



MATERIAL SAFETY DATA SHEET

Revision date: 10-Aug-2012

Version: 4.0

Page 1 of 7

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

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Material Name: Bosulif (Bosutinib) Film Coated Tablets

Trade Name:	BOSULIF
Compound Number:	WAY-173606; SKI-606
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Red and yellow tablet
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.
Very toxic to aquatic life with long lasting effects.

Additional Hazard Information:
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.

EU Indication of danger: Irritant
Dangerous for the Environment



EU Risk Phrases: R43 - May cause sensitization by skin contact.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Australian Hazard Classification (NOHSC): Hazardous Substance. Dangerous Goods.

MATERIAL SAFETY DATA SHEET

Material Name: Bosulif (Bosutinib) Film Coated Tablets
Revision date: 10-Aug-2012

Page 2 of 7
Version: 4.0

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Bosutinib monohydrate	918639-08-4	Not Listed	Xi;R43 N;R50/53	69

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Opadry II yellow	Not Assigned	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Opadry II Red	Not Assigned	Not Listed	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Poloxamer 188	106392-12-5	Not Listed	Not Listed	*
Cellulose microcrystalline	9004-34-4	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

MATERIAL SAFETY DATA SHEET

Material Name: **Bosulif (Bosutinib) Film Coated Tablets**
Revision date: 10-Aug-2012

Page 3 of 7
Version: 4.0

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Bosutinib monohydrate
Pfizer OEL TWA-8 Hr: 40µg/m³, Sensitizer

Magnesium Stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

MATERIAL SAFETY DATA SHEET

Material Name: **Bosulif (Bosutinib) Film Coated Tablets**
Revision date: 10-Aug-2012

Page 4 of 7
Version: 4.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	Red and Yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Bosutinib monohydrate

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

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

Magnesium Stearate

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

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

MATERIAL SAFETY DATA SHEET

Material Name: Bosulif (Bosutinib) Film Coated Tablets
Revision date: 10-Aug-2012

Page 5 of 7
Version: 4.0

11. TOXICOLOGICAL INFORMATION

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 of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Povidone

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.

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

Bosutinib monohydrate

<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	ErC50	72 Hours	0.203 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	OECD	NOEC	33 Days	0.066 mg/L
<i>Daphnia Magna</i> (Water Flea)	OECD	NOEC	21 Days	0.145 mg/L

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

MATERIAL SAFETY DATA SHEET

Material Name: Bosulif (Bosutinib) Film Coated Tablets
Revision date: 10-Aug-2012

Page 6 of 7
Version: 4.0

UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Bosutinib)
Transport hazard class(es): 9
Packing group: III

15. REGULATORY INFORMATION

EU Symbol: Xi N
EU Indication of danger: Irritant
Dangerous for the Environment

EU Risk Phrases:
R43 - May cause sensitization by skin contact.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.
S57 - Use appropriate containment to avoid environmental contamination.
S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.

OSHA Label:
WARNING
May cause allergic skin reaction.
Very toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2b toxic materials



Croscarmellose sodium	
Australia (AICS):	Present
Povidone	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Magnesium Stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

MATERIAL SAFETY DATA SHEET

Material Name: **Bosulif (Bosutinib) Film Coated Tablets**
Revision date: 10-Aug-2012

Page 7 of 7
Version: 4.0

15. REGULATORY INFORMATION

Lactose NF, monohydrate

Australia (AICS): Present

Poloxamer 188

Australia (AICS): Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Reasons for Revision: Updated Section 14 - Transport Information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet