1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Zilpaterol Formulation

Supplier’s company name, address and phone number
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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
Important symptoms and outlines of the emergency as-
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of
sumed the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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

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. HANDLING AND STORAGE

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 Advice on safe handling : Use only with adequate ventilation.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.

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.

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.
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.

Avoidance of contact: Oxidizing agents
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.

Storage
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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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

Material: 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
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chemicals of the aforementioned protective gloves with the
glove manufacturer. Wash hands before breaks and at the
day of workday.

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

Skin and body protection : Skin should be washed after contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : tan

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-
dling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available
### Vapour pressure
- No data available

### Density and/or relative density
- Relative density: No data available
- Relative vapour density: No data available

### Explosive properties
- Not explosive

### Oxidizing properties
- The substance or mixture is not classified as oxidizing.

### Molecular weight
- No data available

### Particle characteristics
- Particle size: No data available

### 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.

**Conditions to avoid**: Heat, flames and sparks.

**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:**

- **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 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

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
- LOAEL: 0.05 mg/kg
### Application Route
- Oral

### Exposure time
- 13 Weeks

### Target Organs
- Cardio-vascular system
- 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

### LOAEL
- 1 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

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

### Experience with human exposure

#### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Route</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilpaterol</td>
<td>Ingestion</td>
<td>Lungs</td>
<td>Tremors, Increased pulse rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

#### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to algae/aquatic plants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilpaterol</td>
<td>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</td>
</tr>
</tbody>
</table>

|       | 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 |

---

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**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: log Koc: 2.8

**Hazardous to the ozone layer**
Not applicable

**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 Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable
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Revision Date: 2020/10/16
SDS Number: 29185-00017
Date of last issue: 2020/03/23
Date of first issue: 2014/11/07

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; 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
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.

JP / EN