SAFETY DATA SHEET

Omarigliptin Formulation

Section 1: Identification

Product name: Omarigliptin Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
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

Section 2: Hazard identification

GHS Classification
Specific target organ toxicity - repeated exposure (Oral): STOT RE2 (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.
SAFETY DATA SHEET

Omarigliptin Formulation

Version 1.9  Revision Date: 09/13/2019  SDS Number: 402548-00010  Date of last issue: 24.04.2019
Date of first issue: 07.01.2016

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;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Omarigliptin</td>
<td>1226781-44-7</td>
<td>&gt;= 10 - &lt; 30</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 firefighting: 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 prod- : Carbon oxides
Product 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 firefighters: 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 and personal protective equipment recommendations. |
| Environmental precautions | Discharge into the environment must be avoided. 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. 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 labelled 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

Components 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>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</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 and quantity of the hazardous substance and 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.
SAFETY DATA SHEET

Omarigliptin Formulation

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
Colour  :  yellow
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
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, dynamic  :  No data available
Viscosity, kinematic  :  No data available
### Section 10: Stability and reactivity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### Section 11: Toxicological information

#### Exposure routes
- 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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Chronic toxicity

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
SAFETY DATA SHEET

Omarigliptin Formulation

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 foetal 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
SAFETY DATA SHEET

Omarigliptin Formulation

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

- **Test Type:** Embryo-foetal 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:**
- **Exposure routes:** 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

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, Diarrhoea, 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
SAFETY DATA SHEET

Omarigliptin Formulation

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.

National Regulations
- NZS 5433: Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
- HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
- Certified handler certificate not required.
- Tracking hazardous substance not required.
- Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined
Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA: 8-hour, time-weighted average
NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average

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 Civil Aviation Organization; IC50 - Half maximal inhibitory concentration; ICAS - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; LD50 - Lethal Dose to 50% of a test population; 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; TCS - Toxicological Concentration for Environmental Stress; (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 - Transport of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNERTD - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

NZ / EN