SAFETY DATA SHEET

Atorvastatin Formulation

Version 3.5
Revision Date: 27.08.2021
SDS Number: 187327-00012
Date of last issue: 10.10.2020
Date of first issue: 17.06.2015

SECTION 1. IDENTIFICATION

Product name: Atorvastatin Formulation

Manufacturer or supplier's details
Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
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

SECTION 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 disposal plant.
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<thead>
<tr>
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</tbody>
</table>

**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.

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

**Substance / Mixture**: Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>134523-03-8</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

**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. 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. 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 (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**: 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. Exposure to combustion products may be a hazard to health.
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| Hazardous combustion products | Carbon oxides  
|                              | Nitrogen oxides (NOx)  
|                              | Fluorine compounds  
|                              | 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 (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.  
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. 
Take care to prevent spills, waste and minimize release to the 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>134523-03-8</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

#### 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.

<table>
<thead>
<tr>
<th>Filter type</th>
<th>Particulates type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td>Remarks</td>
<td>Consider double gloving.</td>
</tr>
</tbody>
</table>
| 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. 
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. 
Use appropriate degowning techniques to remove potentially
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers 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: granular
Color: No data available
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: 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
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
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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:
- 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
Not classified based on available information.

Components:

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:
Atorvastatin:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Atorvastatin:
Species: Rabbit
Result: No eye irritation
Method: Draize Test

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Atorvastatin:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
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
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### Atorvastatin:

**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

### Reproductive toxicity
Not classified based on available information.
Components:

**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

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

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

**STOT-single exposure**
Not classified based on available information.

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

Components:

**Atorvastatin:**
Routes of exposure: Ingestion  
Target Organs: Liver, muscle  
Assessment: May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

Components:

**Cellulose:**
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Species: Rat
NOAEL: \( \geq 9.000 \, \text{mg/kg} \)
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

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Cellulose:**
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): \( > 100 \, \text{mg/l} \)
Exposure time: 48 h
Remarks: Based on data from similar materials

**Atorvastatin:**
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): \( > 92 \, \text{mg/l} \)
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
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

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.

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry: Not applicable

Control of precursors and essential chemicals for the preparation of drugs: Not applicable

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

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information


Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

AR OEL: Argentina. Occupational Exposure Limits
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.