

## Atorvastatin Formulation

Version 2.7      Revision Date: 09/13/2019      SDS Number: 184699-00009      Date of last issue: 2019/04/24  
Date of first issue: 2015/06/17

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Atorvastatin Formulation

**Manufacturer or supplier's details**

Company : MSD  
Address : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia  
Telephone : 908-740-4000  
Emergency telephone number : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@msd.com  
Telefax : 908-735-1496

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical


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**2. HAZARDS IDENTIFICATION****GHS Classification**

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, muscle)

Long-term (chronic) aquatic hazard : Category 3

**GHS label elements**

Hazard pictograms : 

Signal word : Warning

Hazard statements : H373 May cause damage to organs (Liver, muscle) through prolonged or repeated exposure if swallowed.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust.  
P273 Avoid release to the environment.  
**Response:**  
P314 Get medical advice/ attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste

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disposal plant.

**Other hazards which do not result in classification**

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.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture            :    Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Calcium carbonate	471-34-1	>= 30 -< 60
Cellulose	9004-34-6	>= 10 -< 30
Atorvastatin	134523-03-8	>= 10 -< 25

**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.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed            :    May cause damage to organs through prolonged or repeated exposure if swallowed.  
Contact with dust can cause mechanical irritation or drying of the skin.

Protection of first-aiders        :    Dust contact with the eyes can lead to mechanical irritation.  
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.

**5. FIREFIGHTING MEASURES**

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

Unsuitable extinguishing media    :    None known.

Specific hazards during fire-fighting    :    Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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Exposure to combustion products may be a hazard to health.

- |   |   |   |
|---|---|---|
| Hazardous combustion products                 | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Fluorine compounds<br>Metal oxides   |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
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**6. ACCIDENTAL RELEASE MEASURES**

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations.   |
| Environmental precautions   | : | Discharge into the environment must be avoided.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |
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**7. HANDLING AND STORAGE**

- |                         |   |   |
|-------------------------|---|---|
| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety |

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- 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.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Calcium carbonate	471-34-1	NAB (Inhalable)	10 mg/m <sup>3</sup> (Calcium carbonate)	ID OEL
Further information: Total inhalable particulates, containing no asbestos and with a crystalline silica content of < 1%.				
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Atorvastatin	134523-03-8	TWA	0.05 mg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	0.5 mg/100 cm <sup>2</sup>	Internal

- Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
 Minimize open handling.

**Personal protective equipment**

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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

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Skin and body protection	:	<p>potential for direct contact to the face with dusts, mists, or aerosols.</p> <p>Work uniform or laboratory coat.</p> <p>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</p> <p>Use appropriate degowning techniques to remove potentially contaminated clothing.</p>
Hygiene measures	:	<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>

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	granular
Colour	:	No data available
Odour	:	No data available
Odour 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	:	No data available
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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	No data available

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Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition 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

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**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.

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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Calcium carbonate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 420  
Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity : LC50 (Rat): > 3 mg/l

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Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

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

**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

**Atorvastatin:**

Acute oral toxicity : LD50 (Rat, male and female): > 5,000 mg/kg  
LD50 (Mouse, male and female): > 5,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Calcium carbonate:**

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

**Atorvastatin:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Calcium carbonate:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**Atorvastatin:**

Species : Rabbit





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Species: Mouse  
 Application Route: Ingestion  
 Result: negative

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Genotoxicity in vitro : Test Type: reverse mutation assay  
 Test system: Salmonella typhimurium  
 Result: negative

Test Type: reverse mutation assay  
 Test system: Escherichia coli  
 Result: negative

Test Type: In vitro mammalian cell gene mutation test  
 Test system: Chinese hamster lung cells  
 Result: negative

Test Type: sister chromatid exchange assay  
 Test system: Chinese hamster lung cells  
 Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
 Species: Mouse  
 Cell type: Bone marrow  
 Application Route: Oral  
 Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Cellulose:**

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

**Atorvastatin:**

Species : Mouse, male and female  
 Application Route : oral (gavage)  
 Exposure time : 2 Years  
 NOAEL : 200 mg/kg body weight  
 LOAEL : 400 mg/kg body weight  
 Result : negative  
 Target Organs : Liver

Species : Rat, female  
 Application Route : oral (gavage)  
 Exposure time : 2 Years  
 LOAEL : 100 mg/kg body weight  
 Target Organs : Musculo-skeletal system

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**Reproductive toxicity**

Not classified based on available information.

**Components:****Calcium carbonate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 414  
 Result: negative

**Cellulose:**

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

Effects on foetal development : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Atorvastatin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat, female  
 Fertility: NOAEL: 225 mg/kg body weight  
 Result: No effects on fertility

Test Type: Fertility/early embryonic development  
 Species: Rat, male  
 Fertility: NOAEL: 175 mg/kg body weight  
 Result: No effects on fertility

Effects on foetal development : Species: Rat, female  
 Developmental Toxicity: NOAEL: 20 mg/kg body weight  
 Result: No teratogenic effects, Embryo-foetal toxicity  
 Remarks: Maternal toxicity observed.

Species: Rabbit, female  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 100 mg/kg body weight  
 Result: No embryo-foetal toxicity

**STOT - single exposure**

Not classified based on available information.

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**STOT - repeated exposure**

May cause damage to organs (Liver, muscle) through prolonged or repeated exposure if swallowed.

**Components:****Atorvastatin:**

Exposure routes : Ingestion  
Target Organs : Liver, muscle  
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Calcium carbonate:**

Species : Rat  
NOAEL : > 1,000 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days  
Method : OECD Test Guideline 422

**Cellulose:**

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

**Atorvastatin:**

Species : Rat, male and female  
LOAEL : 70 mg/kg  
Application Route : oral (gavage)  
Exposure time : 52 Weeks  
Target Organs : Liver

Species : Dog  
LOAEL : 10 mg/kg  
Application Route : oral (gavage)  
Exposure time : 104 Weeks  
Target Organs : Liver

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Atorvastatin:**

Ingestion : Symptoms: muscle pain, Fatigue, stomach discomfort, Abdominal pain, constipation, flatulence, liver function change

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**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Calcium carbonate:**

- Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201
- EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201
- Toxicity to microorganisms : NOEC: 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209
- EC50: > 1,000 mg/l  
Exposure time: 3 h  
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

**Atorvastatin:**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 92 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 200 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 108 mg/l

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Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 14 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.49 mg/l  
Exposure time: 33 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.2 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

**Persistence and degradability****Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Atorvastatin:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 7.7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

**Bioaccumulative potential****Components:****Atorvastatin:**

Partition coefficient: n-octanol/water : log Pow: 1.62

**Mobility in soil****Components:****Atorvastatin:**

Distribution among environmental compartments : log Koc: 2.84

**Other adverse effects**

No data available

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### 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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### 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.

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### 15. REGULATORY INFORMATION

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

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

#### Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

#### Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

#### Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

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

**16. OTHER INFORMATION****Further information**

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
ID OEL / NAB : Long term exposure limit

AICS - Australian Inventory of Chemical Substances; 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 Inventory; TDG - Transportation of Dangerous Goods; 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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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.

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