

according to the Hazardous Products Regulations

## Zilpaterol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
5.1	09/30/2023	29168-00023	Date of first issue: 11/07/2014

## **SECTION 1. IDENTIFICATION**

Product name	:	Zilpaterol Formulation
Other means of identification	:	No data available

### Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

## Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the Hazardous Products Regulations					
Specific target organ toxicity - repeated exposure	:	Category 1 (Cardio-vascular system, Central nervous system, Lungs)			

#### **GHS** label elements

. . .

Hazard pictograms

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## Signal Word : Danger

Hazard Statements : H372 Causes damage to organs (Cardio-vascular system, Central nervous system, Lungs) through prolonged or repeated exposure.

Precautionary Statements

#### Prevention:

:

P260 Do not breathe dust.P264 Wash skin thoroughly after handling.P270 Do not eat, drink or smoke when using this product.

#### **Response:**

P314 Get medical attention if you feel unwell.

#### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

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#### Other hazards

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

Substance / Mixture : Mixture

#### Components

	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Zilpaterol	No data availa- ble	119520-06-8	>= 1 - < 5 *

Actual concentration or concentration range is withheld as a trade secret

### 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.
In case of eye contact	:	Get medical attention if symptoms occur. 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	:	Causes damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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. FIRE-FIGHTING 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 concentrations, and in the presence of an ignition source is a



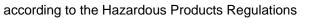
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				potential dust exp Exposure to comb	losion hazard. Soustion products may be a hazard to health.
	Hazardous combustion prod- ucts		:	Carbon oxides Nitrogen oxides (N	NOx)
	Specific ods	c extinguishing meth-	:	Use extinguishing measures that are 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 so.	
	Special protective equipment for fire-fighters		:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.	
SEC	SECTION 6. ACCIDENTAL RELEASE			EMEASURES	
	tive equ	al precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
	Environmental precautions		:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		:	container for disper Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the a Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

## 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.
		Wash skin thoroughly after handling.





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		Handle in accordance with good industrial hygiene and saf 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 environment.			
Conditions for safe storage		: Keep in properly labeled containers.			
Materials to avoid		: Do not store w Strong oxidizin Self-reactive s	•		

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters							
Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis			
		exposure)	concentration				
Zilpaterol	119520-06-8	TWA	1 µg/m³	Internal			
		Wipe limit	10 µg/100 cm <sup>2</sup>	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 equipme							
Respiratory protection	exposure ass	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type					
Filter type Hand protection							
Material	: Chemical-res	istant gloves					
Remarks	on the concer time is not de For special ap resistance to gloves with th	Choose gloves to protect hands against chemicals depending on the concentration 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.					

## Ingredients with workplace control parameters



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Eye p	protection		wing personal protective equipment: s
	ene measures : If exposure to c eye flushing sys working place. When using do		e washed after contact. chemical is likely during typical use, provide ystems and safety showers close to the

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	tan
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Solubility(ies) Water solubility	:	No data available
	:	No data available No data available





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	Decon	nposition temperature	:	No data available	9
		ity cosity, dynamic cosity, kinematic	:	No data available	
		sive properties	:	Not explosive	
	Oxidiz	ing properties	:	The substance o	r mixture is not classified as oxidizing.
	Molec	ular weight	:	No data available	9
	Particl	e size	:	No data available	9

## SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	: :	Not classified as a reactivity hazard. Stable under normal conditions. 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 Hazardous decomposition products	:	Oxidizing agents No hazardous decomposition products are known.

## SECTION 11. TOXICOLOGICAL INFORMATION

## Information on likely routes of exposure

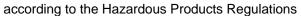
Inhalation Skin contact Ingestion Eye contact

## 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





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	Compo	onents:					
	Zilpate	rol:					
	Acute c	oral toxicity	:	LD50 (Mouse, ma	LD50 (Mouse, male and female): 430 - 580 mg/kg		
				LD50 (Rat, male a	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 c	lermal toxicity	:	LD50 (Rat): > 2,00	00 mg/kg		
		oxicity (other routes of stration)	:	TDLo (Rabbit): 9.6 Application Route Symptoms: Increa	: see user defined free text		
	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
Result	•	wind eye initation

## Respiratory or skin sensitization

## Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

## **Components:**

### Zilpaterol:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Result	:	negative

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Not	m cell mutagenicity classified based on av	ailable i	nformation.	
Con	<u>nponents:</u>			
•	aterol: otoxicity in vitro	:	Test Type: Bacte Result: negative	erial reverse mutation assay (AMES)
				ro mammalian cell gene mutation test inese hamster ovary cells
			Test Type: Mous Test system: mo Result: negative	e Lymphoma use lymphoma cells
			Test Type: unsch Test system: rat Result: negative	neduled DNA synthesis assay hepatocytes
Gen	otoxicity in vivo	:	Test Type: Micro Species: Mouse Application Rout Result: negative	
			Test Type: in viv Species: Mouse Cell type: Bone r Application Rout Result: negative	narrow
Card	cinogenicity			
	classified based on av	ailable i	nformation.	
Con	nponents:			
	aterol:			
Spe App		:	Rat, male and fe oral (feed) 104 weeks 0.05 mg/kg body 0.125 mg/kg bod	veight
Res Targ	ult jet Organs	:	negative Ovary	
	cies lication Route osure time	:	Mouse Oral 18 Months 0.02 mg/kg body 0.05 mg/kg body	
Res Targ	ult jet Organs	:	negative Blood	weight

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•	roductive toxicity classified based on avail	able information.	
Com	ponents:		
Zilpa	terol:		
Effec	ts on fertility	Species: Rat Application F Fertility: NO/ Result: No e development Test Type: T Species: Rat Application F Fertility: NO/ Result: No e	Route: oral (feed) AEL: 1.8 mg/kg body weight ffects on fertility and early embryonic t were detected. wo-generation study
Effec	ts on fetal development	Species: Rat Application F Developmen Embryo-feta Result: No te	Route: Oral tal Toxicity: NOAEL: 10 mg/kg body weight I toxicity.: LOAEL: 50 mg/kg body weight eratogenic effects., Embryotoxic effects and cts on the offspring were detected only at high
STO	T-single exposure		

#### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

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

#### Components:

Target Organs Assessment	Cardio-vascular system, Central nervous system, Lungs 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

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Syr	Symptoms		: Increased pulse rate, Lowered blood pressure		
LÖ App Exp Tar	ecies AEL blication Route bosure time get Organs nptoms		Rat, male and fen 0.05 mg/kg Oral 13 Weeks Cardio-vascular s Lowered blood pr	ystem	
NÖ LO Apr Exr	ecies AEL AEL Dication Route Dosure time get Organs	:	Pig, male and fem 0.05 mg/kg 1 mg/kg Oral 13 Weeks Heart	nale	
NO Apr Exr Tar	ecies AEL blication Route bosure time get Organs nptoms		Rat, male and fen 0.250 mg/kg oral (feed) 52 Weeks Cardio-vascular s slow pulse		
App	ecies blication Route marks	: : :	Dog Dermal No significant adv	verse effects were reported	
Not	piration toxicity classified based on avail perience with human ex				
Co	mponents:				
-	oaterol: estion	:		ungs ors, Increased pulse rate entral nervous system	
SECTIO	N 12. ECOLOGICAL INF	ORI	MATION		
Eco	otoxicity				
Co	mponents:				
-	paterol: kicity to algae/aquatic nts	:	mg/l Exposure time: 72 Method: OECD T Remarks: No toxi		



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			e: 72 h D Test Guideline 201 toxicity at the limit of solubility.
Р	ersistence and degradabi	lity	
<u>c</u>	omponents:		
z	ilpaterol:		
S	tability in water	: Hydrolysis: 0	%(5 d)
В	ioaccumulative potential		
<u>C</u>	omponents:		
Р	<b>ilpaterol:</b> artition coefficient: n- ctanol/water	: log Pow: 1	
Ν	lobility in soil		
<u>c</u>	omponents:		
D	<b>ilpaterol:</b> istribution among environ- nental compartments	: log Koc: 2.8	
0	ther adverse effects		
N	o data available		
SECT	ION 13. DISPOSAL CONSI	DERATIONS	
	isposal methods	· Do not dispos	e of waste into sewer

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 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

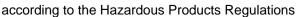
### IATA-DGR

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.





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#### **Domestic regulation**

TDG Not regulated as a dangerous good Special precautions for user

Not applicable

#### SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

AICS	•	:	not determined
DSL		:	not determined
IECSC		:	not determined

### SECTION 16. OTHER INFORMATION

#### 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 - Transportation 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



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Sources of key data used to compile the Material Safety Data Sheet Revision Date Date format		cal data, data from raw material SDSs, OECD search results and European Chemicals Agen- europa.eu/

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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