling point or initial boiling point and boiling range

No data available

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Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

## 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.
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### 10.2. Chemical stability

Stability	Stable under normal conditions.
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#### 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.
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### 10.4. Conditions to avoid

Conditions to avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
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### 10.5. Incompatible materials

Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
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### 10.6. Hazardous decomposition products

Hazardous decomposition products	No data available.
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## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008



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<b>General Information:</b>	There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	May cause eye irritation (based on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.
<b>Long Term:</b>	Animal studies indicate that this material may cause adverse effects on the fetus
<b>Known Clinical Effects:</b>	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, fatigue, hypotension (low blood pressure), edema and dyspnea.
<b>Acute toxicity</b>	Classification is based on mixture calculation methods based on component data
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Classification is based on mixture calculation methods based on component data.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

### **Diltiazem Hydrochloride**

Rat Oral LD50 560 mg/kg  
Rat Para-periosteal LD50 38 mg/kg  
Rat Subcutaneous LD50 520 mg/kg  
Mouse Oral LD50 508 mg/kg  
Mouse Intravenous LD50 58 mg/kg

### **Talc (non-asbestiform)**

Rat Oral LD50 > 1600 mg/kg

### **Sucrose**

Rat Oral LD 50 29,700 mg/kg

### **Povidone**

Rat Oral LD50 100 g/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Diltiazem Hydrochloride	= 560 mg/kg ( Rat )	= 271 mg/kg ( Rat )	-
Fumaric acid	= 9300 mg/kg ( Rat )	> 20000 mg/kg ( Rabbit )	> 1.306 mg/L ( Rat ) 4 h
Sucrose	= 29700 mg/kg ( Rat )	-	-
Povidone	= 100 g/kg ( Rat )	-	-
Water	> 90 mL/kg ( Rat )	-	-

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

### **Fumaric acid**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

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

### **Diltiazem Hydrochloride**

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1 Month(s) Rat Oral 100 mg/kg/day NOAEL Liver, Blood, Heart  
1 Month(s) Dog Oral 5 mg/kg/day NOAEL Kidney, Heart  
6 Month(s) Dog Oral 10 mg/kg/day LOAEL Heart, Liver, Cardiovascular system  
1 Year(s) Dog Oral 5 mg/kg/day LOAEL Cardiovascular system, Heart  
6 Month(s) Rat Oral 10 mg/kg/day NOAEL None identified

## **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Diltiazem Hydrochloride**

Reproductive & Fertility Rat Oral 50 mg/kg/day NOAEL Fertility  
Embryo / Fetal Development Mouse Oral 25 mg/kg/day LOAEL Embryotoxicity  
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Fetotoxicity  
Embryo / Fetal Development Rabbit Intraperitoneal 6.3 mg/kg/day LOAEL Fetotoxicity, Teratogenic  
Embryo / Fetal Development Rabbit Oral 17.5 mg/kg/day NOAEL Fetotoxicity, Teratogenic

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

### **Diltiazem Hydrochloride**

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Mammalian Cell Mutagenicity Negative  
*In Vitro* Mammalian Cell Mutagenicity Negative

## **Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Diltiazem Hydrochloride**

21 Month(s) Mouse Oral 30 mg/kg/day NOAEL Not carcinogenic  
24 Month(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

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

### **Talc (non-asbestiform)**

IARC Group 2A

### **Povidone**

IARC Group 3

## **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 thoroughly investigated. Releases to the environment should be avoided.

### **12.1. Toxicity**

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

**Persistence and degradability** No information available.

### **12.3. Bioaccumulative potential**

**Bioaccumulation** No information available.

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## 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
Talc (non-asbestiform)	Not PBT/vPvB
Fumaric acid	Not PBT/vPvB PBT assessment does not apply

## 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

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

Diltiazem Hydrochloride

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Developmental
<b>EINECS</b>	251-443-3

Talc (non-asbestiform)

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	238-877-9
<b>AICS</b>	Present

Fumaric acid

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	203-743-0
<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
<b>AICS</b>	Present

Povidone

<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

Methacrylic acid copolymer

<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

Starch

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	232-679-6
<b>AICS</b>	Present

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

Ammonio methacrylate coploymer

<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

### National regulations

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Chemical name	French RG number
Talc (non-asbestiform) 14807-96-6	RG 25

## 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

## **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)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Fumaric acid 110-17-8	75	-

## **Persistent Organic Pollutants**

Not applicable

## **Ozone-depleting substances (ODS) Regulation (EU) 2024/590**

Not applicable.

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Talc (non-asbestiform) 14807-96-6	Plant protection agent
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

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**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**

#### **Full text of any hazard and/or precautionary statements referred to under Sections 2-15**

H302 - Harmful if swallowed H360D - May damage the unborn child H319 - Causes serious eye irritation

**Data Sources:** Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 14-Jun-2025

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

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