



# SAFETY DATA SHEET

Revision date: 08-Mar-2019

Version: 6.2

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

### Product Identifier

**Material Name:** NORVASC (Amlodipine besylate) Tablets

**Trade Name:** NORVASC  
**Synonyms:** Amloc; Amlogard; Amlor; Istin; Lomanor; Norvas; Zorem  
**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as Antianginal; antihypertensive

### 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

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Ramsgate Road  
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**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

Skin Corrosion/Irritation: Category 1

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H318 - Causes serious eye damage

**Precautionary Statements:** P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P310 - Immediately call a POISON CENTRE or doctor/physician



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

**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	GHS Classification	%
Amlodipine besylate	111470-99-6	Not Listed	Acute Tox.4 (H302) Eye Dam.1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	3.5
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium starch glycolate	9063-38-1	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 CLP/GHS abbreviations 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.

**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

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### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.

**Fire / Explosion Hazards:** Not determined

**Advice for Fire-Fighters**

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

### 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. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

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

**Conditions for Safe Storage, Including any Incompatibilities**

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

**Specific end use(s):** Pharmaceutical drug product

### 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/m<sup>3</sup>

**Calcium phosphate dibasic, anhydrous**

Latvia OEL - TWA 10 mg/m<sup>3</sup>

**Microcrystalline cellulose**

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

<b>Magnesium stearate</b>	
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Exposure Controls

<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>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablet	<b>Color:</b>	White
<b>Odor:</b>	Odorless	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Boiling Point (°C):** No data available.

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

**Magnesium stearate**

No data available

**Microcrystalline cellulose**

No data available

**Sodium starch glycolate**

No data available

**Amlodipine besylate**

Measured 7 Log P 1.33

**Calcium phosphate dibasic, anhydrous**

No data available

**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

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

**Known Clinical Effects:** Ingestion of this material may cause effects similar to those seen in clinical use including abdominal pain, dizziness, flushing, heart palpitations, and swelling.

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

**Magnesium stearate**

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### 11. TOXICOLOGICAL INFORMATION

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

#### Microcrystalline cellulose

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

##### 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)

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

##### 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)

##### 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))

##### 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

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. The active ingredient in this formulation may be harmful to aquatic organisms. Releases to the environment should be avoided. See aquatic toxicity data, below:

#### Toxicity:

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

##### 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)

##### 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:**

#### **Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

##### Amlodipine besylate

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

#### **Bio-accumulative Potential:**

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

##### Amlodipine besylate

Measured 7 Log P 1.33

**Mobility in Soil:** No data available

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### 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.

### 15. REGULATORY INFORMATION

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

#### Amlodipine besylate

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

#### Calcium phosphate dibasic, anhydrous

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	231-826-1

#### Sodium starch glycolate

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

#### Microcrystalline cellulose

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



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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 232-674-9

#### 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

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

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

**Data Sources:** Publicly available toxicity information. Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
Updated Section 12 - Ecological Information.

**Revision date:** 08-Mar-2019

Product Stewardship Hazard Communication

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

Pfizer Inc believes that the information contained in this 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**