according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Zilpaterol Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

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:

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

P319 Get medical help 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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No. Concentration (
		w/w)
Zilpaterol	119520-06-8	>= 1 - < 5

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.

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 : None known.

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

media

Specific hazards during fire-

fighting

: 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 prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

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 con-

tainer 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 deter-

mine 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 Advice on safe handling Use only with adequate ventilation.

: Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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 as-

sessment

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.

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

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Zilpaterol	119520-06-8	TWA	1 μg/m3	Internal
		Wipe limit	10 μg/100 cm ²	Internal

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Particulates type

Hand protection

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 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:

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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

Appearance : powder

Colour : tar

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, han-

dling 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

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

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: > 5,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 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

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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:

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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:

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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 develop-

ment 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 develop-

ment were detected.

Effects on foetal develop-

ment

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 ma-

ternally 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

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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

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

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

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 environ-

mental compartments

: log Koc: 2.8

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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.

Special precautions for user

Not applicable

according to the Globally Harmonized System



Zilpaterol Formulation

Date of last issue: 04.04.2023 Version Revision Date: SDS Number: 30.09.2023 29182-00022 Date of first issue: 07.11.2014 5.1

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

IECSC not determined

16. OTHER INFORMATION

Revision Date 30.09.2023

Further information

Sources of key data used to

compile the Safety Data Sheet

Date format dd.mm.yyyy

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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 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; 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 - Trans-

according to the Globally Harmonized System



Zilpaterol Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.1 30.09.2023 29182-00022 Date of first issue: 07.11.2014

portation of Dangerous Goods; TECI - Thailand Existing Chemicals 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 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.

IN / EN