



# SAFETY DATA SHEET

Revision date: 22-Oct-2017

Version: 6.1

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## 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

**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

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

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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	%
Bosutinib monohydrate	918639-08-4	Not Listed	Skin Sens.1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	69
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Poloxamer 188	106392-12-5	Not Listed	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Polyvinyl alcohol	9002-89-5	Not Listed	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.

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- 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 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.

**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

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**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical drug product Antineoplastic

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Bosutinib monohydrate

Pfizer OEL TWA-8 Hr: 40µg/m<sup>3</sup>, Sensitizer

#### 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>  
Latvia OEL - TWA 4 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 2 mg/m<sup>3</sup>  
Portugal OEL - TWA 15 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 6 mg/m<sup>3</sup>  
Switzerland OEL - TWAs 10 mg/m<sup>3</sup>  
Vietnam OEL - TWAs 3 mg/m<sup>3</sup>  
5 mg/m<sup>3</sup>

#### Magnesium Stearate

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

#### 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>  
Ireland OEL - TWAs 5 mg/m<sup>3</sup>  
Latvia OEL - TWA 10 mg/m<sup>3</sup>  
Lithuania OEL - TWA 4 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 10 mg/m<sup>3</sup>  
Poland OEL - TWA 15 mg/m<sup>3</sup>  
Portugal OEL - TWA 10.0 mg/m<sup>3</sup>  
Romania OEL - TWA 10 mg/m<sup>3</sup>  
Russia OEL - TWA 10 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>

#### 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>

#### Talc (non-asbestiform)

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

##### 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

#### Color:

Red and Yellow

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Water Solubility:** No data available  
**pH:** No data available.  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.  
**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Croscarmellose sodium**

No data available

**Poloxamer 188**

No data available

**Povidone**

No data available

**Magnesium Stearate**

No data available

**Bosutinib monohydrate**

Measured 8 Log P 3.34

**Titanium dioxide**

No data available

**Ferric oxide red**

No data available

**Microcrystalline cellulose**

No data available

**Polyvinyl alcohol**

No data available

**Polyethylene glycol**

No data available

**Talc (non-asbestiform)**

No data available

**Ferric oxide yellow**

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

### 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

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### 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



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### 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)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
<i>In Vitro</i> 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
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#### 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:

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

#### **Bosutinib monohydrate**

*Pseudokirchneriella 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 foetida* (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

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### 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

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### 15. REGULATORY INFORMATION

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Polyvinyl alcohol</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>	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>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>Talc (non-asbestiform)</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>	238-877-9
<b>Ferric oxide yellow</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>	257-098-5
<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

### 16. OTHER INFORMATION

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

## SAFETY DATA SHEET

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

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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

Product Stewardship Hazard Communication

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

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**End of Safety Data Sheet**