



# MATERIAL SAFETY DATA SHEET

Revision date: 21-Dec-2011

Version: 4.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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

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**Material Name: Caduet® (amlodipine besylate/atorvastatin calcium) Tablets-  
2.5 mg/20 mg, 2.5 mg/40 mg, 5 mg/40 mg, 5 mg/80 mg, and 10 mg/80 mg**

<b>Trade Name:</b>	CADUET
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	Pharmaceutical product for the treatment of high blood pressure (hypertension), high cholesterol (hyperlipidemia).

## 2. HAZARDS IDENTIFICATION

**Appearance:** 2.5 mg/40 mg: White film-coated tablets 5 mg/40 mg: White film-coated tablets 5 mg/80 mg: White film-coated tablets 10 mg/80 mg: Blue film-coated tablets

### Additional Hazard Information:

**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.

### 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.

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Amlodipine besylate	111470-99-6	Not Listed	N;R50/53 Xn;R22 Xi;R41	0.87-1.74
Atorvastatin calcium	134523-03-8	Not Listed	R52/53	10.85
Calcium carbonate	471-34-1	207-439-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Silicon dioxide, NF	7631-86-9	231-545-4 418-260-2	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*

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

#### Additional Information:

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.

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**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Not determined

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**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.

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

**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

**General 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. 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.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<b>Amlodipine besylate</b>	
Pfizer OEL TWA-8 Hr:	100µg/m <sup>3</sup>
<b>Atorvastatin calcium</b>	
Pfizer OEL TWA-8 Hr:	50 µg/m <sup>3</sup>
<b>Calcium carbonate</b>	
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Latvia OEL - TWA	6 mg/m <sup>3</sup>
Poland OEL - TWA	10 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

**Magnesium stearate**

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### Silicon dioxide, NF

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup> inhalable fraction
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
Slovenia OEL - TWA	4 mg/m <sup>3</sup>

#### Starch, pregelatinized

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Film-coated tablets	<b>Color:</b>	White Blue
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

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

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

##### **Atorvastatin calcium**

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

##### **Calcium carbonate**

Rat Oral LD50 6450 mg/kg

##### **Microcrystalline cellulose**

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

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### 11. TOXICOLOGICAL INFORMATION

#### Magnesium stearate

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

#### Silicon dioxide, NF

Rat Oral LD50 10 g/kg

#### Polysorbate 80

Rat Oral LD50 25 g/kg

#### Amlodipine besylate

Rat (M) Oral LD50 393 mg/kg  
Rat (F) Oral LD50 686 mg/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

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### 11. TOXICOLOGICAL INFORMATION

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
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

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

##### Amlodipine besylate

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Cytogenetics	Mouse Bone Marrow	Negative
<i>In Vitro</i> 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.

#### Silicon dioxide, NF

**IARC:** Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

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

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

##### Atorvastatin calcium

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

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### 12. ECOLOGICAL INFORMATION

*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

**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

### 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

**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.

**OSHA Label:**

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision B



#### Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	207-439-9

#### Croscarmellose sodium

Australia (AICS):	Present
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#### Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

#### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

#### Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

#### Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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## 15. REGULATORY INFORMATION

### Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4 418-260-2

### Starch, pregelatinized

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

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

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.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Prepared by:** Product Stewardship Hazard Communication  
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**