SAFETY DATA SHEET

Omarigliptin Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Omarigliptin Formulation

Manufacturer or supplier's details
Company name of supplier : MSD
Address : 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A.  07033
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 (Stomach, Blood, Kidney)

GHS label elements
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.
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
Components :
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 environment. |
| 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/PERSOAL 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>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**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
   Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, dynamic : No data available
   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

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

<table>
<thead>
<tr>
<th>Route</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

#### 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
  - Test Type: In vitro mammalian cell gene mutation test
    - Result: negative

Omarigliptin:
- 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: 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.

### Components:

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

### Components:

### 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

### Components:

### Omarigliptin:
- **Species**: Dog
- **NOAEL**: 10 mg/kg
- **LOAEL**: 75 mg/kg
- **Application Route**: Oral
- **Exposure time**: 40 Days
- **Target Organs**: Stomach

### Components:

### Omarigliptin:
- **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

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 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

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-PPT : Time weighted average limit value
SAFETY DATA SHEET

Omarigliptin Formulation

Version 2.3
Revision Date: 10.10.2020
SDS Number: 402529-00011
Date of last issue: 13.09.2019
Date of first issue: 07.01.2016

AllIC - 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; 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; 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; 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


Revision Date: 10.10.2020

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.

MX / Z8