SAFETY DATA SHEET

Zilpaterol Formulation

Version 4.0  Revision Date: 23.03.2020  SDS Number: 29182-00016  Date of last issue: 13.09.2019
  Date of first issue: 07.11.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Zilpaterol Formulation

Manufacturer or supplier's details
Company: MSD
Address: Brihnager - Off Pune Nagar Road
          Wagholi - Pune - India  412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Specific target organ toxicity - repeated exposure: Category 2 (Cardio-vascular system, Central nervous system, Lungs)

GHS label elements
Hazard pictograms: 

Signal word: Warning

Hazard statements: H373 May cause damage to organs (Cardio-vascular system, Central nervous system, Lungs) through prolonged or repeated exposure.

Precautionary statements: Prevention:
P260 Do not breathe dust.
Response:
P314 Get medical advice/ attention if you feel unwell.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilpaterol</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilpaterol</td>
<td>119520-06-8</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Get medical attention if symptoms occur.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: 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.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire-fighting: Avoid generating dust; fine dust dispersed in air in sufficient
fighting 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)

Specific extinguishing methods:
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures:
Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
Use only with adequate ventilation.

Advice on safe handling:
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety
practice, based on the results of the workplace exposure assessment.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled containers.
Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilpaterol</td>
<td>119520-06-8</td>
<td>TWA</td>
<td>1 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Particulates type
Hand protection: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration 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. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment:
Safety goggles
Skin and body protection: Skin should be washed after contact.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye
flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

9. 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>tan</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>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

**Reactivity:** Not classified as a reactivity hazard.

**Chemical stability:** Stable under normal conditions.

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

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

**Incompatible materials:** Oxidizing agents

**Hazardous decomposition products:** No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

**Acute toxicity**

Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>Acute toxicity estimate: &gt; 5,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse, male and female): 430 - 580 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat, male and female): 890 - 1,325 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>Acute toxicity estimate: &gt; 10 mg/l</td>
<td>Calculation method</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
<td>Dust/mist</td>
</tr>
</tbody>
</table>

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity</th>
<th>Value</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilpaterol</td>
<td>Acute oral toxicity</td>
<td>LD50 (Mouse, male and female): 430 - 580 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD50 (Rat, male and female): 890 - 1,325 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 5 mg/l</td>
<td>Calculation method</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure time: 4 h</td>
<td>Dust/mist</td>
</tr>
</tbody>
</table>
Symptoms: Tremors, Breathing difficulties

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Acute toxicity (other routes of administration) :
- TDLo (Rabbit): 9.6 %
- Application Route: see user defined free text
- Symptoms: Increased pulse rate

Skin corrosion/irritation
Not classified based on available information.

Components:
Zilpaterol:
- Species: Rabbit
- Result: No skin irritation

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

Components:
Zilpaterol:
- Species: Rabbit
- Result: Mild eye irritation

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Zilpaterol:
- Test Type: Maximisation Test
- Species: Guinea pig
- Assessment: Does not cause skin sensitisation.
- Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Zilpaterol:
- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
  - Test system: Chinese hamster ovary cells
  - Result: negative
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Test Type: Mouse Lymphoma
Test system: mouse lymphoma cells
Result: negative

Test Type: unscheduled DNA synthesis assay
Test system: rat hepatocytes
Result: negative

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

Test Type: in vivo assay
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Zilpaterol:
Species: Rat, male and female
Application Route: Oral (feed)
Exposure time: 104 weeks
: 0.05 mg/kg body weight
: 0.125 mg/kg body weight
Result: negative
Target Organs: Ovary

Species: Mouse
Application Route: Oral
Exposure time: 18 Months
: 0.02 mg/kg body weight
: 0.05 mg/kg body weight
Result: negative
Target Organs: Blood

Reproductive toxicity
Not classified based on available information.

Components:

Zilpaterol:
Effects on fertility: Test Type: Two-generation study
Species: Rat, male
Application Route: oral (feed)
Fertility: NOAEL: 1.8 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Test Type: Two-generation study
Species: Rat, male
Application Route: oral (feed)
Fertility: NOAEL: 0.94 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat, female
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 50 mg/kg body weight
Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Cardio-vascular system, Central nervous system, Lungs) through prolonged or repeated exposure.

Components:

Zilpaterol:
Target Organs: Cardio-vascular system, Central nervous system, Lungs
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Zilpaterol:
Species: Monkey
NOAEL: 0.01 mg/kg
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 4 Weeks
Target Organs: Cardio-vascular system
Symptoms: Increased pulse rate, Lowered blood pressure

Species: Rat, male and female
NOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Cardio-vascular system
Symptoms: Lowered blood pressure

Species: Pig, male and female
NOAEL: 0.05 mg/kg
LOAEL: 1 mg/kg
Application Route: Oral
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<table>
<thead>
<tr>
<th>Exposure time</th>
<th>13 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Heart</td>
</tr>
</tbody>
</table>

| Species | Rat, male and female |
| NOAEL | 0.250 mg/kg |
| Application Route | oral (feed) |
| Exposure time | 52 Weeks |
| Target Organs | Cardio-vascular system |
| Symptoms | slow pulse |

| Species | Dog |
| Application Route | Dermal |
| Remarks | No significant adverse effects were reported |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

| Zilpaterol: |
| Ingestion: Target Organs: Lungs |
| Symptoms: Tremors, Increased pulse rate |
| Target Organs: Central nervous system |

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

| Zilpaterol: |
| Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l |
| Exposure time: 72 h |
| Method: OECD Test Guideline 201 |
| Remarks: No toxicity at the limit of solubility |
| EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l |
| Exposure time: 72 h |
| Method: OECD Test Guideline 201 |
| Remarks: No toxicity at the limit of solubility |

**Persistence and degradability**

**Components:**

| Zilpaterol: |
| Stability in water: Hydrolysis: 0 % (5 d) |
Bioaccumulative potential

**Components:**

**Zilpaterol:**
- Partition coefficient: n-octanol/water: log Pow: 1

Mobility in soil

**Components:**

**Zilpaterol:**
- Distribution among environmental compartments: log Koc: 2.8

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- Waste from residues: Dispose of in accordance with local regulations.
- 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.

14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to IMO instruments**
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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

**AICS:** not determined

**DSL:** not determined
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Version 4.0  Revision Date: 23.03.2020  SDS Number: 29182-00016  Date of last issue: 13.09.2019
Date of first issue: 07.11.2014

IECSC : not determined

16. OTHER INFORMATION

Further information

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

Date format : dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; ICH - International Pharmaceutical Conference; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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 Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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 Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.