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

1.1 Product identifier
   Trade name : Sitagliptin / Metformin 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
             Innishannon
             County Cork - Ireland
   Telephone : 353 214329300
   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)
   Acute toxicity, Category 4  H302: Harmful if swallowed.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : !
   Signal word : Warning
   Hazard statements : H302 Harmful if swallowed.
   Precautionary statements : Prevention:
                            P264 Wash skin thoroughly after handling.
                            P270 Do not eat, drink or smoke when using this product.
   Response:
       P301 + P312 + P330  IF SWALLOWED: Call a POISON
Hazardous components which must be listed on the label:
metformin hydrochloride

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td></td>
<td>214-230-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</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 unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
4.2 Most important symptoms and effects, both acute and delayed
Risks: Harmful if swallowed.  
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  
Nitrogen oxides (NOx)  
Metal 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.
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>metformin hydro-chloride</td>
<td>1115-70-4</td>
<td>TWA</td>
<td>2 mg/m³ (OEL 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m³ (OEL 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used

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 expo-
sure assessment demonstrates exposures outside the recom-
mended guidelines, use respiratory protection.
Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
| Flammability (solid, gas)                     | May form explosive dust-air mix-
ture during processing, handling or other means. |
| 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
- 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
  Harmful if swallowed.

Product:
- Acute oral toxicity:
  - Acute toxicity estimate: 1,380 mg/kg
  - Method: Calculation method

Components:
- metformin hydrochloride:
  - Acute oral toxicity:
    - LD50 (Rat): 1,000 mg/kg
    - LD50 (Mouse): 1,450 - 3,500 mg/kg
LD50 (Monkey): 463 mg/kg
LD50 (Rabbit): 350 mg/kg
LD50 (Guinea pig): 500 mg/kg

Sitagliptin:
Acute oral toxicity:
LD50 (Rat): > 3,000 mg/kg
LD50 (Mouse): 3,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

metformin hydrochloride:
Species: Rabbit
Result: Mild skin irritation

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

Serious eye damage/eye irritation
Not classified based on available information.

Components:

metformin hydrochloride:
Species: Rabbit
Result: Mild eye irritation

Sitagliptin:
Species: Rabbit
Method: Draize Test
Result: Irritating to eyes.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Sitagliptin:
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<table>
<thead>
<tr>
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<th>Revision Date</th>
<th>SDS Number</th>
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<th>Date of first issue</th>
</tr>
</thead>
</table>

**Test Type**: Local lymph node assay (LLNA)

**Species**: Mouse

**Method**: OECD Test Guideline 429

**Result**: Not a skin sensitizer.

### Germ cell mutagenicity
Not classified based on available information.

### Components:

**metformin hydrochloride**:

**Genotoxicity in vitro**:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: in vitro assay
  - Test system: mouse lymphoma cells
  - Result: negative
- Test Type: Chromosomal aberration
  - Test system: Human lymphocytes
  - Result: negative

**Genotoxicity in vivo**:
- Test Type: Micronucleus test
  - Species: Mouse
  - Application Route: Oral
  - Result: negative

**Sitagliptin**:

**Genotoxicity in vitro**:
- Test Type: Ames test
  - Result: negative
- Test Type: Chromosome aberration test in vitro
  - Test system: Chinese hamster ovary cells
  - Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Test system: rat hepatocytes
  - Result: negative

**Genotoxicity in vivo**:
- Test Type: Micronucleus test
  - Species: Mouse
  - Application Route: Oral
  - Result: negative

### Carcinogenicity
Not classified based on available information.

### Components:

**metformin hydrochloride**:

**Species**: Mouse

**Exposure time**: 91 weeks
### Dose and Result

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>Dose</td>
<td>900 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>LOAEL</td>
<td>900 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Uterus (including cervix)</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

### Sitagliptin:  

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<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

### Reproductive toxicity

Not classified based on available information.

### Components:

**Metformin hydrochloride:**

- **Effects on fertility**
  - Test Type: Fertility  
  - Species: Rat  
  - Application Route: Oral  
  - Fertility: NOAEL: 600 mg/kg body weight  
  - Result: No effects on fertility

- **Effects on foetal development**
  - Test Type: Development  
  - Species: Rat  
  - Application Route: Oral  
  - Developmental Toxicity: NOAEL: 600 mg/kg body weight  
  - Result: No teratogenic effects  
  - Test Type: Embryo-foetal development
Sitagliptin / Metformin Formulation

<table>
<thead>
<tr>
<th>Specie</th>
<th>Application Route</th>
<th>Test Type</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Oral</td>
<td>Embryo-foetal toxicity</td>
<td>Rat</td>
<td>140 mg/kg body weight</td>
<td>Oral</td>
<td>250 mg/kg body weight</td>
<td>Rabbit</td>
<td>125 mg/kg body weight</td>
<td>Oral</td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>Embryotoxic effects and adverse effects on the offspring were detected</td>
<td>Rat</td>
<td>1,000 mg/kg body weight</td>
<td>Oral</td>
<td></td>
<td>Rabbit</td>
<td>125 mg/kg body weight</td>
<td>Oral</td>
</tr>
</tbody>
</table>

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

**metformin hydrochloride:**

<table>
<thead>
<tr>
<th>Specie</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>125 mg/kg</td>
<td>Oral</td>
<td>1 year</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Rabbit</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>1 Year</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Dog</td>
<td>50 mg/kg</td>
<td>Subcutaneous</td>
<td>2 year</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>
Sitagliptin / Metformin Formulation

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.

- **Species**: Dog
- **NOAEL**: 2 mg/kg
- **LOAEL**: 10 mg/kg
- **Application Route**: Oral
- **Exposure time**: 27 Weeks
- **Target Organs**: Skeletal muscle, Central nervous system
- **Symptoms**: Loss of balance
- **Remarks**: The mechanism or mode of action may not be relevant in humans.

- **Species**: Monkey
- **NOAEL**: 100 mg/kg
- **Application Route**: Oral
- **Exposure time**: 14 Weeks
- **Remarks**: No significant adverse effects were reported

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**metformin hydrochloride:**

- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Remarks: May irritate eyes.
- **Ingestion**: Symptoms: Diarrhoea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache
Sitagliptin / Metformin Formulation

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

**Sitagliptin / Metformin Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
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<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

**12.1 Toxicity**

**Components:**

**metformin hydrochloride:**

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</th>
<th>Exposure time: 72 h</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>(Pseudokirchneriella subcapitata (green algae)): 100 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50 : &gt; 1,000 mg/l</th>
<th>Exposure time: 3 h</th>
<th>Test Type: Respiration inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 209</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>NOEC: 10 mg/l</th>
<th>Exposure time: 33 d</th>
<th>Species: Pimephales promelas (fathead minnow)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 210</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>NOEC: 40 mg/l</th>
<th>Exposure time: 21 d</th>
<th>Species: Daphnia magna (Water flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sitagliptin:**

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>LC50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 203</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50 (Daphnia magna (Water flea)): 60 mg/l</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 202</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 39 mg/l</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sitagliptin / Metformin Formulation

Version 2.2
Revision Date: 09/13/2019
SDS Number: 27108-00014
Date of last issue: 24.04.2019
Date of first issue: 31.10.2014

12.2 Persistence and degradability

Components:

metformin hydrochloride:
Biodegradability: Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 2 hrs

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

12.3 Bioaccumulative potential

Components:

metformin hydrochloride:
Partition coefficient: n-octanol/water: log Pow: -2

Sitagliptin:
Partition coefficient: n-octanol/water: log Pow: -0.03
12.4 Mobility in soil

**Components:**

**metformin hydrochloride:**
Distribution among environmental compartments: log Koc: 4.3  
Method: OECD Test Guideline 106

**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

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.
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according to Regulation (EC) No. 1907/2006

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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
: Not 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
H302 : Harmful if swallowed.
H319 : Causes serious eye irritation.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Eye Irrit. : Eye irritation
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous
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Further information

Classification of the mixture:
Acute Tox. 4 H302 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.

IE / EN