Safety Data Sheet

Bristol-Myers Squibb Company

1. IDENTIFICATION		
Product Information		
Product name	SPRYCEL® (dasatinib) Tablets, 20, 50, 70, 80, 100 and 140 mg	
Version	4.0, 13.06.2018	
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, and Korea.	
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. Non-intended uses such as crushing or grinding of tablets should be avoided to prevent the generation of dust.	
Company/Undertaking Identification		
Address	USA **Bristol-Myers Squibb Company** P.O. Box 191 New Brunswick, New Jersey 08903 United States of America 1-800-332-2056	Ireland **Bristol-Myers Squibb Company** Cruiserath Road, Mulhuddart - Dublin 15 Cruiserath, Ireland MG-GBS-MSDS-Request@bms.com + 353.1.8854000
Emergency Phone No.	USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300 Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.	Ireland: +(353)-19014670

2. HAZARDS IDENTIFICATION	
Classification and Labelling Common to All Jurisdictions	
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 - Chronic Hazard - Category 1
Symbol	
Signal Word	Danger
Hazard Statements	Toxic if swallowed. Suspected of causing cancer.

2. HAZARDS IDENTIFICATION

	Suspected of damaging fertility (male/female fertility) . May damage the unborn child (developmental toxicity) . May cause respiratory irritation . Causes damage to organs (gastrointestinal tract, bone marrow, immune system, cardiovascular system, lungs) through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.
Precautionary Statements	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Do not breathe dust. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Collect spillage.

Classification and Labelling for Specific Jurisdictions

USA

Classification	Hazardous To The Aquatic Environment - Acute Hazard - Category 2
Hazard Statements	Toxic to aquatic life.

EU

Classification	No additional classifications

UN

Classification	Hazardous To The Aquatic Environment - Acute Hazard - Category 2
Hazard Statements	Toxic to aquatic life.
Other information	43.55% of the mixture consists of ingredients(s) of unknown hazards to the aquatic environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	Concentration	CAS No.	EU only		Other Registration No.
			EC No./REACH Registration No.	H-code(s)	
Hazardous components					
Dasatinib hydrate	25 %	863127-77-9	--	H300 H351 H361f H360D H372 H410/M=	--

				1	
Microcrystalline Cellulose	< 50 %	9004-34-6	232-674-9	H335	--
Titanium Dioxide	< 5 %	13463-67-7	236-675-5	H335 H372 H413	--
Other ingredients Non-Hazardous Ingredients	< 30 %	Not available	--	--	--
See section 16 for 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. If exposed or concerned: Get medical attention/advice.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Inhalation	Oxygen or artificial respiration if needed. 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 CENTER or doctor/physician. Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
Notes to Physician	Medical conditions aggravated include: liver disorders, cardiovascular disease, bleeding, oedema, prolonged QT interval. This product has been reported to interact with the following medications: drugs that inhibit cytochrome P-450, drugs that induce cytochrome P-450, cardiovascular drugs, anticoagulants, live viruses vaccine, antacids, proton pump inhibitors. Refer to Section 11.
Medical Surveillance	The need for a pre-placement, follow-up 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.

5. FIRE-FIGHTING MEASURES	
Flammable Properties	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.

5. FIRE-FIGHTING MEASURES	
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.

6. ACCIDENTAL RELEASE MEASURES	
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	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. Protect against light. Keep away from heat, sparks and flames. Store locked up. Store in well-ventilated place. Keep container tightly closed.
Specific use(s)	Refer to Section 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION				
Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Dasatinib hydrate	3 µg/m3 8 hour-TWA	--	--	--
Microcrystalline Cellulose		10 mg/m3 TWA	--	--
Titanium Dioxide		10 mg/m3 TWA	--	--

8. EXPOSURE CONTROLS / PERSONAL PROTECTION			
Magnesium Stearate	10 mg/m3 8 hour-TWA	--	--
Polyethylene Glycol 400 - N/A	--	1,000 mg/m3 TWA 8,000 mg/m3 Peak average molecular weight 200-600 1,000 mg/m3 MAK average molecular weight 200-600	--

Microcrystalline Cellulose	Occupational Exposure Limits have been established by: - Belgium - Switzerland - Estonia - Spain - France - Ireland - Portugal - Latvia
Titanium Dioxide	Occupational Exposure Limits have been established by: - Austria - Belgium - Switzerland - Denmark - Estonia - Spain - France - Greece - Ireland - Norway - Poland - Portugal - Sweden - Latvia
Magnesium Stearate	Occupational Exposure Limits have been established by: - Belgium - Spain - Ireland - Portugal - Sweden
Polyethylene Glycol 400 - N/A	Occupational Exposure Limits have been established by: - Austria - Switzerland - The Netherlands
Recommended Industrial Hygiene Monitoring Methods	General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional.

EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED

This formulation contains an active pharmaceutical ingredient (API) with the guideline limit noted above. To keep the API below the recommended guideline, the material as supplied should be controlled during handling to limit total airborne aerosol exposure to: 12 μg/m³ (Material is assigned to Exposure Control Band 3 (range 10-< 100 μg/m3)).

Engineering Controls and Ventilation	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 15 milligrams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling quantities from 15 milligrams to 1 kilogram, work in a standard laboratory using a fume hood, biological safety cabinet(Class II, all types), or approved vented enclosure. Quantities exceeding 1 kilogram should be handled in a designated laboratory. A laminar flow/powder containment booth is recommended for handling >1 kilograms of active substance. FOR MANUFACTURING PROCESSES (BULK): For manufacturing and pilot plant operations, use direct coupling and closed transfer systems for all bulk transfers. Use dust tight valves as appropriate. HEPA filtration of local exhaust ventilation (LEV) is required.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Respiratory protection	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.
Eye protection	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.
Hand protection	Impervious nitrile, rubber and latex gloves are recommended (EN 420, EN 374). If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	Wear a laboratory coat (EN 340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat(EN 340)or coverall of low permeability (EN 1149-1). For manufacturing operations, wear coverall of low permeability (EN 465/1149-1). For manufacturing operations, wear coverall of low permeability (EN 1149-1).
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance	
Physical State	solid
Color	white to off-white
Form	film coated tablets
Odour	
Odour	Not available
Odor Threshold	Not available
pH	Not available
Other information	
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 Coefficient [log Kow]	Not available

9. PHYSICAL AND CHEMICAL PROPERTIES	
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
Thermal/Stability properties	
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.
Vapor Properties	
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 (COx), nitrogen oxides (NOx), 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.).

11. TOXICOLOGICAL INFORMATION	
Routes of Entry	Ingestion, inhalation, Eye contact, Skin contact
Eye Irritation	Dasatinib hydrate Not an eye irritant based on in vitro assay Microcrystalline Cellulose Mildly and/or transiently irritating to eyes Hydroxypropyl Methylcellulose Dust may cause mechanical irritation. Titanium Dioxide Mildly and/or transiently irritating to eyes
Skin Irritation	Dasatinib hydrate Not irritating to skin. Microcrystalline Cellulose Not irritating to skin. Titanium Dioxide Mildly and/or transiently irritating to skin.
Respiratory Irritation	Microcrystalline Cellulose Irritating to respiratory tract. Titanium Dioxide Irritating to respiratory tract.
Sensitization	Dasatinib hydrate Not a dermal sensitizer in an experimental study Microcrystalline Cellulose Not a dermal sensitizer Titanium Dioxide Not a dermal sensitizer
Acute Toxicity Study	**Acute Oral** Dasatinib hydrate LD50 (rat, males and females): 50 - 100 mg/kg low exposure effects include (<= 300 mg/kg): 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 (<= 300 mg/kg): clinical signs, gastrointestinal tract toxicity, bone marrow effects, lymphoid depletion, kidney toxicity, mortality. Microcrystalline Cellulose

11. TOXICOLOGICAL INFORMATION	
	LD50 (rat, males and females): > 5,000 mg/kg Titanium Dioxide 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 **Acute inhalation toxicity** Microcrystalline Cellulose LC50 (rat, males and females): > 5350 mg/m3/4 H Titanium Dioxide LC50 (rat): > 2.29 mg/l/4 H **Acute toxicity (other routes of administration)** Microcrystalline Cellulose LD50 (rat, males, intraperitoneal): > 3,150 mg/kg Hydroxypropyl Methylcellulose LD50 (rat, intraperitoneal): 5,200 mg/kg LD50 (mouse, intraperitoneal): 5,000 mg/kg
Repeated Dose Toxicity	Dasatinib hydrate 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 (< = 100 mg/kg): 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 hydrate **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

11. TOXICOLOGICAL INFORMATION

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

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.

Carcinogenicity

Dasatinib hydrate

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.

Carcinogenicity	ACGIH	IARC	NTP
Dasatinib hydrate	--	--	--
Microcrystalline Cellulose	--	--	--
Hydroxypropyl Methylcellulose	--	--	--
Titanium Dioxide	A4	2B	--

Reproductive Toxicity

Dasatinib hydrate

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: embryolethality. 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.

11. TOXICOLOGICAL INFORMATION

	Microcrystalline Cellulose **Assessment Reproductive Toxicity** Data indicate that this compound is not a reproductive hazard.
Developmental Toxicity	Dasatinib hydrate oral Study of Embryo-Fetal Development (rat) (parent, females) NOAEL = 5 mg/kg (embryo/fetus) LOAEL = 2.5 mg/kg Fetal effects include: embryolethality, 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. 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. **Developmental Toxicity Assessment** Selective developmental toxicant Microcrystalline Cellulose **Developmental Toxicity Assessment** Available data do not indicate a potential for selective developmental toxicity.
Human experience	**Experiences with Human Exposure** Dasatinib hydrate 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. Titanium Dioxide Incident report(s) worker exposure low exposure - acute effects include: cough, breathing difficulties, rhinitis, Irritating to respiratory tract..
Target Organs	Dasatinib hydrate gastrointestinal tract, bone marrow, immune system, cardiovascular system Titanium Dioxide lungs

11. TOXICOLOGICAL INFORMATION	
Symptoms	Dasatinib hydrate See "Human Experience". Microcrystalline Cellulose labored respiration, noisy respiration, chest pain, breathing difficulties, shortness of breath, lung inflammation Titanium Dioxide See "Human Experience".
Pharmacokinetics/ Toxicokinetics	Dasatinib hydrate Absorption: Data available upon request. Distribution: Data available upon request. Metabolism: Data available upon request. Elimination: Half-life = 5 - 6 Hour(s) (Human).
Other Toxicity Information	**Other Toxicity Tests** Dasatinib hydrate in vivo phototoxicity study (mouse) : NOAEL = 30 mg/kg
Other Information:	Some of the toxicological information provided in this SDS is based on a different salt form.

12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Acute Toxicity to Fish

Dasatinib hydrate

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)

Microcrystalline Cellulose

LC50 (Oncorhynchus mykiss (rainbow trout), 96 H): > 100 mg/l.

Acute Toxicity to Aquatic Invertebrates

Dasatinib hydrate

EC50 (Daphnia magna (Water flea), 48 H): 3.7 mg/l.

NOEC (Daphnia magna (Water flea), 48 H): 0.47 mg/l.

Microcrystalline Cellulose

LC50 (Daphnia, 48 H): > 100 mg/l.

Titanium Dioxide

EC50 (Daphnia magna (Water flea), 48 H): > 100 mg/l.

Toxicity to aquatic plants

Dasatinib hydrate

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

Microcrystalline Cellulose

EC50 (Algae, 96 H): > 100 mg/l

Toxicity to microorganisms

Dasatinib hydrate

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

Chronic toxicity to fish

Dasatinib hydrate

NOEC (Pimephales promelas (fathead minnow)): 0.018 mg/l

LOEC (Pimephales promelas (fathead minnow)): 0.034 mg/l

Chronic toxicity to aquatic invertabrates

Dasatinib hydrate

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

Toxicity to sediment/soil dwelling organisms

Dasatinib hydrate

NOEC (Chironomus sp. (midge)): 100 mg/kg soil dm

Mobility Not available

Persistence and degradability

Biodegradation

Dasatinib hydrate

Inherent biodegradation (21 Days): 100 %; Inherently biodegradable - biodegrades in the environment. Parent compound degrades to metabolites. Not considered rapidly biodegradable according to GHS criteria.

Microcrystalline Cellulose

Inherently biodegradable - biodegrades in the environment.

Stability in water

Dasatinib hydrate

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

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

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

Dasatinib hydrate

12. ECOLOGICAL INFORMATION

Koc (Estimation by HPLC, Activated Sludge) : 2,430
Kd (Estimation by HPLC, Activated Sludge) : 661

Bioaccumulative potential

Dasatinib hydrate

Bioconcentration factor (BCF): 3 (Bluegill sunfish) Does not bioaccumulate.
Log Octanol/Water Partition Coefficient [log Kow]: pH 5 = 1.85, pH 7 = 3.56, pH 9 = 3.56

Summary Statements

Chemical Fate

Dasatinib hydrate

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

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
Labelling	6.1
US DOT	
UN/ID No.	UN3249
Proper shipping name	Medicine, solid, toxic, n.o.s. (Dasatinib)

14. TRANSPORT INFORMATION

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 Regulation (EC) No 1272/2008)

DRUG PRODUCT

Classification: Medicinal products are exempt from classification and labeling requirements under EU Regulation (EC) No 1272/2008.

Regulatory Authorizations and Restrictions: Not available

16. OTHER INFORMATION

Text of 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.
H410/M=1	Very toxic to aquatic life with long lasting effects.(M=1)
H413	May cause long lasting harmful effects to aquatic life.

Recommended Restrictions for Use:

Not available

SDS preparation information

Prepared by	Global Environment, Health, Safety, and Sustainability 1-732-227-7380
Prepared on	13.06.2018 DD/MM/YYYY
	This Safety Data Sheet has been revised. This data sheet contains changes from the previous version in section(s): 2, 4, 11, 15, and 16.

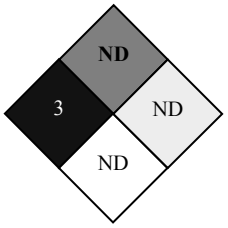
Other information

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

Country	Local # or Toll Free in Country*	Greeting Language	Country	Local # or Toll Free in Country*	Greeting Language
AMERICAS			Latvia (Riga)	+(371)-66165504	Latvian
Argentina (Buenos Aires)	+(54)-1159839431	Latin American Spanish	Lithuania (Vilnius)	+(370)-52140238	Lithuanian
Brazil (Rio De Janeiro)	+(55)-2139581449	Portuguese	Luxembourg	+(352)-20202416	French, German, Luxembourgish
Cayman Islands	+(1)-345-749-8392	English	Netherlands	+(31)-858880596	Dutch
Chile (Santiago)	+(56)-225814934	Latin American Spanish	Norway (Oslo)	+(47)-21930678	Norwegian
Colombia *	01800-710-2151	Latin American Spanish	Poland (Warsaw)	+(48)-223988029	Polish
Costa Rica*	+(506)-40003869	Latin American Spanish	Portugal	+(351)-308801773	Portuguese
Mexico*	01-800-681-9531	Latin American Spanish	Romania	(+40)-37-6300026	Romanian
Panama	+(507)-8322475	Latin American Spanish	Russia*	8-800-100-6346	Russian
Peru (Lima)	+(51)-17071295	Latin American Spanish	Slovakia (Bratislava)	+(421)-233057972	Slovak
Trinidad and Tobago*	+(1)-868-224-5716	English	Slovenia (Ljubljana)	+(386)-18888016	Slovene/Slovenian
EUROPE			Spain (Barcelona)	+(34)-931768545	European Spanish
			Spain*	900-868538	European Spanish
Austria (Vienna)	+(43)-13649237	German	Sweden (Stockholm)	+(46)-852503403	Swedish
Belgium (Brussels)	+(32)-28083237	French, Flemish, German	Switzerland (Zurich)	+(41)-435082011	Swiss German, French and Italian
Bulgaria (Plovdiv)	+(359)-32570104	Bulgarian	Turkey (Istanbul)	+(90)-212-7055340	Turkish
Croatia (Zagreb)	+(385)-17776920	Croatian	Ukraine	+(380)-947101374	Ukrainian
Czech Republic (Prague)	+(420)-228880039	Czech	UK (London)	+(44)-870-8200418	English
Finland (Helsinki)	+(358)-942419014	Finnish	**EAST ASIA**		
France	+(33)-975181407	French	China	86-21-33235036	Mandarin
Germany *	0800-181-7059	German	Hong Kong*	800-968-793	Cantonese
Denmark	+(45)-69918573	Danish	Japan	+(81)-345209637	Japanese
Estonia	+(372-6681294	Estonian	Singapore	+(65)-31581349	English and Mandarin
Germany (Frankfurt)	+(49)-69643508409	German	South Korea	+(82) 070-7686-0086	Korean
Greece (Athens)	+(30)-2111768478	Greek	**AUSTRALIA & OCEANIA**		
Hungary (Budapest)	+(36)-18088425	Hungarian	Australia (Sydney)	+(61)-290372994	English
Italy *	800-789-767	Italian	New Zealand*	+(64)-98010034	English
Italy (Milan)	+(39)-245557031	Italian	India *	000-800-100-7141	Hindi
*Phone numbers for countries marked with an asterisk must be dialed within the country.					

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