



# SAFETY DATA SHEET

Revision date: 19-Oct-2018

Version: 2.0

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

### Product Identifier

**Material Name:** Glasdegib Film-Coated Tablets

**Trade Name:** DAURISMO  
**Compound Number:** PF-04449913  
**Synonyms:** Glasdegib  
**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical product

### 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

Reproductive Toxicity: Category 2  
Specific target organ systemic toxicity (repeated exposure): Category 2

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** H361d - Suspected of damaging the unborn child  
H373 - May cause damage to organs through prolonged or repeated exposure: kidneys, reproductive system.

**Precautionary Statements:** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations

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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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	%
Glasdegib	1095173-27-5	Not Listed	STOT RE 2 (H373) Repr 2 (H361d)	20-30
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	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.

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**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 CO<sub>2</sub>, 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. May include oxides of carbon and nitrogen.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all firefighting 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 the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum 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 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.

### Conditions for Safe Storage, Including any Incompatibilities

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

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Glasdegib

Pfizer OEL TWA-8 Hr: 4 µg/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>

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>

#### Magnesium Stearate

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Polyethylene glycol

Austria OEL - MAKs 1000 mg/m<sup>3</sup>

Germany - TRGS 900 - TWAs 1000 mg/m<sup>3</sup>

Germany (DFG) - MAK 1000 mg/m<sup>3</sup> average molecular weight 200-600

Slovakia OEL - TWA 1000 mg/m<sup>3</sup>

Slovenia OEL - TWA 1000 mg/m<sup>3</sup>

Switzerland OEL -TWAs 1000 mg/m<sup>3</sup>

#### Titanium dioxide

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

Australia TWA 10 mg/m<sup>3</sup>

Austria OEL - MAKs 5 mg/m<sup>3</sup>

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

Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>

Denmark OEL - TWA 6 mg/m<sup>3</sup>

Estonia OEL - TWA 5 mg/m<sup>3</sup>

France OEL - TWA 10 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>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELS - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 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	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	6 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

**Ferric oxide red**

ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup>
Australia TWA	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Belgium OEL - TWA	5 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5.0 mg/m <sup>3</sup>
Denmark OEL - TWA	3.5 mg/m <sup>3</sup>
Estonia OEL - TWA	3.5 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	5 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Hungary OEL - TWA	6 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Lithuania OEL - TWA	3.5 mg/m <sup>3</sup>
OSHA - Final PELS - TWAs:	10 mg/m <sup>3</sup>
	15 mg/m <sup>3</sup>
Poland OEL - TWA	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 mg/m <sup>3</sup>
Romania OEL - TWA	5 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Slovakia OEL - TWA	1.5 mg/m <sup>3</sup>
Spain OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	3.5 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 mg/m <sup>3</sup>

**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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Hands:</b>	Impervious disposable gloves (e.g. Nitrile, etc.) (double 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 disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Film-coated tablets	<b>Color:</b>	Yellow or Pale orange
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

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

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

**Glasdegib**

Predicted 7.4 Log D 2.59

**Microcrystalline cellulose**

No data available

**Calcium phosphate dibasic, anhydrous**

No data available

**Sodium starch glycolate**

No data available

**Magnesium Stearate**

No data available

**Titanium dioxide**

No data available

**Lactose Monohydrate**

No data available

**Polyethylene glycol**

No data available

**Triacetin**

No data available

**Ferric oxide yellow**

No data available

**Hydroxypropyl methylcellulose**

No data available

**Ferric oxide red**

No data available

**PF-04449913-01**

No data available

**PF-04449913-11**

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**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:**

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 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 in this section describes the hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus.

**Known Clinical Effects:** Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: fatigue, nausea, lack of appetite, impairment of male fertility dizziness, diarrhea, dehydration, vomiting, loss of hair, excessive muscle movement and neutropenia.

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

**Microcrystalline cellulose**

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

**Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD50 50 mg/kg

**Lactose Monohydrate**

Rat Oral LD 50 29700 mg/kg

**Triacetin**

Rat Oral LD 50 3000 mg/kg  
Mouse Oral LD 50 1100mg/kg

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### 11. TOXICOLOGICAL INFORMATION

#### Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 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.

**Safety Pharmacology:** **PF-04449913:** *In vitro* Cardiovascular Respiratory and Neurofunctional not significant  
**PF-04449913-01:** *In vivo* Cardiovascular increased QT interval QTc interval (5 mg/kg or greater) Pulmonary not significant

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

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

##### Polyethylene glycol

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

##### PF-04449913-11

Skin Corrosivity (*In vitro*, RHE) Not applicable Negative  
Eye Irritation (*In vitro*, BCOP) Not applicable Negative  
Skin Irritation Rabbit Negative  
Eye Irritation Rabbit Slight  
Skin Sensitization - LLNA Mouse Negative

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

##### Glasdegib

13 Week(s) Dog Oral 1 mg/kg/day NOAEL Kidney, Liver  
1 Month(s) Rat Oral 10 mg/kg/day NOAEL Kidney, Bone  
7 Day(s) Dog Oral 3 mg/kg/day NOAEL Kidney, Gastrointestinal system  
1 Month(s) Dog Oral 1 mg/kg/day NOAEL Kidney

##### Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

##### PF-04449913-01

10 Day(s) Rat Oral 5 mg/kg/day NOAEL Kidney

##### PF-04449913-11

13 Week(s) Rat Oral 10 mg/kg/day NOAEL Central nervous system, Kidney, Bone growth plate, Teeth  
26 Week(s) Rat Oral 10 mg/kg/day NOAEL Kidney, Reproductive system, Central Nervous System  
39 Week(s) Dog Oral 1 mg/kg/day LOAEL Liver, Kidney, Gastrointestinal system

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

##### PF-04449913-11

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Maternal toxicity  
Embryo / Fetal Development Rat Oral 10 mg/kg/day LOAEL Developmental toxicity  
Embryo / Fetal Development Rabbit Oral 5 mg/kg/day LOAEL Maternal Toxicity, Developmental toxicity



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### 11. TOXICOLOGICAL INFORMATION

**Reproductive & Development Toxicity Comments:** Note: The above reproduction and developmental toxicity studies are based on preliminary information.

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

##### **Glasdegib**

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

##### **Lactose Monohydrate**

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

##### **PF-04449913-01**

*In Vitro* Cytogenetics Human Lymphocytes Negative

#### **Carcinogen Status:**

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

#### **Titanium dioxide**

##### **IARC:**

Group 2B (Possibly Carcinogenic to Humans)

#### **Ferric oxide red**

##### **IARC:**

Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

#### **Toxicity:**

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

##### **PF-04449913-11**

*Tisbe battagliai* (Marine Copepod) OECD LC50 48 Hours 26 mg/L  
*Cyprinodon variegatus* (Sheepshead Minnow) OECD LC50 96 Hours > 100 mg/L  
*Skeletonema costatum* (Marine Diatom) OECD EC50 72 Hours 1.5 mg/L

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

##### **PF-04449913-11**

Activated sludge OECD EC50 110 mg/L

**Persistence and Degradability:** No data available

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

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

##### **Glasdegib**

Predicted 7.4 Log D 2.59

#### **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  
Caution - Substance not fully tested (VIIA)

#### Glasdegib

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

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<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	232-674-9
<b>Magnesium Stearate</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-150-3
<b>Hydroxypropyl methylcellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Lactose Monohydrate</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Polyethylene glycol</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 2
	Schedule 3
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Titanium dioxide</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	carcinogen 9/2/2011 airborne, unbound particles of respirable size
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	236-675-5
<b>Ferric oxide red</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	215-168-2
<b>Triacetin</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present

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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	203-051-9

#### Ferric oxide yellow

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	257-098-5

### 16. OTHER INFORMATION

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

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure  
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date:** 19-Oct-2018

Product Stewardship Hazard Communication

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

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**End of Safety Data Sheet**