SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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Date of first issue: 09.11.2017

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

1.1 Product identifier
   Trade name : Sitagliptin 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
              Kilsheelan
              Clonmel Tipperary, IE
   Telephone : 353-51-601000
   E-mail address of person responsible for the SDS : EHSDATATESTWARD@msd.com

1.4 Emergency telephone number
   National Poison Control Center (UZEM): 114
   Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification T.R. SEA No 28848
   Eye irritation, Category 2  H319: Causes serious eye irritation.

2.2 Label elements
   Labelling T.R. SEA No 28848
   Hazard pictograms :
      
   Signal word : Warning
   Hazard statements : H319  Causes serious eye irritation.
   Precautionary statements :
      Prevention:
      P264  Wash skin thoroughly after handling.
      P280  Wear eye protection/ face protection.
   Response:
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P305 + P351 + P338  **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313  **If eye irritation persists:** Get medical advice/attention.

2.3 Other hazards
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>=&gt; 30 - &lt; 50</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>022-006-00-2</td>
<td></td>
<td>Carc. 2; H351</td>
<td>=&gt; 0.1 - &lt; 1</td>
</tr>
<tr>
<td>Substances with a workplace exposure limit:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td></td>
<td></td>
<td></td>
<td>=&gt; 20 - &lt; 30</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.
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</tr>
</tbody>
</table>

- **In case of eye contact**: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
- **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**: Causes serious eye irritation. Contact with dust can cause mechanical irritation or drying of the skin.

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, Metal oxides, Oxides of phosphorus

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
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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

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.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
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.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

**Occupational Exposure Limits**

<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>Sitagliptin</td>
<td>654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>ZOAD/TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information:</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Allowable occupational exposure limit values of chemicals in dust form</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ZOAD/TWA (Respirable dust)</td>
<td>5 mg/m3</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information:</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Allowable occupational exposure limit values of chemicals in dust form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>ZOAD/TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Allowable occupational exposure limit values of chemicals in dust form</td>
<td></td>
<td></td>
</tr>
</tbody>
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These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.

Titanium dioxide

8.2 Exposure controls

Engineering measures
Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment
Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection
Work uniform or laboratory coat.

Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 143
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance: powder
Colour: No data available
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: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
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- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
- Vapour pressure: Not applicable
- Relative vapour density: Not applicable
- Relative density: No data available
- Density: No data available
- Solubility (ies)
  - Water solubility: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Auto-ignition temperature: No data available
- Decomposition temperature: No data available
- Viscosity
  - Viscosity, kinematic: Not applicable
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.

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
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</tbody>
</table>

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:

**Sitagliptin:**
- Acute oral toxicity: LD50 (Rat): > 3.000 mg/kg
  LD50 (Mouse): 3.000 mg/kg

**Titanium dioxide:**
- Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
- Acute inhalation toxicity:
  - LC50 (Rat): > 6.82 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity

**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

Skin corrosion/irritation
Not classified based on available information.
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</tr>
</tbody>
</table>

### Components:

**Sitagliptin:**
- **Species:** Rabbit
- **Method:** Draize Test
- **Result:** No skin irritation

**Titanium dioxide:**
- **Species:** Rabbit
- **Result:** No skin irritation

### Serious eye damage/eye irritation
Causes serious eye irritation.

### Respiratory or skin sensitisation

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

### Components:

**Sitagliptin:**
- **Test Type:** Local lymph node assay (LLNA)
- **Species:** Mouse
- **Method:** OECD Test Guideline 429
- **Result:** Not a skin sensitizer.

**Titanium dioxide:**
- **Test Type:** Local lymph node assay (LLNA)
- **Exposure routes:** Skin contact
- **Species:** Mouse
- **Result:** negative

### Germ cell mutagenicity
Not classified based on available information.
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<table>
<thead>
<tr>
<th>Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sitagliptin:</strong></td>
</tr>
<tr>
<td>Genotoxicity in vitro:</td>
</tr>
<tr>
<td>Test Type: Ames test</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
</tr>
<tr>
<td>Test system: Chinese hamster ovary cells</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
</tr>
<tr>
<td>Test system: rat hepatocytes</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vivo:</td>
</tr>
<tr>
<td>Test Type: Micronucleus test</td>
</tr>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Titanium dioxide:**

| Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) | Result: negative |
| Genotoxicity in vivo: Test Type: In vivo micronucleus test |
| Species: Mouse |
| Result: negative |

**Cellulose:**

| Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) | Result: negative |
| Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test |
| (in vivo cytogenetic assay) |
| Species: Mouse |
| Application Route: Ingestion |
| Result: negative |

**Carcinogenicity**

Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Sitagliptin:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Exposure time: 2 Years</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Result</th>
<th>negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>oral (drinking water)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

**Carcinogenicity - Assessment:**

Weight of evidence does not support classification as a carcinogen.

**Titanium dioxide:**

Species: Rat
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.
These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.

**Cellulose:**

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

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Sitagliptin:**

Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL Parent: 1,000 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Teratogenicity: LOAEL: 250 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected. No teratogenic effects.
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Test Type: Embryo-foetal development
Species: Rabbit
Teratogenicity: NOAEL: 125 mg/kg body weight
Result: No teratogenic effects

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Sitagliptin:

Species: Mouse
NOAEL: 500 mg/kg
LOAEL: 1.000 mg/kg
Application Route: Oral
Exposure time: > 2 yr
Target Organs: Kidney

Species: Rat
NOAEL: 500 mg/kg
LOAEL: 1.000 mg/kg
Application Route: Oral
Exposure time: 14 Weeks
Target Organs: Liver, Kidney, Heart, Teeth

Species: Dog
NOAEL: 10 mg/kg
LOAEL: 50 mg/kg
Application Route: Oral
Exposure time: 53 Weeks
Target Organs: Central nervous system
Symptoms: Loss of balance
Remarks: The mechanism or mode of action may not be relevant in humans.
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>2 mg/kg</td>
<td>10 mg/kg</td>
<td>Oral</td>
<td>27 Weeks</td>
<td>Skeletal muscle, Central nervous system</td>
<td>Loss of balance</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
<tr>
<td>Monkey</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>14 Weeks</td>
<td></td>
<td></td>
<td></td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Titanium dioxide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>24.000 mg/kg</td>
<td>Ingestion</td>
<td>28 Days</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 9.000 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Sitagliptin:**

- **Inhalation**
  - Symptoms: upper respiratory tract infection, pharyngitis, Headache

- **Ingestion**
  - Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea
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**SECTION 12: Ecological information**

### 12.1 Toxicity

**Components:**

**Sitagliptin:**

- **Toxicity to fish:**
  - Toxicity to fish (Chronic toxicity):
    - NOEC: 9.2 mg/l
    - Exposure time: 33 d
    - Species: Pimephales promelas (fathead minnow)
    - Method: OECD Test Guideline 210

- **Toxicity to daphnia and other aquatic invertebrates:**
  - Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
    - NOEC: 9.8 mg/l
    - Exposure time: 21 d
    - Species: Daphnia magna (Water flea)
    - Method: OECD Test Guideline 211

**Titanium dioxide:**

- **Toxicity to fish:**
  - LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
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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>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>27.08.2021</td>
<td>2160736-00004</td>
<td>09.04.2021</td>
<td>09.11.2017</td>
</tr>
</tbody>
</table>

12.2 Persistence and degradability

Components:

Sitagliptin:

- **Biodegradability**: Result: not rapidly degradable
  - Biodegradation: 39.7 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 314

- **Stability in water**:
  - pH: 7
  - Hydrolysis: 50 % (401 d)
  - Method: OECD Test Guideline 111

Cellulose:

- **Biodegradability**: Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Sitagliptin:

- **Partition coefficient: n-octanol/water**: log Pow: -0.03

12.4 Mobility in soil

Components:

Sitagliptin:

- **Distribution among environmental compartments**: log Koc: 4.37

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available
SAFETY DATA SHEET
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SECTION 13: Disposal considerations

13.1 Waste treatment methods

<table>
<thead>
<tr>
<th>Product</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminated packaging</td>
<td>Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>KKDIK (30105 (Bi)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)</td>
<td></td>
</tr>
<tr>
<td>Regulation on Persistent Organic Pollutants (Number 30595)</td>
<td></td>
</tr>
<tr>
<td>Regulation on prevention of major industrial accidents. Reg number 30702</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Other regulations:
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

**Sitagliptin Formulation**

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Dust Control (No: 28812, 2013). Occupational Dust Exposure Limit Values (Annex 1)

The components of this product are reported in the following inventories:

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

**SECTION 16: Other information**

Other information: The SDS has been prepared by; Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

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**

- H319: Causes serious eye irritation.
- H351: Suspected of causing cancer if inhaled.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

**Full text of other abbreviations**

- Carc.: Carcinogenicity
- Eye Irrit.: Eye irritation
- TR OEL DU: Turkey. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)
- TR OEL DU / ZOAD/TWA: Time Weighted Average Value

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; AIIC - Australian Inventory of Industrial Chemicals; 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; 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
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Further information:

Classification of the mixture:
Eye Irrit. 2  H319

Classification procedure:
Calculation method

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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.

TR / EN