



SAFETY DATA SHEET

Revision date: 19-Mar-2014

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: CADUET (AMLODIPINE BESYLATE-ATORVASTATIN CALCIUM) TABLETS: 2.5 MG-40 MG; 5 MG-80 MG

Trade Name: CADUET
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension), high cholesterol (hyperlipidemia)

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Dangerous for the Environment

EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Label Elements

Other Hazards
Australian Hazard Classification (NOHSC):

No data available
Non-Dangerous Goods. Hazardous Substance.

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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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Amlodipine besylate	111470-99-6	Not Listed	N;R50/53 Xn;R22 Xi;R41	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	0.87
Atorvastatin calcium	134523-03-8	Not Listed	R52/53	Aquatic Acute 3; H402 Aquatic Chronic 3; H412	10.85
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Silicon dioxide, NF	7631-86-9	231-545-4	Not Listed	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	Not Listed	*
Opadry blue	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry clear	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*

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.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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

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

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not determined

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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7. HANDLING AND STORAGE

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. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Amlodipine besylate

Pfizer OEL TWA-8 Hr: 100µg/m³

Atorvastatin calcium

Pfizer OEL TWA-8 Hr: 50 µg/m³

Calcium carbonate

Australia TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
France OEL - TWA 10 mg/m³
Latvia OEL - TWA 6 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³
Vietnam OEL - TWAs 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³

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Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
	5 mg/m ³
Silicon dioxide, NF	
Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 mg/m ³
	0.3 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Finland OEL - TWA	5 mg/m ³
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³
Ireland OEL - TWAs	6 mg/m ³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m ³
Switzerland OEL -TWAs	4 mg/m ³
	0.3 mg/m ³
Starch, pregelatinized	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
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).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Film-coated tablets	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

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

Atorvastatin calcium

No data available

Calcium carbonate

No data available

Microcrystalline cellulose

No data available

Starch, pregelatinized

No data available

Croscarmellose sodium

No data available

Hydroxypropyl cellulose

No data available

Magnesium stearate

No data available

Silicon dioxide, NF

No data available

Polysorbate 80

No data available

Opadry blue

No data available

Opadry white

No data available

Opadry clear

No data available

Amlodipine besylate

Measured 7 Log P 1.33

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

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Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available
Polymerization:	Will not occur

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye irritation May be harmful if swallowed. (based on components)
Antihypertensive drug: has blood pressure-lowering properties

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver

Known Clinical Effects: Adverse effects associated with therapeutic use of amlodipine include headache, swelling, dizziness, flushing, and palpitations. The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Therapeutic use of atorvastatin has been associated with changes in liver function and muscle aches or weakness.

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

Atorvastatin calcium

Rat/Mouse	Oral	LD50	> 5000 mg/kg
Rabbit	Dermal	LD50	> 2000mg/kg

Calcium carbonate

Rat	Oral	LD50	6450 mg/kg
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Microcrystalline cellulose

Rat	Oral	LD50	> 5000 mg/kg
Rabbit	Dermal	LD50	> 2000 mg/kg

Magnesium stearate

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m ³

Polysorbate 80

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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 25 g/kg

Amlodipine besylate

Rat (M) Oral LD50 393 mg/kg

Rat (F) Oral LD50 686mg/kg

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)

Atorvastatin calcium

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Mild

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Amlodipine besylate

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

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

Atorvastatin calcium

104 Week(s) Dog Oral 10 mg/kg/day LOAEL Liver

13 Week(s) Mouse Oral 100 mg/kg/day LOAEL Liver

52 Week(s) Rat Oral 5 mg/kg/day NOAEL Liver

13 Week(s) Rat Oral 5 (male); 20 (female) mg/kg/day NOAEL Liver

Amlodipine besylate

3 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Heart

1 Month(s) Rat Oral 3.5 mg/kg/day LOEL Heart

1 Year(s) Rat Oral 2 mg/kg/day NOAEL Adrenal gland, Heart

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Atorvastatin calcium

Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative

Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Negative

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity

Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity

Peri-/Postnatal Development Rat Oral 20 mg/kg/day NOAEL Fetotoxicity

Amlodipine besylate

Fertility and Embryonic Development Rat Oral 25 mg/kg/day NOAEL Not teratogenic, Maternal toxicity

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Peri-/Postnatal Development	Rat	Oral	4 mg/kg/day	NOAEL	Fetotoxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	25 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Rabbit	Oral	25 mg/kg/day	NOAEL	Not Teratogenic

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

Atorvastatin calcium

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Amlodipine besylate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vivo Cytogenetics Mouse Bone Marrow Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative

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

Atorvastatin calcium

104 Week(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic
104 Week(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

Amlodipine besylate

24 Month(s) Rat Oral, in feed 2.5 mg/kg/day NOAEL Not carcinogenic, No effects at maximum dose
24 Month(s) Mouse Oral, in feed 0.5 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status:

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

12. ECOLOGICAL INFORMATION

Environmental Overview:

This formulation has not been tested as a whole, the following apply to component substance(s):

Toxicity:

No data available

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Atorvastatin calcium

Daphnia magna (Water Flea) EC50 48 Hours 200 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 92 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EbC50 72 Hours 75 mg/L
Daphnia magna (Water Flea) OECD NOEC 21 Days 0.14 mg/L
Pimephales promelas (Fathead Minnow) OECD NOEC 32 Days 0.45 mg/L

Amlodipine besylate

Daphnia magna (Water Flea) OECD EC50 48 Hours 9.9 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 14 mg/L
Green algae OECD EbC50 72 Hours 0.28 mg/L
Green Algae OECD ErC50 72 Hours > 0.91 mg/L

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Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

Atorvastatin calcium

Aspergillus niger (Fungus) MIC > 1000 mg/L
Trichoderma viride (Fungus) MIC > 1000 mg/L
Clostridium perfringens (Bacterium) MIC 100 mg/L
Activated sludge OECD EC50 >1000 mg/L

Amlodipine besylate

Nostoc sp. (Freshwater Cyanobacteria) MIC 20 mg/L
Aspergillus Niger MIC > 100 mg/L
Trichoderma viride MIC > 100 mg/L
Clostridium perfringens MIC >100 mg/L
Bacillus subtilis MIC 80 mg/L

Persistence and Degradability: No data available

Atorvastatin calcium

TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready
OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready

Amlodipine besylate

OECD Activated sludge Ultimate (CO2 Evolution) 8.11% After 28 Day(s) Not Ready

Atorvastatin calcium

OECD 7 Half-Life 0.339 Day(s)

Bio-accumulative Potential: No data available

Amlodipine besylate

Measured 7 Log P 1.33

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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 waste water 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.

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.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Amlodipine besylate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Atorvastatin calcium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Calcium carbonate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	207-439-9

Croscarmellose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Hydroxypropyl cellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

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Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Magnesium stearate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3
Microcrystalline cellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 12/18/09
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9
Opadry blue	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Opadry clear	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Opadry white	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Silicon dioxide, NF	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4
Starch, pregelatinized	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

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Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

N - Dangerous for the environment
Xi - Irritant
Xn - Harmful

R22 - Harmful if swallowed.
R41 - Risk of serious damage to eyes.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

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Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet