PHARMASCIENCE INC.

SAFETY DATA SHEET

Section 1: Identification

Material	Dasatinib Tablets, 20, 50, 70, 80, 100 and 140 mg
Manufacturer by	Pharmascience Inc. Candiac Quebec, J5R 1J1, Canada
Manufacturer for	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States
Recommended use of the chemical and restrictions on use	Finished Pharmaceutical Product This material is a finished drug product for patient use. It is used in the treatment of cancer.

Section 2: Hazard(s) Identification

Classification

Acute toxicity	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) 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.

Precautionary statements	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.

Section 3: Composition/Information on Ingredients

Hazardous components

Chemical Name	Concentration (%)	CAS-No.
Dasatinib	25 %	863127-77-9
Microcrystalline Cellulose	< 50 %	9004-34-6
Hydroxypropyl Methylcellulose	< 5 %	9004-65-3
Titanium Dioxide	< 5 %	13463-67-7
Other ingredients Non-Hazardous Ingredients	< 20 %	Not available

Section 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.
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 workplace 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.

Section 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.
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.

Section 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 lab coat, 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.

Section 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

Section 8: Exposure Controls/Personal Protection

Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Dasatinib	3 µg/m3 8 hour-TWA	--	--	--
Microcrystalline Cellulose		10 mg/m3 TWA	--	--
Titanium Dioxide		10 mg/m3 TWA	--	--
Magnesium Stearate		10 mg/m3 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

EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED

Dasatinib Tablets, 20, 50, 70, 80, 100 and 140 mg

4 -- Material is assigned to Exposure Control Band 4 (range 1 - <10 µg/m3).

EXPOSURE CONTROLS / PERSONAL PROTECTION

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 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 (<500 g) or designated laboratory (500 g to <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.
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 tightfitting, 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	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.
Skin and body protection	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.
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

Section 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
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not available
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
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

Section 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.).

Section 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.
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
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/m3/4 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

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.

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.

Carcinogenicity	ACGIH	IARC	NTP
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: embryo lethality. 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 tomale 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.

Developmental Toxicity

Dasatinib
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 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 system.
Target Organs	Dasatinib gastrointestinal tract, bone marrow, immune system Methylcellulose Eyes Titanium Dioxide Lungs
Symptoms	Dasatinib See "Human Experience". Microcrystalline Cellulose labored respiration, noisy respiration, chest pain, breathing difficulties, shortness of breath, lung inflammation.
Pharmacokinetics/Toxicokinetics	Not available

Other Toxicity Information	**Other Toxicity Tests** Dasatinib in vitro phototoxicity (mouse) : NOAEL = 30 mg/kg

Section 12: Ecological Information

Ecotoxicity effects

Acute Toxicity to Fish
Dasatinib
LC50 (Oncorhynchus mykiss (rainbow trout), 96 H) : > 0.50 mg a.i (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, 72H) : 0.073 mg/l

Toxicity to microorganisms
Dasatinib
Respiration inhibition, EC50 (Activated Sludge, 3 H) : > 1,000mg/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 invertabrates
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
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.
Bio accumulative potential	Dasatinib Bioconcentration factor (BCF): 3 (Bluegill sunfish) Does not bioaccumulate.
PBT and vPvB Assessment	Not available

Section 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.

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

Section 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	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.

Section 16: Other Information

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

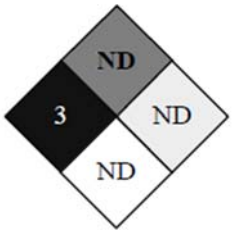
H300	Fatal if swallowed.
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H360D	May damage the unborn child
H361f	Suspected of damaging fertility
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life 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

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



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