

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

SECTION 1. IDENTIFICATION

Product name : Ceftibuten Capsules Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Acute toxicity (Inhalation) : Category 4

Respiratory sensitization : Category 1

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H332 Harmful if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements : **Prevention:**
P261 Avoid breathing dust.
P271 Use only outdoors or in a well-ventilated area.
P285 In case of inadequate ventilation wear respiratory protection.

Ceftibuten Capsules Formulation

Version Revision Date: SDS Number: Date of last issue: 05/03/2017
3.0 10/18/2017 559528-00005 Date of first issue: 03/15/2016

Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

|| Dust contact with the eyes can lead to mechanical irritation.
|| Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Ceftibuten	97519-39-6	$\geq 50 - < 70$
Cellulose	9004-34-6	$\geq 10 - < 20$
Magnesium stearate	557-04-0	$\geq 1 - < 5$

SECTION 4. FIRST AID MEASURES

|| General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

|| If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

|| In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

|| In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

|| If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

|| Most important symptoms and effects, both acute and delayed : Harmful if inhaled.
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Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

	Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
Notes to physician	: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Metal oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Ceftibuten Capsules Formulation

Version 3.0 Revision Date: 10/18/2017 SDS Number: 559528-00005 Date of last issue: 05/03/2017
 Date of first issue: 03/15/2016

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use with local exhaust ventilation.
- Advice on safe handling : Do not breathe dust.
 Do not swallow.
 Avoid contact with eyes.
 Avoid prolonged or repeated contact with skin.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Keep container tightly closed.
 Minimize dust generation and accumulation.
 Keep container closed when not in use.
 Keep away from heat and sources of ignition.
 Take precautionary measures against static discharges.
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
 Keep tightly closed.
 Keep in a cool, well-ventilated place.
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
 Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ceftibuten	97519-39-6	TWA	1 mg/m ³ (OEB 1)	Merck
	Further information: DSEN, RSEN			
		Wipe limit	0.1 mg/100 cm ²	Merck
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL

Ceftibuten Capsules Formulation

Version 3.0 Revision Date: 10/18/2017 SDS Number: 559528-00005 Date of last issue: 05/03/2017
 Date of first issue: 03/15/2016

		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Magnesium stearate	557-04-0	TWA	10 mg/m ³	ACGIH

Engineering measures : Use feasible engineering controls to minimize exposure to compound.
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.
 When using do not eat, drink or smoke.
 Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

Color	:	No data available
Odor	:	No information available.
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if inhaled.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 2.25 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

Ingredients:**Ceftibuten:**

Acute oral toxicity	:	LD50 (Rat): 10,000 mg/kg LD50 (Dog): 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 3.94 mg/l Exposure time: 4 h Test atmosphere: dust/mist

Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,500 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

Skin corrosion/irritation

Not classified based on available information.

Ingredients:**Ceftibuten:**

Species: Rabbit
Result: No skin irritation

Cellulose:

Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:**Ceftibuten:**

Species: Rabbit
Result: No eye irritation

Cellulose:

Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingredients:**Ceftibuten:**

Assessment: Probability or evidence of high respiratory sensitization rate in humans

Cellulose:

Test Type: Local lymph node assay (LLNA)

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

Routes of exposure: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

Magnesium stearate:

Routes of exposure: Skin contact
Result: negative

Germ cell mutagenicity

Not classified based on available information.

Ingredients:**Ceftibuten:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosome aberration test in vitro Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Cellulose:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Ceftibuten Capsules Formulation

Version 3.0	Revision Date: 10/18/2017	SDS Number: 559528-00005	Date of last issue: 05/03/2017 Date of first issue: 03/15/2016
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NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Ingredients:**Ceftibuten:**

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: NOAEL: 2,000 mg/kg body weight Result: No effects on fertility.
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: > 4,000 mg/kg body weight Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: > 40 mg/kg body weight Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: >= 125 mg/kg body weight Result: Reduced offspring weight gain.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Ingredients:****Ceftibuten:**

Species: Rat LOAEL: 3,000 mg/kg Application Route: Oral Exposure time: 3 Months Target Organs: Gastro-intestinal system, Heart Symptoms: No adverse effects.	Species: Dog LOAEL: 800 mg/kg Application Route: Oral Target Organs: Gastro-intestinal system, Heart Symptoms: No adverse effects.
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Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

Cellulose:

Species: Rat
NOAEL: > 5,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Magnesium stearate:

Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 3 Months

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Ingredients:****Ceftibuten:**

Inhalation : Symptoms: Nausea, Vomiting, Abdominal pain, vaginitis,
Headache, Dizziness, dry mouth, Fatigue, constipation, colitis

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Ingredients:****Ceftibuten:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 600 mg/l
Exposure time: 48 h
Method: FDA 4.08

Cellulose:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

Remarks: Based on data from similar materials

Persistence and degradability**Ingredients:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

Magnesium stearate:

Biodegradability : Result: Not biodegradable.

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**49 CFR**

Not regulated as a dangerous good

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Combustible dust Acute toxicity (any route of exposure) Respiratory or skin sensitization
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SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
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US State Regulations**Pennsylvania Right To Know**

Ceftibuten	97519-39-6
Starch, carboxymethyl ether, sodium salt	9063-38-1
Cellulose	9004-34-6

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Magnesium stearate	557-04-0

The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

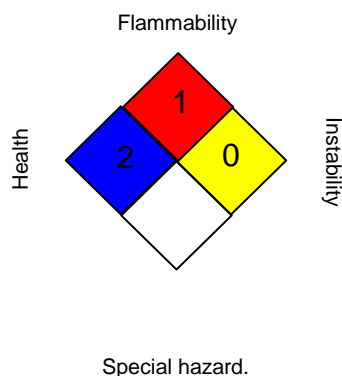
Ceftibuten Capsules Formulation

Version 3.0 Revision Date: 10/18/2017 SDS Number: 559528-00005 Date of last issue: 05/03/2017
 Date of first issue: 03/15/2016

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:

HEALTH	*	1
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-

Ceftibuten Capsules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/03/2017
3.0	10/18/2017	559528-00005	Date of first issue: 03/15/2016

stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 10/18/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8