

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 7.0

Revision Date 24.08.2022

Print Date 02.05.2025

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifiers

Product name : Formoterol Fumarate, United States  
Pharmacopeia (USP) Reference Standard

Product Number : 1286107  
Brand : US Pharmacopeia  
REACH No. : A registration number is not available for this substance as the  
substance or its uses are exempted from registration, the  
annual tonnage does not require a registration or the  
registration is envisaged for a later registration deadline.  
CAS-No. : 183814-30-4

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

### 1.3

### 1.4 Emergency telephone

Emergency Phone # : 000 800 1007 141 (CHEMTREC)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008

Acute toxicity, Inhalation (Category 4), H332

Reproductive toxicity (Category 2), H361d

Specific target organ toxicity - single exposure (Category 1), H370

Specific target organ toxicity - repeated exposure (Category 2), H373

Long-term (chronic) aquatic hazard (Category 3), H412

For the full text of the H-Statements mentioned in this Section, see Section 16.

## 2.2 Label elements

### Labelling according Regulation (EC) No 1272/2008

#### Pictogram

Signal Word	Danger
Hazard statement(s)	
H332	Harmful if inhaled.
H361d	Suspected of damaging the unborn child.
H370	Causes damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.
Precautionary statement(s)	
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust.
P264	Wash skin thoroughly after handling.
P273	Avoid release to the environment.
P304 + P340 + P312	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P308 + P311	IF exposed or concerned: Call a POISON CENTER/ doctor.
Supplemental Hazard Statements	none

### Reduced Labeling (<= 125 ml)

#### Pictogram

Signal Word	Danger
Hazard statement(s)	
H370	Causes damage to organs.
H412	Harmful to aquatic life with long lasting effects.
H361d	Suspected of damaging the unborn child.
Precautionary statement(s)	
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust.
P264	Wash skin thoroughly after handling.
P308 + P311	IF exposed or concerned: Call a POISON CENTER/ doctor.
Supplemental Hazard Statements	none

## 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Caution: Physiologically highly active, therapeutically usable substance. The substance must be handled with the care required for hazardous materials.

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Formula : (C<sub>19</sub>H<sub>24</sub>N<sub>2</sub>O<sub>4</sub>)<sub>2</sub>.C<sub>4</sub>H<sub>4</sub>O<sub>4</sub>.2H<sub>2</sub>O  
Molecular weight : 840,91 g/mol  
CAS-No. : 183814-30-4  
EC-No. : 680-657-3

Component		Classification	Concentration
<b>Formoterol fumarate dihydrate</b>			
CAS-No.	183814-30-4	Acute Tox. 4; Repr. 2; STOT SE 1; STOT RE 2; Aquatic Chronic 3; H332, H361d, H370, H373, H412	<= 100 %
EC-No.	680-657-3		

For the full text of the H-Statements mentioned in this Section, see Section 16.

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## SECTION 4: First aid measures

### 4.1 Description of first-aid measures

#### General advice

Show this material safety data sheet to the doctor in attendance.

#### If inhaled

After inhalation: fresh air. Immediately call in physician. If breathing stops: immediately apply artificial respiration, if necessary also oxygen.

#### In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Call a physician immediately.

#### In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

#### If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

### 4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

### 4.3 Indication of any immediate medical attention and special treatment needed

No data available

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Water Foam Carbon dioxide (CO<sub>2</sub>) Dry powder

#### Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

## **5.2 Special hazards arising from the substance or mixture**

Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

## **5.3 Advice for firefighters**

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

## **5.4 Further information**

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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## **SECTION 6: Accidental release measures**

### **6.1 Personal precautions, protective equipment and emergency procedures**

Advice for non-emergency personnel: Avoid generation and inhalation of dusts in all circumstances. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

### **6.2 Environmental precautions**

Do not let product enter drains.

### **6.3 Methods and materials for containment and cleaning up**

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully. Dispose of properly. Clean up affected area. Avoid generation of dusts.

### **6.4 Reference to other sections**

For disposal see section 13.

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## **SECTION 7: Handling and storage**

### **7.1 Precautions for safe handling**

#### **Advice on safe handling**

Work under hood. Do not inhale substance/mixture.

#### **Hygiene measures**

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

For precautions see section 2.2.

### **7.2 Conditions for safe storage, including any incompatibilities**

#### **Storage conditions**

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.

#### **Storage stability**

Recommended storage temperature

2 - 8 °C

#### **Storage class**

Storage class (TRGS 510): 6.1C: Combustible, acute toxic Cat.3 / toxic compounds or compounds which causing chronic effects

### **7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## **SECTION 8: Exposure controls/personal protection**

### **8.1 Control parameters**

#### **Ingredients with workplace control parameters**

### **8.2 Exposure controls**

#### **Personal protective equipment**

##### **Eye/face protection**

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

##### **Skin protection**

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

##### **Body Protection**

protective clothing

##### **Respiratory protection**

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P3

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

##### **Control of environmental exposure**

Do not let product enter drains.

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## **SECTION 9: Physical and chemical properties**

### **9.1 Information on basic physical and chemical properties**

- |                   |                   |
|-------------------|-------------------|
| a) Physical state | solid             |
| b) Color          | No data available |
| c) Odor           | No data available |

- |   |  |
|---|--|
| d) Melting point/freezing point                 | No data available  |
| e) Initial boiling point and boiling range      | No data available  |
| f) Flammability (solid, gas)                    | No data available  |
| g) Upper/lower flammability or explosive limits | No data available  |
| h) Flash point                                  | Not applicable   |
| i) Autoignition temperature                     | No data available  |
| j) Decomposition temperature                    | No data available  |
| k) pH   | No data available  |
| l) Viscosity                                    | Viscosity, kinematic: No data available<br>Viscosity, dynamic: No data available |
| m) Water solubility                             | No data available  |
| n) Partition coefficient: n-octanol/water       | No data available  |
| o) Vapor pressure                               | No data available  |
| p) Density                                      | No data available  |
| Relative density                                | No data available  |
| q) Relative vapor density                       | No data available  |
| r) Particle characteristics                     | No data available  |
|   |  |
| s) Explosive properties                         | No data available  |
| t) Oxidizing properties                         | none   |

## 9.2 Other safety information

No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

### 10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

no information available

## 10.5 Incompatible materials

Strong oxidizing agents

## 10.6 Hazardous decomposition products

In the event of fire: see section 5

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

LD50 Oral - Rat - 3.130 mg/kg

Remarks: (Lit.)

(in analogy to similar compounds)

The value is given in analogy to the following substances: rel-N-[2-Hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-formamide (2E)-2-butenedioate (2:1) (salt)

LC50 Inhalation - Rat - 4 h - 1,35 mg/l - dust/mist

Remarks: (Lit.)

(in analogy to similar products)

The value is given in analogy to the following substances: rel-N-[2-Hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-formamide (2E)-2-butenedioate (2:1) (salt)

Dermal: No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitization

No data available

#### Germ cell mutagenicity

No data available

#### Carcinogenicity

No data available

#### Reproductive toxicity

Suspected of damaging fertility or the unborn child. Some evidence of adverse effects on development, based on animal experiments.

#### Specific target organ toxicity - single exposure

Causes damage to organs.

Remarks: (in analogy to similar products)

The value is given in analogy to the following substances: rel-N-[2-Hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-formamide (2E)-2-butenedioate (2:1) (salt)

#### Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure. Remarks: The value is given in analogy to the following substances: rel-N-[2-Hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-formamide (2E)-2-butenedioate (2:1) (salt)

#### Aspiration hazard

No data available

## 11.2 Additional Information

### Endocrine disrupting properties

#### Product:

Assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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## SECTION 12: Ecological information

### 12.1 Toxicity

Toxicity to fish

LC50 - other fish - > 268 mg/l - 96 h

Remarks: (External MSDS)

(in analogy to similar products)

The value is given in analogy to the following substances: rel-N-[2-Hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-formamide (2E)-2-butenedioate (2:1) (salt)

Toxicity to daphnia and other aquatic invertebrates

EC50 - Daphnia magna (Water flea) - 54 mg/l - 48 h

Remarks: (External MSDS)

(in analogy to similar products)

The value is given in analogy to the following substances: rel-N-[2-Hydroxy-5-[(1R)-1-hydroxy-2-[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-formamide (2E)-2-butenedioate (2:1) (salt)

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



## 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

No data available

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## SECTION 14: Transport information

### 14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

### 14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### 14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

### 14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

### 14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

### 14.6 Special precautions for user

#### Further information

Not classified as dangerous in the meaning of transport regulations.

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## SECTION 15: Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

#### National legislation

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE

#### Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

Take note of Dir 94/33/EC on the protection of young people at work.

### 15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

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**SECTION 16: Other information****Full text of H-Statements referred to under sections 2 and 3.**

H332	Harmful if inhaled.
H361d	Suspected of damaging the unborn child.
H370	Causes damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.

**Relevant changes since previous version****2. Hazards identification****Further information**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See [www.sigma-aldrich.com](http://www.sigma-aldrich.com) and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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