SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Omarigliptin Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A Parque Industrial Vice Presidente José Alencar Aparecida de Goias – GO, Brazil
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 in accordance with ABNT NBR 14725 Standard
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Stomach, Blood, Kidney)

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms: 

Signal Word: Warning

Hazard Statements: H373 May cause damage to organs (Stomach, Blood, Kidney) through prolonged or repeated exposure if swallowed.
Precautionary Statements: Prevention:
P260 Do not breathe dust.
Response:
P314 Get medical advice/attention if you feel unwell.

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
SAFETY DATA SHEET

Omarigliptin Formulation

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Omarigliptin</td>
<td>1226781-44-7</td>
<td>Specific target organ toxicity - repeated exposure (Oral) (Stomach, Blood, Kidney), Category 2</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.

**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.

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
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.

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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Omarigliptin</td>
<td>1226781-44-7</td>
<td>TWA</td>
<td>10 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are
designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

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: 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 goggles
Skin and body protection: Skin should be washed after contact.
### Appearance
- Tablet

### Color
- 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
- 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

### Autoignition temperature
- No data available

### Decomposition temperature
- No data available

### Viscosity
- Dynamic viscosity: No data available
- Kinematic viscosity: 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

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

Omarigliptin:
Acute oral toxicity : LD50 (Rat): 750 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Omarigliptin:
Result : No skin irritation

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

Omarigliptin:
Species: Bovine cornea
Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Omarigliptin:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Assessment: Does not cause skin sensitization.
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

Genotoxicity in vitro: 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

Omarigliptin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: negative
Carcinogenicity
Not classified based on available information.

Components:

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

Omarigliptin:
Species: Rat
Application Route: Oral
Exposure time: 2 Years: 20 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 2 Years: 20 mg/kg body weight
Result: negative

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

Omarigliptin:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL: 100 mg/kg body weight
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rabbit
Developmental Toxicity: NOAEL: > 50 mg/kg body weight
Result: No effects on fetal development.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Reduced offspring weight gain., Reduced maternal food consumption., Skeletal malformations.
Remarks: The effects were seen only at maternally toxic doses.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (Stomach, Blood, Kidney) through prolonged or repeated exposure if swallowed.

Components:

Omarigliptin:
Routes of exposure : Ingestion
Target Organs : Stomach, Blood, Kidney
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:
Species : Rat
NOAEL : >= 9.000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Omarigliptin:
Species : Rat
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 Days
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 10 mg/kg
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 180 Days
Target Organs : Blood, Kidney

Species : Dog
NOAEL : 10 mg/kg
LOAEL : 75 mg/kg
Application Route : Oral
Exposure time : 40 Days
Target Organs : Stomach
SAFETY DATA SHEET

Omarigliptin Formulation

Species: Dog
NOAEL: 10 mg/kg
LOAEL: 75 mg/kg
Application Route: Oral
Exposure time: 270 Days
Target Organs: Stomach

Species: Monkey
NOAEL: 9 mg/kg
Application Route: Oral
Exposure time: 90 Days
Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Omarigliptin:
Ingestion: Symptoms: Headache, stomach discomfort, Dizziness, Tiredness, Diarrhea, flu-like symptoms, Back pain, Vomiting, chills

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Omarigliptin:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
EC50 (Americamysis): > 100 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

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)): 25 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity):
- NOEC (Pimephales promelas (fathead minnow)): 11 mg/l
- Exposure time: 32 d
- Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 11 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
- Method: OECD Test Guideline 209
- NOEC: 0,1 mg/l
- Exposure time: 3 h
  - Test Type: Respiration inhibition
- Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:
- Biodegradability: Result: Readily biodegradable.

Omarigliptin:
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 50 %
  - Exposure time: 11 d
  - Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Omarigliptin:
- Partition coefficient: n-octanol/water: log Pow: 0,525

Mobility in soil

Components:

Omarigliptin:
- Distribution among environmental compartments: log Koc: 4,01
  - Method: OECD Test Guideline 106

Other adverse effects
No data available
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH):
Not applicable

Brazil. List of chemicals controlled by the Federal Police:
Not applicable

International Regulations

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
Sources of key data used to:
Internal technical data, data from raw material SDSs, OECD
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.