

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 4750798-00009 Date of last issue: 30.09.2023 Date of first issue: 15.08.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fidaxomicin Solid Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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 or doctor/ physician if you feel unwell. Rinse mouth.
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.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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Components

Chemical name	CAS-No.	Concentration (% w/w)
Fidaxomicin	873857-62-6	>= 50 -< 70
Cellulose	9004-34-6	>= 20 -< 30
Sodium benzoate	532-32-1	>= 1 -< 5
Citric acid	77-92-9	>= 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.
Get medical attention if symptoms occur.
- 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 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 : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
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 (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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
Chlorine compounds
- 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

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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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment. 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. 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 only with adequate ventilation.

Advice on safe handling : Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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. Do not eat, drink or smoke when using this product.

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Hygiene measures	<p>Take care to prevent spills, waste and minimize release to the environment.</p> <p>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Wash contaminated clothing before re-use.</p> <p>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.</p>
Conditions for safe storage	Keep in properly labeled containers.
Materials to avoid	Store in accordance with the particular national regulations.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Fidaxomicin	873857-62-6	TWA	200 µg/m ³ (OEB 2)	Internal
Cellulose	9004-34-6	VLE-PPT	10 mg/m ³	NOM-010-STPS-2014
Sodium benzoate	532-32-1	TWA (Inhalable particulate matter)	2.5 mg/m ³	ACGIH

Engineering measures	<p>Use feasible engineering controls to minimize exposure to compound.</p> <p>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</p>
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Personal protective equipment

Respiratory protection	<p>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</p>
Filter type	Particulates type
Hand protection	
Material	Chemical-resistant gloves
Eye protection	<p>Wear safety glasses with side shields or goggles.</p> <p>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</p> <p>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</p>

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Skin and body protection : Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	granules
Color	:	White to light yellow
Odor	:	No data 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	:	Not applicable
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	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

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Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
Particle size	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
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 swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 875.04 mg/kg
Method: Calculation method

Components:

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

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Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Sodium benzoate:

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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium benzoate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Citric acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium benzoate:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Citric acid:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

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Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sodium benzoate:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Fidaxomicin:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosome aberration test in vitro Test system: 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
		Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

Sodium benzoate:

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Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

Citric acid:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: in vitro micronucleus test Result: positive
	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 72 weeks
Result	: negative

Sodium benzoate:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 24 month(s)
Result	: negative

Reproductive toxicity

Not classified based on available information.

Components:

Fidaxomicin:

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat
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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

Cellulose:

- Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
- Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Sodium benzoate:

- Effects on fertility : Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials
- Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Citric acid:

- Effects on fetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure

Not classified based on available information.

Components:

Citric acid:

- Assessment : May cause respiratory irritation.

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STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

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
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	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Sodium benzoate:

Species	:	Rat
NOAEL	:	1,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	24 Months

Citric acid:

Species	:	Rat
NOAEL	:	4,000 mg/kg

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LOAEL	:	8,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	10 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Fidaxomicin:

Ingestion	:	Symptoms: Abdominal pain, Nausea, Vomiting, constipation
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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Fidaxomicin:

Toxicity to algae/aquatic plants	:	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.
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 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
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Sodium benzoate:

- | | | |
|---|---|--|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 484 mg/l
Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 96 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201 |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 32 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201 |

Citric acid:

- | | | |
|---|---|--|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1,535 mg/l
Exposure time: 24 h |

Persistence and degradability

Components:

Cellulose:

- | | | |
|------------------|---|--------------------------------|
| Biodegradability | : | Result: Readily biodegradable. |
|------------------|---|--------------------------------|

Sodium benzoate:

- | | | |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.
Biodegradation: 75 %
Exposure time: 28 d |
|------------------|---|---|

Citric acid:

- | | | |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B |
|------------------|---|---|

Bioaccumulative potential

Components:

Fidaxomicin:

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

Sodium benzoate:

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Partition coefficient: n-octanol/water : log Pow: 1.88

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1.72

Mobility in soil

Components:

Fidaxomicin:

Distribution among environmental compartments : log Koc: 0.80

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
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

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Federal Law for the control of chemical precursors, essential chemical products and machinery for : Not applicable

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producing capsules, tablets and pills.

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

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

SECTION 16. OTHER INFORMATION

Revision Date	: 14.04.2025
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Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014	: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-	: Time weighted average limit value
PPT	

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; KECL - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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