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**

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

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
### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glasdegib</td>
<td>1095173-27-5</td>
<td>Not Listed</td>
<td>STOT RE 2 (H373) Repr 2 (H361d)</td>
<td>20-30</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Triacetin</td>
<td>102-76-1</td>
<td>203-051-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

**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

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. 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
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/m³

Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA 10 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 - TWA 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
Switzerland OEL - TWAs 3 mg/m³

Vietnam OEL - TWAs 10 mg/m³
5 mg/m³

Magnesium Stearate

Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Polyethylene glycol

Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL - TWAs 1000 mg/m³

Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Denmark OEL - TWA 6 mg/m³
Estonia OEL - TWA 5 mg/m³
France OEL - TWA 10 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³

Ireland OEL - TWAs 10 mg/m³
4 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latvia</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia</td>
<td>10 mg/m³</td>
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<tr>
<td>Spain</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Sweden</td>
<td>5 mg/m³</td>
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<tr>
<td>Switzerland</td>
<td>3 mg/m³</td>
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<tr>
<td>Vietnam</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

Ferric oxide red

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - MAKs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>5.0 mg/m³</td>
</tr>
<tr>
<td>Denmark</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Estonia</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Finland</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Greece</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Hungary</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Ireland</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Lithuania</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Romania</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Russia</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Slovakia</td>
<td>1.5 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** 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.)

**Eyes:** 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.)

**Skin:** 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.)

**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 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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Film-coated tablets</th>
<th>Color:</th>
<th>Yellow or Pale orange</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>Methanol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Glasdegib Predicted 7.4 Log D 2.59</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Glasdegib**

**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
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decomposition Temperature (°C)</td>
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<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
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<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
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<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C)</td>
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<tr>
<td>Flammability (Solids)</td>
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<tr>
<td>Flash Point (Liquid) (°C)</td>
<td>No data available</td>
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<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
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</table>

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

<table>
<thead>
<tr>
<th>General Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term</td>
<td>Animal studies have shown a potential to cause adverse effects on the fetus.</td>
</tr>
<tr>
<td>Known Clinical Effects</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 7500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD50</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>29700 mg/kg</td>
</tr>
<tr>
<td>Triacetin</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>3000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>1100mg/kg</td>
</tr>
</tbody>
</table>

PZ03440
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

PZ03440
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
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
15. REGULATORY INFORMATION

### 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

### Hydroxypropyl methylcellulose
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **Standard for the Uniform Scheduling for Drugs and Poisons**: Schedule 4
- **EU EINECS/ELINCS List**: Not Listed

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

### Polyethylene glycol
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **Standard for the Uniform Scheduling for Drugs and Poisons**: Schedule 2
- **EU EINECS/ELINCS List**: Not Listed

### Titanium dioxide
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Carcinogenic 9/2/2011 airborne, unbound particles of respirable size
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 236-675-5

### Ferric oxide red
- **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**: 215-168-2

### Triacetin
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
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
Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet