SAFETY DATA SHEET

Zilpaterol Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Zilpaterol Formulation

Manufacturer or supplier's details
Company : MSD
Address : 91-105 Harpin Street
          Bendigo 3550, Victoria Australia
Telephone : 908-740-4000
Emergency telephone number : 1 800 033 461
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 1 800 817 414

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

SECTION 2. HAZARDS IDENTIFICATION

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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<tbody>
<tr>
<td>Zilpaterol</td>
<td>119520-06-8</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

SECTION 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.

SECTION 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media
None known.

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
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**ucts**

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.

SECTION 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.

SECTION 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.

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.

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

SECTION 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.

Eye protection: Wear the following personal protective equipment:
Safety goggles

Skin and body protection: Skin should be washed after contact.
SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: powder
- **Colour**: tan
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
- **Solubility(ies)**: Water solubility: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**:
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: No data available

**SECTION 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.

**SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes: Inhalation

Skin contact

Ingestion

Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: Calculation method

**Components:**

**Zilpaterol:**

Acute oral toxicity: LD50 (Mouse, male and female): 430 - 580 mg/kg

LD50 (Rat, male and female): 890 - 1,325 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Symptoms: Tremors, Breathing difficulties

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

Acute toxicity (other routes of): TDLo (Rabbit): 9.6 %
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

Chronic toxicity

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
Test Type: Mouse Lymphoma
Test system: mouse lymphoma cells
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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
\[ \begin{align*}
0.05 \text{ mg/kg body weight} \\
0.125 \text{ mg/kg body weight}
\end{align*} \]
Result: negative
Target Organs: Ovary

Species: Mouse
Application Route: Oral
Exposure time: 18 Months
\[ \begin{align*}
0.02 \text{ mg/kg body weight} \\
0.05 \text{ mg/kg body weight}
\end{align*} \]
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:
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
Exposure time: 13 Weeks
Target Organs: Heart
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

SECTION 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

SECTION 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.

SECTION 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

ADG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:
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
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>3.12</td>
<td>23.03.2020</td>
<td>29162-00016</td>
<td>Date of first issue: 07.11.2014</td>
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</table>

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.

AU / EN