SAFETY DATA SHEET

Omarigliptin Formulation

Version 4.0 Revision Date: 04/04/2023 SDS Number: 402445-00017 Date of last issue: 10/01/2022 Date of first issue: 01/07/2016

SECTION 1. IDENTIFICATION

Product name: Omarigliptin Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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 attention if you feel unwell.
Disposal:
P501 Dispose of contents and 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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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<tbody>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
<td></td>
</tr>
<tr>
<td>Omarigliptin</td>
<td>No data available</td>
<td>1226781-44-7</td>
<td>&gt;= 10 - &lt; 30 *</td>
<td></td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

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 : Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May cause damage to organs through prolonged or repeated exposure if swallowed.

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
Metal oxides
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tr>
<td>4.0</td>
<td>04/04/2023</td>
<td>402445-00017</td>
<td>10/01/2022</td>
<td>01/07/2016</td>
</tr>
</tbody>
</table>

### 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.
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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>TWA (Total dust)</td>
<td>TWA 10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>TWA 3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>TWAEV 10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Omarigliptin</td>
<td>1226781-44-7</td>
<td>TWA</td>
<td>TWA 10 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Wipe limit 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 should be washed after contact.

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.

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: No data available

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
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

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 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

#### 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:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Stomach, Blood, Kidney</td>
</tr>
<tr>
<td>Assessment</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

Repeated dose toxicity

Components:

Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 9,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

Omarigliptin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
</tbody>
</table>
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, 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

Exposure time:
Method:

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

Exposure time:
Method:

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.  
Do not dispose of waste into sewer.  
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
TDG: Not regulated as a dangerous good
Special precautions for user: Not applicable

SECTION 15. REGULATORY INFORMATION

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)
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CA BC OEL  :  Canada. British Columbia OEL
CA QC OEL  :  Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA  :  8-hour, time-weighted average
CA AB OEL / TWA  :  8-hour Occupational exposure limit
CA BC OEL / TWA  :  8-hour time weighted average
CA QC OEL / TWAEV  :  Time-weighted average exposure value

All sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/04/2023  Date format: mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

CA / Z8