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

Product Identifier

Material Name: Bosulif (Bosutinib) Film Coated Tablets

Trade Name: BOSULIF

Chemical Family: Not determined

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

Intended Use: Pharmaceutical product; Antineoplastic

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

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

Skin Sensitization: Category 1
Acute aquatic toxicity: Category 1
Chronic aquatic toxicity: Category 1

Label Elements

Signal Word: Warning

Hazard Statements:
H317 - May cause an allergic skin reaction
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements:
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing must not be allowed out of the workplace
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental first aid instructions on this label)
P363 - Wash contaminated clothing before reuse
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Bosulif (Bosutinib) Film Coated Tablets
Revision date: 22-Oct-2017

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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bosutinib monohydrate</td>
<td>918639-08-4</td>
<td>Not Listed</td>
<td>Skin Sens.1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)</td>
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<tr>
<td>Microcrystalline cellulose</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
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<tr>
<td>Polyethylene glycol</td>
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<td>238-877-9</td>
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<td>215-168-2</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
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<tr>
<td>Poloxamer 188</td>
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<tr>
<td>Magnesium Stearate</td>
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<td>209-150-3</td>
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<tr>
<td>Croscarmellose sodium</td>
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<td>Povidone</td>
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<tr>
<td>Polyvinyl alcohol</td>
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<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.

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 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 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Bosutinib monohydrate</th>
<th>Pfizer OEL TWA-8 Hr:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>ACGIH Threshold Limit Value (TWA) 10 mg/m³</td>
<td>40µg/m³, Sensitizer</td>
</tr>
<tr>
<td></td>
<td>Australia TWA 10 mg/m³</td>
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</tr>
<tr>
<td></td>
<td>Belgium OEL - TWA 10 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Estonia OEL - TWA 10 mg/m³</td>
<td></td>
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<tr>
<td></td>
<td>France OEL - TWA 10 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ireland OEL - TWAs 10 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Latvia OEL - TWA 2 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OSHA - Final PELS - TWAs: 15 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Portugal OEL - TWA 10 mg/m³</td>
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<td></td>
<td>Romania OEL - TWA 10 mg/m³</td>
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<td>Russia OEL - TWA 6 mg/m³</td>
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<td>Spain OEL - TWA 10 mg/m³</td>
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<td></td>
<td>Switzerland OEL -TWAs 3 mg/m³</td>
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<td></td>
<td>Vietnam OEL - TWAs 10 mg/m³</td>
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</tr>
<tr>
<td></td>
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<td>5 mg/m³</td>
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<table>
<thead>
<tr>
<th>Magnesium Stearate</th>
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<tbody>
<tr>
<td></td>
<td>Lithuania OEL - TWA 5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Sweden OEL - TWAs 5 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Titanium dioxide</th>
<th>ACGIH Threshold Limit Value (TWA) 10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Australia TWA 10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Austria OEL - MAKs 5 mg/m³</td>
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<tr>
<td></td>
<td>Belgium OEL - TWA 10 mg/m³</td>
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<td></td>
<td>Bulgaria OEL - TWA 10.0 mg/m³</td>
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<td>Denmark OEL - TWA 6 mg/m³</td>
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<td>France OEL - TWA 10 mg/m³</td>
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<td></td>
<td>Greece OEL - TWA 10 mg/m³</td>
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<td></td>
<td>Ireland OEL - TWAs 10 mg/m³</td>
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<td></td>
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<tr>
<td></td>
<td>Latvia OEL - TWA 10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Lithuania OEL - TWA 5 mg/m³</td>
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<tr>
<td></td>
<td>OSHA - Final PELS - TWAs: 15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Poland OEL - TWA 10.0 mg/m³</td>
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<tr>
<td></td>
<td>Portugal OEL - TWA 10 mg/m³</td>
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<tr>
<td></td>
<td>Romania OEL - TWA 10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Russia OEL - TWA 10 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Talc (non-asbestiform)
- ACGIH Threshold Limit Value (TWA): 2 mg/m³
- Australia TWA: 2.5 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Belgium OEL - TWA: 2 mg/m³
- Bulgaria OEL - TWA: 1.0 fiber/cm³
- 6.0 mg/m³
- 3.0 mg/m³
- Czech Republic OEL - TWA: 2.0 mg/m³
- Denmark OEL - TWA: 0.3 fiber/cm³
- Finland OEL - TWA: 0.5 fiber/cm³
- Greece OEL - TWA: 10 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- 0.8 mg/m³
- Lithuania OEL - TWA: 2 mg/m³
- 1 mg/m³
- Netherlands OEL - TWA: 0.25 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Poland OEL - TWA: 4.0 mg/m³
- 1.0 mg/m³
- Portugal OEL - TWA: 2 mg/m³
- Romania OEL - TWA: 2 mg/m³
- Slovakia OEL - TWA: 2 mg/m³
- 10 mg/m³
- Slovenia OEL - TWA: 2 mg/m³
- Spain OEL - TWA: 2 mg/m³
- Sweden OEL - TWAs: 2 mg/m³
- 1 mg/m³
- Switzerland OEL - TWAs: 2 mg/m³

Ferric oxide red
- ACGIH Threshold Limit Value (TWA): 5 mg/m³
- Australia TWA: 5 mg/m³
- Austria OEL - MAKs: 5 mg/m³
- Belgium OEL - TWA: 5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Hands: 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.)

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 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 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

Physical State: Tablet
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available

Color: Red and Yellow
Odor Threshold: No data available.
Molecular Weight: Mixture
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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<td>Boiling Point (°C)</td>
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<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
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<td>Povidone</td>
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<tr>
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<td>Polyethylene glycol</td>
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<td>Decomposition Temperature (°C)</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

| Reactivity                            | No data available            |
| Chemical Stability                     | Stable under normal conditions of use. |
| Possibility of Hazardous Reactions     | No data available            |
| 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 minimal eye irritation (based on animal data).

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: nausea, diarrhea, vomiting, fatigue, loss of appetite (anorexia), and skin rash.

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

**Bosutinib monohydrate**

- Mouse Oral LD50 > 2000 mg/kg
- Rat (M) Oral LD50 > 700mg/kg

**Titanium dioxide**

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

**Microcrystalline cellulose**

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

**Talc (non-asbestiform)**

- Rat Oral LD50 > 1600 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)

**Bosutinib monohydrate**

- Skin Corrosivity (In vitro, RHE) Human Negative
- Eye Irritation (In vitro, BCOP) Negative
- Skin Sensitization - LLNA Mouse Positive
- Skin Irritation Rabbit Negative
- Eye Irritation Rabbit Minimal

**Microcrystalline cellulose**

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

**Polyethylene glycol**

- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

**Magnesium Stearate**

- 13 Week(s) Rat Oral 1092 g/kg LOAEL Liver
11. TOXICOLOGICAL INFORMATION

Bosutinib monohydrate
1 Month(s)  Rat  Oral  70 mg/kg/day  NOAEL  No effects at maximum dose
6 Month(s)  Rat  Oral  10 mg/kg/day  NOAEL  Gastrointestinal system
1 Month(s)  Dog  Oral  5 mg/kg/day  NOAEL  No effects at maximum dose
9 Month(s)  Dog  Oral 10 mg/kg/day  NOAEL  No effects at maximum dose

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

Bosutinib monohydrate
Reproductive & Fertility  Rat  Oral 3 mg/kg/day  NOAEL  Embryotoxicity, Maternal toxicity
Embryo / Fetal Development  Rat  Oral 10 mg/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Rabbit  Oral 10 mg/kg/day  NOAEL  Fetotoxicity, Maternal Toxicity

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

Bosutinib monohydrate
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
In Vivo  Micronucleus  Mouse  Negative
In Vitro  Chromosome Aberration  Human Lymphocytes  Negative

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

Bosutinib monohydrate
2 Year(s)  Rat  Oral  (M) 2.5 / (F) 1.5 mg/kg/day  LOAEL  Not carcinogenic, Gastrointestinal system

Carcinogen Status:  None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Povidone
IARC:  Group 3 (Not Classifiable)

Titanium dioxide
IARC:  Group 2B (Possibly Carcinogenic to Humans)

Ferric oxide red
IARC:  Group 3 (Not Classifiable)

Polyvinyl alcohol
IARC:  Group 3 (Not Classifiable)

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients.

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

**Bosutinib monohydrate**
*Pseudokirchineriella subcapitata* (Green Alga) OECD ErC50 72 Hours 0.203 mg/L
*Pimephales promelas* (Fathead Minnow) OECD NOEC 33 Days 0.066 mg/L
*Daphnia Magna* (Water Flea) OECD NOEC 21 Days 0.145 mg/L

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

**Bosutinib monohydrate**
Activated sludge OECD EC50 > 1000 mg/L

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

**Bosutinib monohydrate**
*Eisenia fetida* (Earthworm) LC50 14 Days > 10 mg/kg
*Folsomia candida* (Collembola) OECD NOEC 28 Days 250 mg/kg

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
**Bosutinib monohydrate**
OECD Activated sludge Ultimate (CO2 Evolution) 0.2% After 28 Day(s)

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
**Bosutinib monohydrate**
Measured 8 Log P 3.34

Mobility in Soil:
Sorption: (Method, Inoculum, Sorption Endpoint, Endpoint, Results)
**Bosutinib monohydrate**
OECD Activated sludge Adsorption Kd 3791
OECD Sediment Adsorption Kd 2262

---

**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.

This material is regulated for transportation as a hazardous material/dangerous good.

**UN number:** UN 3077
**UN proper shipping name:** Environmentally Hazardous Substance, Solid, n.o.s (Bosutinib)
**Transport hazard class(es):** 9
**Packing group:** III
5 kg/5L Exception:
UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not regulated as dangerous goods for transport by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

15. REGULATORY INFORMATION

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

Bosutinib monohydrate

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
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
EU EINECS/ELINCS List 232-674-9

Poloxamer 188

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
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

Croscarmellose sodium

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

Povidone

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
15. REGULATORY INFORMATION

<table>
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</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
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: Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.
Revision date: 22-Oct-2017
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet