

**Fidaxomicin Formulation**

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Version 1.0	Revision Date: 06/05/2017	SDS Number: 1731985-00001	Date of last issue: - Date of first issue: 06/05/2017
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**SECTION 1. IDENTIFICATION**

Product name : Fidaxomicin 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

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

Acute toxicity (Oral) : Category 4

**GHS label elements**

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.

Precautionary Statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

**Disposal:**

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

**Fidaxomicin Formulation**

Version 1.0 Revision Date: 06/05/2017 SDS Number: 1731985-00001 Date of last issue: - Date of first issue: 06/05/2017

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**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous ingredients**

Chemical name	CAS-No.	Concentration (% w/w)
Fidaxomicin	873857-62-6	>= 40 - <= 60
Cellulose	9004-34-6	>= 15 - <= 30
Starch	9005-25-8	>= 5 - <= 15

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**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.  
Get medical attention if symptoms occur.

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

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.

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.

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**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

**Fidaxomicin Formulation**

---

Version 1.0	Revision Date: 06/05/2017	SDS Number: 1731985-00001	Date of last issue: - Date of first issue: 06/05/2017
----------------	------------------------------	------------------------------	--

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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

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.

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**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.  
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.

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**SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice.  
Take care to prevent spills, waste and minimize release to the

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## Fidaxomicin Formulation

Version 1.0 Revision Date: 06/05/2017 SDS Number: 1731985-00001 Date of last issue: - Date of first issue: 06/05/2017

environment.

Conditions for safe storage : Keep in properly labeled containers. 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
Fidaxomicin	873857-62-6	TWA	200 µg/m <sup>3</sup> (OEB 2)	Merck
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1

**Engineering measures** : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

#### 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

**Fidaxomicin Formulation**

Version 1.0	Revision Date: 06/05/2017	SDS Number: 1731985-00001	Date of last issue: - Date of first issue: 06/05/2017
----------------	------------------------------	------------------------------	--

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Material	: Chemical-resistant gloves
Remarks	: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection	: Wear the following personal protective equipment: Safety glasses
Skin and body protection	: Skin should be washed after contact.
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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	: solid
Color	: white to off-white
Odor	: No information available.
Odor Threshold	: No data available
pH	: Not applicable
Melting point/freezing point	: 175 - 185 °C Active ingredient
Initial boiling point and boiling range	: Not applicable
Flash point	: Not applicable
Evaporation rate	: No data available
Flammability (solid, gas)	: Not classified as a flammability hazard
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

**Fidaxomicin Formulation**

---

Version 1.0	Revision Date: 06/05/2017	SDS Number: 1731985-00001	Date of last issue: -
			Date of first issue: 06/05/2017

---

Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 4.4 Active ingredient
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	:	Not applicable
Particle size	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

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

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

Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity :

Acute toxicity estimate: 833.33 mg/kg

**Fidaxomicin Formulation**

Version 1.0 Revision Date: 06/05/2017 SDS Number: 1731985-00001 Date of last issue: - Date of first issue: 06/05/2017

---

Method: Calculation method

**Ingredients:****Fidaxomicin:**

Acute oral toxicity : LD50 (Rat): > 1,000 mg/kg  
LD50 (Dog): > 120 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 200 mg/kg  
Application Route: Intravenous

**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

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

**Starch:**

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Ingredients:****Cellulose:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Ingredients:****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**

Not classified based on available information.

**Fidaxomicin Formulation**

Version 1.0 Revision Date: 06/05/2017 SDS Number: 1731985-00001 Date of last issue: - Date of first issue: 06/05/2017

---

**Ingredients:****Cellulose:**

Test Type: Local lymph node assay (LLNA)  
Routes of exposure: Skin contact  
Species: Mouse  
Method: OECD Test Guideline 429  
Result: negative  
Remarks: Based on data from similar materials

**Germ cell mutagenicity**

Not classified based on available information.

**Ingredients:****Fidaxomicin:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	: Test Type: Chromosome aberration test in vitro Species: Chinese hamster ovary cells Result: positive
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: Intravenous Result: negative
	Test Type: comet assay Species: Rat 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.

**Fidaxomicin Formulation**

Version 1.0 Revision Date: 06/05/2017 SDS Number: 1731985-00001 Date of last issue: - Date of first issue: 06/05/2017

---

**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:****Fidaxomicin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Fertility: NOAEL: 6.3 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 12.6 mg/kg body weight  
Remarks: No significant adverse effects were reported

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 7 mg/kg body weight  
Remarks: No significant adverse effects were reported

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Ingredients:****Fidaxomicin:**

Species: Rat  
NOAEL: 90 mg/kg  
Application Route: Oral  
Exposure time: 28 D  
Remarks: No significant adverse effects were reported

Species: Rat  
NOAEL: 62.5 mg/kg  
Application Route: Intravenous  
Exposure time: 14 D

Species: Dog  
NOAEL: 9,600 mg/kg  
Application Route: Oral  
Exposure time: 3 M  
Symptoms: Vomiting

**Fidaxomicin Formulation**

---

Version 1.0	Revision Date: 06/05/2017	SDS Number: 1731985-00001	Date of last issue: - Date of first issue: 06/05/2017
----------------	------------------------------	------------------------------	--

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Remarks: No significant adverse effects were reported

Species: Monkey

NOAEL: 90 mg/kg

Application Route: Oral

Exposure time: 28 D

Remarks: No significant adverse effects were reported

Species: Juvenile rat

NOAEL: 200 mg/kg

Application Route: Oral

Exposure time: 28 D

Remarks: No significant adverse effects were reported

**Cellulose:**

Species: Rat

NOAEL: > 5,000 mg/kg

Application Route: Ingestion

Exposure time: 90 Days

Remarks: Based on data from similar materials

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Ingredients:****Fidaxomicin:**

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, constipation

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

Toxicity to algae : EC50 (Anabaena flos-aquae (cyanobacterium)): > 18.4 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

NOEC (Anabaena flos-aquae (cyanobacterium)): 5.8 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 8.91 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility.

**Fidaxomicin Formulation**

Version 1.0	Revision Date: 06/05/2017	SDS Number: 1731985-00001	Date of last issue: - Date of first issue: 06/05/2017
----------------	------------------------------	------------------------------	--

---

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 19.6 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 50 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 5.9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**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  
Remarks: Based on data from similar materials

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

Biodegradability : Result: Readily biodegradable.

**Bioaccumulative potential****Ingredients:****Fidaxomicin:**

Partition coefficient: n-octanol/water : log Pow: 4.4

**Mobility in soil****Ingredients:****Fidaxomicin:**

Distribution among environmental compartments : log Koc: 0.80

**Fidaxomicin Formulation**

---

Version 1.0	Revision Date: 06/05/2017	SDS Number: 1731985-00001	Date of last issue: - Date of first issue: 06/05/2017
----------------	------------------------------	------------------------------	--

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**Other adverse effects**

No data available

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**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.

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**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

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**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** : Acute Health Hazard

**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.

**Fidaxomicin Formulation**

Version 1.0 Revision Date: 06/05/2017 SDS Number: 1731985-00001 Date of last issue: - Date of first issue: 06/05/2017

---

**US State Regulations****Pennsylvania Right To Know**

Fidaxomicin	873857-62-6
Cellulose	9004-34-6
Starch	9005-25-8

**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.

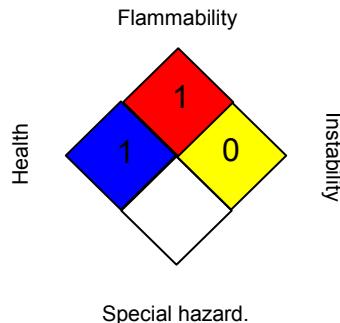
**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
Starch	9005-25-8

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

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

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**SECTION 16. OTHER INFORMATION****Further information****NFPA:****HMIS® IV:**

HEALTH	/	1
FLAMMABILITY		1
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

**Fidaxomicin Formulation**Version  
1.0Revision Date:  
06/05/2017SDS Number:  
1731985-00001Date of last issue: -  
Date of first issue: 06/05/2017

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 substance; 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 : 06/05/2017

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