

## Safety Data Sheet



<b>1. IDENTIFICATION</b>											
<i>Product Information</i>											
Product name	SPRYCEL® (dasatinib) Tablets, 20, 50, 70, 80, 100 and 140 mg										
Version	3.0, 15.05.2013										
Jurisdiction	This Safety Data Sheet was prepared in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN). The following countries utilize the UN GHS classification process: Mexico, Brazil, China, New Zealand, Canada, Japan, Korea and Australia.										
Active substance	Dasatinib										
Synonyms	Dasatinib 20, 50, 70, 80, 100 and 140 mg Tablets; BMS-354825-03 Tablets 20, 50, 70, 80, 100 and 140 mg										
Intended Uses	This material is a finished drug product for patient use. It is used in the treatment of cancer.										
<i>Company/Undertaking Identification</i>											
Address	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><u>USA</u></td> <td style="width: 33%;"><u>Ireland</u></td> </tr> <tr> <td><b>Bristol-Myers Squibb Company</b></td> <td><b>Bristol-Myers Squibb Company</b></td> </tr> <tr> <td>P.O. Box 191</td> <td>Swords Laboratories, Watery Lane</td> </tr> <tr> <td>New Brunswick, New Jersey 08903</td> <td>Swords, Ireland</td> </tr> <tr> <td>United States of America</td> <td>MG-GBS-MSDS-Request@bms.com</td> </tr> </table>	<u>USA</u>	<u>Ireland</u>	<b>Bristol-Myers Squibb Company</b>	<b>Bristol-Myers Squibb Company</b>	P.O. Box 191	Swords Laboratories, Watery Lane	New Brunswick, New Jersey 08903	Swords, Ireland	United States of America	MG-GBS-MSDS-Request@bms.com
<u>USA</u>	<u>Ireland</u>										
<b>Bristol-Myers Squibb Company</b>	<b>Bristol-Myers Squibb Company</b>										
P.O. Box 191	Swords Laboratories, Watery Lane										
New Brunswick, New Jersey 08903	Swords, Ireland										
United States of America	MG-GBS-MSDS-Request@bms.com										
Emergency Phone Number	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300</td> <td style="width: 33%;"><u>Ireland</u>: 353-1813-9456</td> </tr> <tr> <td colspan="2">Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.</td> </tr> </table>	USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300	<u>Ireland</u> : 353-1813-9456	Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.							
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Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.											

<b>2. HAZARDS IDENTIFICATION</b>	
<b>Classification and Labelling Common to All Jurisdictions</b>	
Classification	Acute Toxicity - Oral - Category 3 Carcinogenicity - Category 2 Toxic To Reproduction - Reproductive Toxicity - Category 2 Toxic To Reproduction - Developmental Toxicity - Category 1B Specific Target Organ Systemic Toxicity (Single Exposure) - Category 3 Specific Target Organ Systemic Toxicity (Repeated Exposure) - Category 1 Hazardous To The Aquatic Environment - Acute Hazard - Category 1 Hazardous To The Aquatic Environment - Chronic Hazard - Category 1
Symbol	
Signal Word	Danger
Hazard Statements	Toxic if swallowed. Suspected of causing cancer. Suspected of damaging fertility (female reproductive toxicity) .

## 2. HAZARDS IDENTIFICATION

	<p>May damage the unborn child (developmental toxicity) .                  May cause respiratory irritation .                  Causes damage to organs (gastrointestinal tract, bone marrow, immune system, lungs, eyes) through prolonged or repeated exposure.                  Very toxic to aquatic life.                  Very toxic to aquatic life with long lasting effects.</p>
Precautionary Statements	<p>Do not breathe dust/fume/gas/mist/vapours/spray.                  Wash thoroughly after handling.                  Do not eat, drink or smoke when using this product.                  Use personal protective equipment as required.                  Obtain special instructions before use.                  Avoid release to the environment.</p>

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS-No.	EU only		
			EINECS/ELINCS/ REACH Registration Number	Symbol(s)/ R-phrase(s)	H-code(s)
<i>Hazardous components</i>					
Dasatinib	25 %	863127-77-9	--	T, Xn, N: R25, R40, R48/25, R50/53, R61, R62	H300 H351 H361f H360D H372 H400 H410
Microcrystalline Cellulose	< 50 %	9004-34-6	232-674-9	Xi: R37	H335
Hydroxypropyl Methylcellulose	< 5 %	9004-65-3	--	--	H372
Titanium Dioxide	< 5 %	13463-67-7	236-675-5	Xi, Xn: R37, R40, R53	H351 H335 H372 H413
<i>Other ingredients</i>					
Non-Hazardous Ingredients	< 20 %	Not available	--	--	--
See section 16 for Symbol, R-phrase and H-code text.					

## 4. FIRST AID MEASURES

Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Discard contaminated clothing or wash before re-use.

<b>4. FIRST AID MEASURES</b>	
Inhalation	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Rinse mouth.
Notes to Physician	Medical conditions aggravated include: liver disorders, vascular disorders, bleeding, oedema. This product has been reported to interact with the following medications: drugs that inhibit cytochrome P-450, cardiovascular drugs, anticoagulants. Refer to Section 11.
Medical Surveillance	The need for a pre-placement physical examination and history for employees with potential exposure to this compound is to be evaluated by a physician that is thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. Baseline testing would include: a complete blood count with differential, a blood test for liver function, EKG. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. It is recommended that the content be similar to the pre-placement exam. Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

<b>5. FIRE-FIGHTING MEASURES</b>	
Flammable Properties	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Highly Toxic Developmental toxicant Reproductive Toxicity Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), nitrogen oxides (NOx), trace magnesium, trace titanium, sulphur compounds, and, gaseous hydrogen chloride (HCl). Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.
Other information	Decontaminate protective clothing and equipment before reuse.

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
Personal precautions	Refer to protective measures listed in sections 7 and 8. If tablets are unbroken wear gloves, safety glasses and a lab coat to pick-up. If tablets are crushed, broken or chipped, wear gloves, safety glasses, a labcoat, shoe covers and appropriate respirator for pick-up of the spilled material.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Wet down any dust to prevent generation of aerosols, if appropriate. Cover with suitable material.
Cleanup Methods	Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. (This applies for crushed, broken or chipped tablets.) Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

**7. HANDLING AND STORAGE**

Handling Precautions	Highly potent material. Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Container Requirements	Store in the original primary packaging as provided. Keep container tightly closed.
Storage Conditions	Store at room temperature. 15 - 30°C Protect against light. Keep away from heat, sparks and flames. Do not store near incompatible substances.
Specific use(s)	Refer to Section 1

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Dasatinib	3 µg/m <sup>3</sup> 8 hour-TWA	--	--	--
Microcrystalline Cellulose		10 mg/m <sup>3</sup> TWA	--	--
Titanium Dioxide		10 mg/m <sup>3</sup> TWA	--	--
Magnesium Stearate		10 mg/m <sup>3</sup> TWA	--	--
Microcrystalline Cellulose	Occupational Exposure Limits have been established by: - Belgium - Switzerland - Estonia - Spain - France - Ireland - Portugal			
Titanium Dioxide	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Denmark - Estonia - Spain - France - Greece - Ireland - Norway - Poland - Portugal - Sweden			
Magnesium Stearate	Occupational Exposure Limits have been established by: - Belgium - Spain - Ireland - Portugal - Sweden			
Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at 732-227-6338.			

**EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED**

**SPRYCEL® (dasatinib) Tablets, 20, 50, 70, 80, 100 and 140 mg**  
**4** -- Material is assigned to Exposure Control Band 4 (range 1 - <10 µg/m<sup>3</sup>).

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls and Ventilation	<p>FOR CLINICAL SETTING USE (DRUG PRODUCT): Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 3 milligrams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling quantities up to 1 kilogram, work in either a standard laboratory (&lt;500 g) or designated laboratory (500 g to &lt;1 kg) using a fume hood, biological safety cabinet(Class II, Type A2 with thimble connection, B1, or B2)or approved vented enclosure. HEPA filtered exhaust preferred for fume hoods containing particularly "dusty" operations. FOR MANUFACTURING PROCESSES (BULK): Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment facility using appropriate containment technology. A laminar flow/powder containment booth or appropriate isolation technology should be considered for handling more than 1 kilogram of active compound. HEPA filtered exhaust preferred. For manufacturing and pilot plant operations, barrier/containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) with use of double or split butterfly valves, hybrid unidirectional airflow/local exhaust ventilation solutions (e.g. powder containment booth) should be used. Glove bags, isolator/glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.</p>
Respiratory protection	<p>Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.</p>
Eye protection	<p>Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.</p>
Hand protection	<p>Wear gloves at all times when handling containers, including when unpacking, inspecting or transporting within a facility. Impervious gloves are recommended. (EN 420, EN 374). Double gloving for all manufacturing personnel potentially in direct contact with the compound should be considered. If material is handled in solution, the solvent should also be considered when selecting protective clothing material.</p>
Skin and body protection	<p>Wear a laboratory coat (EN 340) when handling quantities up to 500 grams. For quantities up to 1 kilogram, wear disposable laboratory coat (EN 340) or coverall of low permeability (EN 1149-1) . For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability (EN 1149-1) and disposable shoe covers.</p>
Hygiene	<p>Wash hands and face before breaks and immediately after handling the product.</p>
Environmental exposure controls	<p>Prevent release to drains and waterways.</p>

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<i>General Information</i>	
<i>Appearance</i>	
Physical State	solid
Color	white to off-white
Form	film coated tablets
<i>Odour</i>	
Odour	Not available
Odor Threshold	Not available
pH	Not available
<i>Other information</i>	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Not available
Specific Gravity/ Relative density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Non-explosive based on chemical structure.
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	The compound contains oxygen, fluorine, or chlorine and these elements are not chemically bonded only to carbons or hydrogen.
<i>Vapor Properties</i>	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

## 10. STABILITY AND REACTIVITY

### Stability

Chemical Stability	Stable under normal conditions.
Conditions to avoid	Not available
Materials to avoid	strong oxidizing agents chlorinating agents
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), trace magnesium, trace titanium, sulphur compounds, and, gaseous hydrogen chloride (HCl).
Hazardous reactions	None known.

### Sensitivity to static discharge/Dust exp.

Summary Statements	Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).
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## 11. TOXICOLOGICAL INFORMATION

Routes of Entry      Ingestion, inhalation, Eye contact, Skin contact

Eye Irritation      Dasatinib  
Not an eye irritant based on in vitro assay

Microcrystalline Cellulose  
Mildly irritating to eyes.

Hydroxypropyl Methylcellulose  
Dust may cause mechanical irritation.

Titanium Dioxide  
Dust may cause mechanical irritation.

Skin Irritation      Dasatinib  
Not irritating to skin.

Microcrystalline Cellulose  
Not irritating to skin.

Titanium Dioxide  
Dust may cause mechanical irritation.

**11. TOXICOLOGICAL INFORMATION**

Respiratory Irritation      Microcrystalline Cellulose  
Respiratory Irritant

Titanium Dioxide  
Irritating to respiratory tract.

Sensitization                Dasatinib  
Not a dermal sensitizer in an experimental study

Microcrystalline Cellulose  
Not a dermal sensitizer

Titanium Dioxide  
Not a dermal sensitizer



## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity Study

#### **Acute Oral**

##### Dasatinib

LD50 (rat, males and females): 50 - 100 mg/kg low exposure effects include: clinical signs, gastrointestinal tract toxicity, bone marrow effects, lymphoid depletion, liver toxicity, kidney toxicity, cardiac toxicity, male reproductive organs, mortality.

LD50 (monkey, males and females): 25 - 45 mg/kg low exposure effects include: clinical signs, gastrointestinal tract toxicity, bone marrow effects, lymphoid depletion, kidney toxicity, mortality.

##### Microcrystalline Cellulose

LD50 (rat, males and females): > 5,000 mg/kg

##### Titanium Dioxide

LD50 (rat): > 10,000 mg/kg

LD50 (rat): > 10,000 mg/kg

#### **Acute Dermal**

##### Microcrystalline Cellulose

LD50 (rat, males and females): > 2,000 mg/kg

##### Titanium Dioxide

LD50 (rabbit): > 10,000 mg/kg

LD50 (rabbit): > 10,000 mg/kg

#### **Acute inhalation toxicity**

##### Microcrystalline Cellulose

LC50 (rat, males and females): > 5350 mg/m<sup>3</sup>/4 H

##### Titanium Dioxide

LC50 (rat): > 2.29 mg/l/4 H/4 H

#### **Acute toxicity (other routes of administration)**

##### Microcrystalline Cellulose

LD50 (rat, males, intraperitoneal): > 3,160 mg/kg

##### Hydroxypropyl Methylcellulose

LD50 (rat, intraperitoneal): 5,200 mg/kg

LD50 (mouse, intraperitoneal): 5,000 mg/kg

## 11. TOXICOLOGICAL INFORMATION

Repeated Dose Toxicity      Dasatinib  
2 weeks - 2 years oral (5/week-daily) monkey, rat study with recovery period (2 - 4 weeks) (males and females): NOAEL = 0.3 mg/kg; Low dose effects include: abnormal posture, hypoactivity, tremors, labored respiration, swelling, paleness, fecal changes, menstrual irregularities, gastrointestinal tract toxicity, decreased weight gain, decreased food consumption, changes in clinical chemistry parameters, decreased red blood cell count, changes in white blood cell parameters, lymphoid depletion, ovary effects, changes in the uterus, decreased organ weights included:, spleen, pituitary gland, increased organ weights included:, heart, liver, thyroid gland, ovary, adrenal glands, mortality. Low dose microscopic effects include: liver, lymph nodes, ovary, uterus, large intestine, small intestine, adrenal glands, thyroid gland, kidney, thymus, bone marrow, spleen, stomach, lungs.

### Titanium Dioxide

#### **Assessment Repeat Dose Toxicity**

Several studies were conducted. See "Human Experience".

Genetic Toxicity

### Dasatinib

#### **In vitro**

Ames reverse-mutation assay -- negative

This study(s) was conducted on a different salt form.

In vitro cytogenicity study in mammalian cells -- positive

This study(s) was conducted on a different salt form.

#### **in vivo**

3 Days oral, Mutagenicity (micronucleus test) (rat) -- negative

This study(s) was conducted on a different salt form.

#### **Mutagenicity Assessment**

The weight of evidence demonstrates that this material is not genotoxic.

### Microcrystalline Cellulose

#### **Mutagenicity Assessment**

This material was negative in a battery of in vivo and in vitro genotoxicity assays.

### Titanium Dioxide

#### **Mutagenicity Assessment**

This material was negative in a battery of in vivo and in vitro genotoxicity assays.

**11. TOXICOLOGICAL INFORMATION**

**Carcinogenicity** Dasatinib  
2 years oral (daily) rat study : Tumor LOAEL = 0.3 mg/kg (males and females). [tumor organs: uterus/cervix, prostate]

**Carcinogenicity Assessment**

This material was a carcinogen in animal studies.

Microcrystalline Cellulose

**Carcinogenicity Assessment**

This material did not show carcinogenic potential in animal studies. Not classifiable as to its carcinogenicity to humans.

Titanium Dioxide

**Carcinogenicity Assessment**

Tumors were observed at high dose in animal studies by inhalation and intratracheal administration. Tumors were not observed by other routes.

<b>Carcinogenicity</b>	<b>ACGIH</b>	<b>IARC</b>	<b>NTP</b>
Dasatinib	--	--	--
Microcrystalline Cellulose	--	--	--
Hydroxypropyl Methylcellulose	--	--	--
Titanium Dioxide	A4	2B	--

**Reproductive Toxicity** Dasatinib  
oral Study of Fertility and Early Embryonic Development (rat)  
(parent, males and females) NOAEL = 5 mg/kg  
(embryo/fetus) NOAEL = 2.5 mg/kg  
Fetal effects include: embryoletality. Maternal effects include: decreased body weight, decreased food consumption. Males - No effects were found on mating or fertility.  
Compound may be toxic during early embryonic development.

**Assessment Reproductive Toxicity**

Animal studies indicate that reproductive effects can occur. Compound may cause injury to male reproductive organs. Compound may cause changes in female reproductive organs.

Microcrystalline Cellulose

**Assessment Reproductive Toxicity**

Data indicate that this compound is not a reproductive hazard.

**11. TOXICOLOGICAL INFORMATION**

<p>Developmental Toxicity</p>	<p><u>Dasatinib</u> oral Study of Embryo-Fetal Development (rat) (parent, females) NOAEL = 5 mg/kg (embryo/fetus) LOAEL = 2.5 mg/kg Fetal effects include: embryoletality, changes in skeletal development, malformations. Maternal effects include: decreased weight gain, reduction in litter size, decreased food consumption, fecal changes, lethargy, bristling of hair, death. Substance was harmful to the fetus at doses that did not produce adverse effects in the maternal animal.</p> <p>oral Study of Embryo-Fetal Development (rabbit) (parent, females) NOAEL = 6 mg/kg (embryo/fetus) LOAEL = 0.5 mg/kg Fetal effects include: developmental delay, changes in sexual development. No adverse maternal effects were observed.</p> <p><b>Developmental Toxicity Assessment</b> Selective developmental toxicant</p> <p><u>Microcrystalline Cellulose</u> <b>Developmental Toxicity Assessment</b> Available data do not indicate a potential for selective developmental toxicity.</p>
<p>Human experience</p>	<p><b>Experiences with Human Exposure</b></p> <p><u>Dasatinib</u> General effects therapeutic use low exposure - acute effects include: gastrointestinal disturbance, diarrhoea, headache, mental disturbance, fever, hair loss, breathing difficulties, Pulmonary hypertension, hypoxia, rash, fatigue, chest pain, male breast growth, muscle pain, dizziness, ringing in ears, death. low exposure - long term exposure effects include: hemorrhage, bone marrow suppression, infection, fluid retention, skin effects, eye effects, prolonged QT interval, heart attack, congestive heart failure, cardiac irregularities, changes in blood pressure, neuropathy, abnormal liver enzymes, hyperuricemia.</p> <p><u>Titanium Dioxide</u> Incident report(s) worker exposure low exposure - acute effects include: cough, breathing difficulties, rhinitis, Irritating to respiratory system..</p>
<p>Target Organs</p>	<p><u>Dasatinib</u> gastrointestinal tract, bone marrow, immune system</p> <p><u>Hydroxypropyl Methylcellulose</u> Eyes</p> <p><u>Titanium Dioxide</u> lungs</p>

## 11. TOXICOLOGICAL INFORMATION

Symptoms	<p><u>Dasatinib</u> See "Human Experience".</p> <p><u>Microcrystalline Cellulose</u> labored respiration, noisy respiration, chest pain, breathing difficulties, shortness of breath, lung inflammation</p>
Pharmacokinetics/ Toxicokinetics	Not available
Other Toxicity Information	<p><b>Other Toxicity Tests</b></p> <p><u>Dasatinib</u> in vitro phototoxicity (mouse) : NOAEL = 30 mg/kg</p>

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity effects

#### **Acute Toxicity to Fish**

##### Dasatinib

LC50 (Oncorhynchus mykiss (rainbow trout), 96 H) : > 0.50 mg a.i./L. (limit of solubility)

NOEC (Oncorhynchus mykiss (rainbow trout), 96 H) : 0.50 mg a.i./L. (limit of solubility)

#### **Toxicity to aquatic plants**

##### Dasatinib

EC50 (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae biomass, 72 H) :  
0.14 mg/l

NOEC (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae biomass, 72 H) :  
0.03 mg/l

EC50 (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae growth rate, 72 H)  
: > 0.18 mg/l (limit of solubility)

NOEC (Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum), Algae growth rate, 72  
H) : 0.073 mg/l

#### **Toxicity to microorganisms**

##### Dasatinib

Respiration inhibition, EC50 (Activated Sludge, 3 H) : > 1,000 mg/l

#### **Chronic toxicity to fish**

##### Dasatinib

Early-life Stage LOEC (Pimephales promelas (fathead minnow)) : 0.018 mg/l NOEC : 0.034 mg/l

#### **Chronic toxicity to aquatic invertebrates**

##### Dasatinib

LOEC (Daphnia magna (Water flea), 21 D) : 0.17 mg/l (limit of solubility)

NOEC (Daphnia magna (Water flea), 21 D) : 0.068 mg/l

**Mobility** Not available

### Persistence and degradability

#### **Biodegradation**

##### Dasatinib

Inherent biodegradation (21 Days) : 0.4 % ; Not readily biodegradable.

#### **Stability in water**

##### Dasatinib

Photolysis ( pH 5): Half-life - 3.17 H

Photolysis ( pH 7): Half-life - 2.21 H

## 12. ECOLOGICAL INFORMATION

Photolysis ( pH 9): Half-life - 1.35 H

Dasatinib

Koc (Estimation by HPLC, Activated Sludge) : 2,430

Kd (Estimation by HPLC, Activated Sludge) : 661

### Summary Statements

#### Chemical Fate

Dasatinib

High rate of photolysis in water Inherently biodegradable - biodegrades in the environment. Low mobility in soil.

#### Bioaccumulative potential

Dasatinib

Bioconcentration factor (BCF): 3 (Bluegill sunfish) Does not bioaccumulate.

**PBT and vPvB Assessment:** Not available

## 13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.

Other information Disposal by incineration is recommended.

## 14. TRANSPORT INFORMATION

### IMDG

UN/ID No.	UN3249
Proper shipping name	Medicine, solid, toxic, n.o.s. (Dasatinib)
Class	6.1
Packing group	III
Labelling	6.1
EmS	6.1-04

### ICAO/IATA-DGR

UN/ID No.	UN3249
Proper shipping name	Medicine, solid, toxic, n.o.s. (Dasatinib)
Class	6.1
Packaging group	III
Labelling	6.1

### ADR

UN/ID No.	UN3249
Proper shipping name	Medicine, solid, toxic, n.o.s. (Dasatinib)
Class	6.1
Packaging group	III
Labelling	6.1

### RID

UN/ID No.	UN3249
Proper shipping name	Medicine, solid, toxic, n.o.s. (Dasatinib)
Class	6.1
Packaging group	III

**14. TRANSPORT INFORMATION**

Labelling	6.1
US DOT	
UN/ID No.	UN3249
Proper shipping name	Medicine, solid, toxic, n.o.s. (Dasatinib)
Class	6.1
Packing group	III
Labelling	6.1
Other information: Marine pollutant	

**15. REGULATORY INFORMATION**

**United States of America**

313 Toxic Release Inventory No components listed on the SARA 313 inventory.

TSCA Inventory Not listed. Food, drug and cosmetic products are exempt from TSCA.

**EU Directive 1999/45/EC**

BULK MATERIAL

Symbol(s) T: Toxic  
Xn: Harmful  
N: Dangerous for the environment

R-phrase(s) R25: Toxic if swallowed.  
R40: Limited evidence of a carcinogenic effect.  
R48/25: Toxic: danger of serious damage to health by prolonged exposure if swallowed.  
R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R61: May cause harm to the unborn child.  
R62: Possible risk of impaired fertility.

S-phrase(s) S22: Do not breathe dust.  
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.  
S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).  
S53: Avoid exposure - obtain special instructions before use.  
S60: This material and its container must be disposed of as hazardous waste.  
S61: Avoid release to the environment. Refer to special instructions/ Safety data sheets.

DRUG PRODUCT

Classification Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.

Regulatory Authorizations and Restrictions: Not available

**16. OTHER INFORMATION**

*Text of Symbol(s), R-phrase(s) and H-code(s) mentioned in Section 3*

H300	Fatal if swallowed.
H335	May cause respiratory irritation

H351	Suspected of causing cancer.
H360D	May damage the unborn child
H361f	Suspected of damaging fertility
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.
N	Dangerous for the environment
R25	Toxic if swallowed.
R37	Irritating to respiratory system.
R40	Limited evidence of a carcinogenic effect.
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R53	May cause long-term adverse effects in the aquatic environment.
R61	May cause harm to the unborn child.
R62	Possible risk of impaired fertility.
T	Toxic
Xi	Irritant
Xn	Harmful

*Recommended Restrictions for Use:*

Not available

*SDS preparation information*

Prepared by Research and Development Environment, Health and Safety 1-732-227-7380

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This Safety Data Sheet has been revised. This data sheet contains changes from the previous version in section(s): 14, and 16.

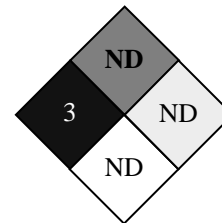
*Other information*

HMIS

Health	3*
Flammability	Not Determined (ND)
Reactivity	Not Determined (ND)
Personal protective equipment	See Section 8.

NFPA

Health	3
Fire	ND
Reactivity	ND
Special	ND





Country- Specific Emergency  
Phone Numbers

<b>CHEMTREC</b> In-Country Dial Numbers	Local # Provided in Country	Toll Free in Country*	Greeting Language
CHEMTREC South Africa*		0-800-983-611	English
CHEMTREC Argentina (Buenos Aires)	+(54)-1159839431		Latin American Spanish
CHEMTREC Brazil (Rio De Janeiro)	+(55)-2139581449		Portuguese
CHEMTREC Chile (Santiago)	+(56)-25814934		Latin American Spanish
CHEMTREC Colombia *		01800-710-2151	Latin American Spanish
CHEMTREC Mexico*		01-800-681-9531	Latin American Spanish
CHEMTREC Peru (Lima)	+(51)-17071295		Latin American Spanish
CHEMTREC China*	4001-204937		Mandarin
CHEMTREC Hong Kong (Hong Kong)*		800-968-793	Cantonese
CHEMTREC India *		000-800-100-7141	Hindi
CHEMTREC Indonesia *		001-803-017-9114	Indonesian
CHEMTREC Japan (Tokyo)	+(81)-345209637		Japanese
CHEMTREC Malaysia *		1-800-815-308	Malay
CHEMTREC Philippines *		1-800-1-116-1020	Tagalog
CHEMTREC Singapore*		800-101-2201	Mandarin
CHEMTREC Singapore	+(65)-31581349		Mandarin
CHEMTREC South Korea*		00-308-13-2549	Korean
CHEMTREC Taiwan*		00801-14-8954	Mandarin
CHEMTREC Thailand *		001-800-13-203-9987	Thai
CHEMTREC Vietnam (Ho Chi Minh City)	+(84)-838012436		Vietnamese
CHEMTREC Australia (Sydney)	+(61)-290372994		English
CHEMTREC Belgium (Brussels)	+(32)-28083237		French and Flemish
CHEMTREC Czech Republic (Prague)	+(420)-228880039		Czech
CHEMTREC France	+(33)-975181407		French
CHEMTREC Germany *		0800-181-7059	German
CHEMTREC Hungary (Budapest)	+(36)-18088425		Hungarian
CHEMTREC Italy *		800-789-767	Italian
CHEMTREC Italy (Milan)	+(39)-0245557031		Italian
CHEMTREC Netherlands	+(31)-858880596		Dutch
CHEMTREC Poland (Warsaw)	+(48)-223988029		Polish
CHEMTREC Spain*		900-868538	European Spanish
CHEMTREC Sweden (Stockholm)	+(46)-852503403		Swedish
CHEMTREC Switzerland (Zurich)	+(41)-435016715		German
CHEMTREC UK (London)	+(44)-870-8200418		English
CHEMTREC Bahrain (Bahrain)	+(973)-16199372		Arabic
CHEMTREC Israel (Tel Aviv)	+(972)-37630639		Hebrew

\*Phone numbers for countries marked with an asterisk must be dialed within the country

The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information. and we assume no liability from its use.