



SAFETY DATA SHEET

Revision date 14-Jun-2025

Version 5

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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

Hazard statements

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

Precautionary Statements - EU (§28, P201 - Obtain special instructions before use

1272/2008)

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 >=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, CO ₂ , 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.
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Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
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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.
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For emergency responders	Use personal protection recommended in Section 8.
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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/m³

Talc (non-asbestiform)

ACGIH TLV

Austria
Bulgaria

Czech Republic
Denmark

Finland

TWA: 2 mg/m³ particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter
TWA-TMW: 2 mg/m³; respirable fraction
TWA: 1.0 fiber/cm³; respirable fraction, fibers
TWA: 6.0 mg/m³; inhalable fraction
TWA: 3.0 mg/m³; respirable fraction
2.0 mg/m³
TWA: 0.003 fiber/cm³;
STEL: 0.006 fiber/cm³;
TWA: 0.5 fiber/cm³;
TWA: 2 mg/m³; inhalable dust

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

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United Kingdom

TWA: 10 mg/m³; total inhalable
TWA: 4 mg/m³; respirable
STEL: 30 mg/m³; total inhalable
STEL: 12 mg/m³; 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

Melting point / freezing point
Boiling point or initial boiling point and boiling range

Values

No data available
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.

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 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

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General Information:

There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients

Short term

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.

Long Term:

Known Clinical Effects:

Animal studies indicate that this material may cause adverse effects on the fetus
Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, fatigue, hypotension (low blood pressure), edema and dyspnea.

Acute toxicity

Serious eye damage/eye irritation

Skin corrosion/irritation

Respiratory or skin sensitization

STOT - single exposure

STOT - repeated exposure

Reproductive toxicity

Germ cell mutagenicity

Carcinogenicity

Aspiration hazard

Classification is based on mixture calculation methods based on component data

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

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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.

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

Section 15: REGULATORY INFORMATION

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

Diltiazem Hydrochloride

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

Talc (non-asbestiform)

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

Fumaric acid

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

Sucrose

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

Povidone

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS Not Listed
AICS Present

Methacrylic acid copolymer

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS Not Listed
AICS Present

Starch

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

Water

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

Ammonio methacrylate copolymer

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS Not Listed
AICS 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

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

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/NDSL - 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.

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Prepared By Pfizer Global Environment, Health, and Safety

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