SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Omarigliptin Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Omarigliptin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Specific target organ toxicity - repeated exposure, Category 2
H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Warning

Hazard statements : H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : Prevention:
P260 Do not breathe dust.
Response:
Hazardous components which must be listed on the label:

Omarigliptin

2.3 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

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omarigliptin</td>
<td>1226781-44-7</td>
<td></td>
<td></td>
<td>STOT RE 2; H373</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks:

May cause damage to organs through prolonged or repeated
exposure.

Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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 products: Carbon oxides

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers:
- Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information:
For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omarigliptin</td>
<td>TWA</td>
<td>10 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**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**

Eye protection: Wear the following personal protective equipment:
- Safety goggles
- Equipment should conform to BS EN 166

Hand protection

- Material: 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.
- Skin and body protection: Skin should be washed after contact.
- 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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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.
Omarigliptin Formulation

9.2 Other information

Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

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

Germ cell mutagenicity
Not classified based on available information.

Components:
Omarigliptin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: 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:
Omarigliptin:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Exposure: 20 mg/kg body weight
Result: negative
Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Exposure: 20 mg/kg body weight
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:
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 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 through prolonged or repeated exposure.

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:

Omarigliptin:
Species: Rat
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 90 Days
Remarks: No significant adverse effects were reported

Species: Rat
NOAEL: 100 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
according to Regulation (EC) No. 1907/2006

Omarigliptin Formulation

<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>
</thead>
</table>

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

12.1 Toxicity

Components:

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 microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
12.2 Persistence and degradability

**Components:**

**Omarigliptin:**

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

12.3 Bioaccumulative potential

**Components:**

**Omarigliptin:**

Partition coefficient: n-octanol/water: log Pow: 0.525

12.4 Mobility in soil

**Components:**

**Omarigliptin:**

Distribution among environmental compartments: log Koc: 4.01  
Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks:
Not applicable for product as supplied.

SECTION 15: Regulatory information

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

- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
- REACH - List of substances subject to authorisation (Annex XIV): Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
- Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.
The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information
Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements
H373: May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations
STOT RE: Specific target organ toxicity - repeated exposure
GB EH40: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL: Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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, Evalua-
Omarigliptin Formulation

Version 2.2 | Revision Date: 09/13/2019 | SDS Number: 443745-00010 | Date of last issue: 24.04.2019
| | | | Date of first issue: 07.01.2016

Further information


Classification of the mixture: STOT RE 2 H373

Classification procedure: Calculation method

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.

GB / EN