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

1.1 Product identifier
Trade name : Sitagliptin / Simvastatin 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
            Kilsheean
            Clonmel Tipperary, IE
Telephone : 353-51-601000
E-mail address of person responsible for the SDS : EHSDATATESTWARD@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)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye irritation</td>
<td>Category 2</td>
<td>H319: Causes serious eye irritation.</td>
</tr>
<tr>
<td>Skin sensitisation</td>
<td>Category 1</td>
<td>H317: May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Category 2</td>
<td>H373: May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard</td>
<td>Category 3</td>
<td>H412: Harmful to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 🌟⚠️
Signal word : Warning
Hazard statements : 
                    H317: May cause an allergic skin reaction.
                    H319: Causes serious eye irritation.
                    H373: May cause damage to organs through prolonged or repeated exposure.
                    H412: Harmful to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/eye protection/face protection.

**Response:**
- P314 Get medical advice/attention if you feel unwell.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
- P337 + P313 If eye irritation persists: Get medical advice/attention.

Hazardous components which must be listed on the label:

**Simvastatin**

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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>Sitagliptin</td>
<td>654671-77-9</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>Skin Irrit. 2; H315 Skin Sens. 1; H317 STOT RE 1; H372 (Liver, muscle, optic nerve, Eye) Aquatic Chronic 2; H411</td>
<td>&gt;= 2.5 - &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.

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

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: May cause an allergic skin reaction. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.

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 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 (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 get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. 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. Do not eat, drink or smoke when using this product. 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. Contaminated work clothing should not be allowed out of the workplace. 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 Organic peroxides Explosives Gases

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>Sitagliptin</td>
<td>654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN

Wipe limit 250 µg/100 cm² Internal

8.2 Exposure controls

Engineering measures
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

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
- Remarks: Consider double gloving.
- Skin and body protection: Work uniform or laboratory coat.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

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 NS EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: powder
Colour: pink
Sitagliptin / Simvastatin Formulation

Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: 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
Flash point: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature
Decomposition temperature: No data available
pH: No data available
Viscosity
Viscosity, kinematic: Not applicable
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water
Vapour pressure: Not applicable
Relative density: No data available
Density: No data available
Relative vapour density: Not applicable
Particle characteristics
Particle size: No data available

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sitagliptin / Simvastatin Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 24509-00016 Date of last issue: 16.10.2020
Date of first issue: 21.10.2014

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 hazard classes as defined in Regulation (EC) No 1272/2008
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

Simvastatin:
Acute oral toxicity:
- LD50 (Rat): 5.000 mg/kg
- LD50 (Mouse): 3.800 mg/kg

Skin corrosion/irritation
Not classified based on available information.
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Components:

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

Simvastatin:
Species : Rabbit
Remarks : Moderate skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.
Components:

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

Simvastatin:
Species : Rabbit
Remarks : slight irritation

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

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.

Simvastatin:
Assessment : Probability or evidence of skin sensitisation in humans
Result : positive

Germ cell mutagenicity
Not classified based on available information.
Components:

Sitagliptin:
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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

Simvastatin:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Alkaline elution assay
  Result: negative
- Test Type: Chromosomal aberration
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

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

Germ cell mutagenicity - Assessment:
- Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity:
Not classified based on available information.

Components:

Sitagliptin:
- Species: Mouse
- Application Route: Oral
- Exposure time: 2 Years
- Result: negative

- Species: Rat
  Application Route: oral (drinking water)
  Exposure time: 2 Years
  Result: positive
Target Organs: Liver
Remarks: Significant toxicity observed in testing

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Simvastatin:
Species: Mouse
Application Route: Oral
Exposure time: < 92 weeks
Target Organs: Harderian gland
Tumor Type: Liver, Lungs
Remarks: The significance of these findings for humans is not certain.

Species: Rat
Application Route: Oral
Exposure time: 2 Years
Tumor Type: Liver, Thyroid
Remarks: The significance of these findings for humans is not certain.

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

Simvastatin:
Effects on fertility: Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 25 mg/kg body weight

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight
Result: Teratogenic potential
Remarks: Based on data from similar materials

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Simvastatin:
Target Organs: Liver, muscle, optic nerve, Eye
Assessment: Causes damage to organs through prolonged or repeated exposure.

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

- **Sitagliptin**
  - 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.

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

### Species

- **Rat**
  - NOAEL: 5 mg/kg
  - LOAEL: 30 mg/kg
  - Application Route: Oral
  - Exposure time: 14 - 104 Weeks
  - Target Organs: Liver, Testis, Musculo-skeletal system, Eye

- **Dog**
  - NOAEL: 10 mg/kg
  - Application Route: Oral
  - Exposure time: 14 - 104 Weeks
  - Target Organs: Liver, Testis, Eye

- **Rabbit**
  - NOAEL: 30 mg/kg
  - LOAEL: 50 mg/kg
  - Application Route: Oral
  - Target Organs: Liver, Kidney

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

**Product:**

**Assessment:**

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at
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

**Simvastatin:**
- **Skin contact:** Remarks: May produce an allergic reaction.
- **Ingestion:** Target Organs: Liver
  - Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea
  - Target Organs: Musculo-skeletal system

**SECTION 12: Ecological information**

12.1 Toxicity

**Components:**

**Sitagliptin:**
- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): 60 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): > 39 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 2,2 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201

- **Toxicity to microorganisms**: EC50: > 150 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - NOEC: 150 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition

- **Toxicity to fish (Chronic tox-)**: NOEC: 9,2 mg/l
Sitagliptin / Simvastatin Formulation

Exposure time: 33 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

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

Simvastatin:

Toxicity to fish  
: LC50 (Pimephales promelas (fathead minnow)): 2.91 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates  
: EC50 (Daphnia magna (Water flea)): 3.5 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants  
: EC50 (Pseudokirchneriella subcapitata (green algae)): > 25 mg/l  
Exposure time: 96 h  
NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l  
Exposure time: 96 h

Toxicity to microorganisms  
: EC50 : > 30 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
NOEC : 21 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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

Simvastatin:

Biodegradability  
: Result: rapidly degradable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Stability in water : Hydrolysis: 50% (3.2 d)

12.3 Bioaccumulative potential

Components:

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

Simvastatin:
Partition coefficient: n-octanol/water : log Pow: > 4.07

12.4 Mobility in soil

Components:

Sitagliptin:
Distribution among environmental compartments : log Koc: 4.37

12.5 Results of PBT and vPvB assessment

Product:
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:
Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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 or ID 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 Maritime transport in bulk according to IMO instruments
   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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
   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 (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
   Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

   Other regulations:
   Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

   The components of this product are reported in the following inventories:
   AICS : not determined
   DSL : not determined
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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I ECSC : 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
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H372 : Causes damage to organs through prolonged or repeated exposure.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

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 - 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; KECl - 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, Evaluation, Authorisation and Re-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Sitagliptin / Simvastatin Formulation

Version: 3.5  
Revision Date: 09.04.2021  
SDS Number: 24509-00016  
Date of last issue: 16.10.2020

Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bio-accumulative

Further information

Classification of the mixture:
Eye Irrit. 2: H319  
Skin Sens. 1: H317  
STOT RE 2: H373  
Aquatic Chronic 3: H412

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.

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