

## Formoterol fumarate dihydrate

Version: 8.1

Revision Date: 22.01.2025

SDS Number: 100000000095

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

#### 1.1 Product identifier

Trade name : Formoterol fumarate dihydrate  
REACH Registration Number : NA  
CAS-No. : 183814-30-4  
Unique Formula Identifier : -

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

Use of the Sub-  
stance/Mixture : Active pharmaceutical ingredients  
  
Recommended restrictions : No data available  
on use

#### 1.3 Details of the supplier of the safety data sheet

Company : Fermion Oy  
Street address : Koivu-Mankkaan tie 6 A  
Post-office box: : P.O. Box 28  
Postcode : 02101 Espoo, Finland  
Telephone : +358 10 4261  
E-mail address of person : chemicalsafety@orion.fi  
responsible for the SDS  
VAT Reg. No: : FI18552129

#### 1.4 Emergency telephone number

Poison Center : +358 800 147111  
+358 9 471 977

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - single exposure, Category 1	H370: Causes damage to organs.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.
Acute toxicity, Category 2	H330: Fatal if inhaled.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.

For explanation of abbreviations see section 16.

#### 2.2 Label elements

##### Labeling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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Signal Word : Danger

### Hazard Statements

H370 Causes damage to organs.  
H372 Causes damage to organs through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects.  
H330 Fatal if inhaled.  
H361d Suspected of damaging the unborn child.

### Precautionary Statements

#### General:

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P273 Avoid release to the environment.  
P501 Dispose of contents according to national and local law.  
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

### 2.3 Other hazards

Other hazards : No data available  
  
PBT : No data available  
  
vPvB : No data available  
  
Endocrine disrupting properties : Ecological information: No data available  
Toxicological information: No data available

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Formoterol fumarate dihydrate	183814-30-4		

**Other information** : No data available

### 3.2 Mixtures

Not applicable

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## SECTION 4: First aid measures

### 4.1 Description of first-aid measures

General advice : Symptoms of poisoning may be delayed. Exposed should be monitored for at least 48 hours.

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Helpers should ensure their own protection.

- |                         |   |  |
|-------------------------|---|--|
| If inhaled              | : | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.<br>Get medical advice/attention.                      |
| In case of skin contact | : | Remove/ Take off immediately all contaminated clothing.<br>IF ON SKIN: Wash with soap and water.<br>Rinse continuously with water for several minutes. |
| In case of eye contact  | : | IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.   |
| If swallowed            | : | Rinse mouth.<br>Get medical advice/attention.  |

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

- |          |   |                                |
|----------|---|--------------------------------|
| Symptoms | : | Nausea<br>Spasm<br>tachycardia |
| Risks    | : | No data available              |

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

- |           |   |                        |
|-----------|---|------------------------|
| Treatment | : | Treat symptomatically. |
|-----------|---|------------------------|

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- |                                |   |  |
|--------------------------------|---|--|
| Suitable extinguishing media   | : | Water spray<br>Carbon dioxide (CO <sub>2</sub> )<br>Powder<br>Large fires: water or alcohol-resistant foam |
| Unsuitable extinguishing media | : | No data available  |

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

- |                                       |   |   |
|---------------------------------------|---|---|
| Specific hazards during fire fighting | : | May emit toxic fumes of oxides of carbon and nitrogen during heating or fire. |
| Hazardous combustion products         | : | No data available   |

### 5.3 Advice for firefighters

- |  |   |   |
|--|---|---|
| Special protective equipment for fire-fighters | : | Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing. |
| Specific extinguishing methods                 | : | No data available   |
| Further information                            | : | Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.                                     |

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

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

Personal precautions : Use personal protective equipment as required.

#### **6.2 Environmental precautions**

Environmental precautions : Do not put into water system, drain or soil.  
Avoid release to the environment.

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

Methods for cleaning up : Collect spilled powder without dusting into tight closed container.

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

See Section 8 and 13

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

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

Advice on safe handling : Handle in well-ventilated space.  
Handle in accordance with good industrial hygiene and safety procedures.

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

Requirements for storage areas and containers : Keep container tightly closed.  
Protect from light.  
Keep away from heat/sparks/open flames/hot surfaces - No smoking.  
Store at +15 - 25 °C.  
See incompatible materials in section 10.5.

Packaging material : Suitable material: No data available  
Unsuitable material: No data available

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

Specific use(s) : No information identified.

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

#### **8.1 Control parameters**

Contains no substances with occupational exposure limit values.

#### **8.2 Exposure controls**

Engineering measures : Provide sufficient ventilation (local exhaust).  
Ground/bond container and receiving equipment.  
Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment.

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### Personal protective equipment

Respiratory protection	:	In open handling use respirator (P3) with a minimum protection factor of 200. See standard working procedures/instructions or department's instructions for more detailed protection measures.
Eye/face protection	:	Use protective goggles.
Hand protection	:	
Remarks	:	Use protective gloves (e.g. nitrile or neopren gloves).
Skin and body protection	:	Wear protective clothing.
Protective measures	:	No data available
Environmental exposure controls	:	No data available

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Form	:	crystalline
Physical state	:	solid
Color	:	white
Odor	:	odorless
Odor Threshold	:	No data available
	:	No data available
Boiling point/boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Autoignition temperature	:	400 °C
Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	6 (20 °C) Concentration: 0,1 % w/V
Viscosity	:	

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Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Solubility(ies)		
Water solubility	:	slightly soluble
Solubility in other solvents	:	Solvent: methanol Description: soluble
Dissolution Rate	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 2,6
Dispersion Stability	:	No data available
Vapor pressure	:	No data available
Relative density	:	No data available
Density	:	200 g/l (20 °C)
Bulk density	:	No data available
Relative vapor density	:	No data available
Dissociation constant	:	No data available
Particle characteristics	:	No data available

### 9.2 Other information

Self-ignition	:	No data available
Hygroscopic properties	:	No data available
Henry's Constant	:	No data available
Further information	:	No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Hazardous polymerization does not occur.

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### 10.4 Conditions to avoid

Conditions to avoid : Light  
Keep away from heat/sparks/open flames/hot surfaces - No smoking.

### 10.5 Incompatible materials

Materials to avoid : Strong oxidants

### 10.6 Hazardous decomposition products

May emit toxic fumes of oxides of carbon and nitrogen during heating or fire.

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### Acute toxicity

Health hazard information : Fatal if inhaled.

Acute oral toxicity : LD50 (Rat): 3 130 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0,26-1,25 mg/l  
Exposure time: 4 h  
LDLo (Rat): 156 mg/kg

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 1 000 mg/kg  
Target Organs: subcutaneous  
Symptoms: Swallowing of the substance may induce:, Nausea, mouth dryness  
feeling of thirst  
LD50 (Rat): 98 mg/kg  
Target Organs: intravenous  
Symptoms: Potential impacts of exposure include:, muscular spasms, nervousness, Headache, tremble, Dizziness, Fatigue, hypokalemia, hyperglycemia, angina pectoris, hypotension, hypertension, tachycardia, arrhythmia  
LD50 (Rat): 170 mg/kg  
Target Organs: Intraperitoneal

#### Skin corrosion/irritation

Result : May irritate the skin.

#### Serious eye damage/eye irritation

Result : May irritate eyes.

#### Respiratory or skin sensitization

No data available

#### Germ cell mutagenicity

Genotoxicity in vitro : The product was not mutagenic or clastogenic in the following tests: mutagenicity test in

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bacterial and mammalian cells, chromosomal analyses in mammalian cells, unscheduled DNA synthesis repair tests in rat hepatocytes and human fibroblasts, transformation assay in mammalian fibroblasts and micronucleous tests in mice and rats.

Genotoxicity in vivo : No data available

### Carcinogenicity

Remarks : Substance is not classified as a carcinogen by IARC, NTP or OSHA.

The carcinogenic potential of product has been evaluated in 2-year drinking water and dietary studies in both rats and mice. In rats, the incidence of ovarian leiomyomas was increased at doses of 15 mg/kg and above in the drinking water study and at 20 mg/kg in the dietary study, but not at dietary doses up to 5 mg/kg. In the dietary study, the incidence of benign ovarian theca-cell tumors was increased at doses of 0.5 mg/kg and above. This finding was not observed in the drinking water study, nor was it seen in mice. In mice, the incidence of adrenal subcapsular adenomas and carcinomas was increased in males at doses of 69 mg/kg and above in the drinking water study, but not at doses up to 50 mg/kg in the dietary study. The incidence of hepatocarcinomas was increased in the dietary study at doses of 20 and 50 mg/kg in females and 50 mg/kg in males, but not at doses up to 5 mg/kg in either males or females. Also in the dietary study, the incidence of uterine leiomyomas and leiomyosarcomas was increased at doses of 2 mg/kg and above. Increases in leiomyomas of the rodent female genital tract have been similarly demonstrated with other beta-agonist drugs.

### Reproductive toxicity

Effects on fertility : Suspected of damaging the unborn child.

Reproduction studies in rats revealed no impairment of fertility at oral doses up to 3 mg/kg.

The product has been shown to cause stillbirth and neonatal mortality at oral doses of 6 mg/kg and above in rats receiving the product during the late stage of pregnancy. These effects, however, were not produced at a dose of 0.2 mg/kg. When the product was given to rats throughout organogenesis, oral doses of 0.2 mg/kg and above delayed ossification of the fetus, and doses of 6 mg/kg and above decreased fetal weight. The product did not cause malformations in rats or rabbits following oral administration. In reproductive studies in rats the product was excreted in the milk.



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Effects on fetal development : No data available

### **STOT-single exposure**

Assessment : Causes damage to organs.

### **STOT-repeated exposure**

Assessment : Causes damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

No data available

### **Aspiration toxicity**

No data available

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

No data available

### **Experience with human exposure**

General Information : No data available

Inhalation : No data available

Skin contact : No data available

Eye contact : No data available

Ingestion : No data available

### **Toxicology, Metabolism, Distribution**

Remarks : No data available

### **Neurological effects**

Remarks : No data available

### **Further information**

Remarks : May cause respiratory irritation.

### **Other Health Hazards**

No data available

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### **SECTION 12: Ecological information**

#### **12.1 Toxicity**

Toxicity to fish	: LC50 (zebra fish): 268 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 54 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: No data available
Toxicity to fish (Chronic toxicity)	: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: No data available
Toxicity to microorganisms	: No data available
Toxicity to soil dwelling organisms	: No data available
Plant toxicity	: No data available
Sediment toxicity	: No data available
Toxicity to terrestrial organisms	: No data available

#### **Ecotoxicology Assessment**

Acute aquatic toxicity	: Harmful to aquatic life with long lasting effects.
Chronic aquatic toxicity	: No data available
Toxicity Data on Soil	: No data available
Other organisms relevant to the environment	: No data available

#### **12.2 Persistence and degradability**

Biodegradability	: No data available
Biochemical Oxygen Demand (BOD)	: No data available
Chemical Oxygen Demand (COD)	: No data available
BOD/COD	: No data available

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ThOD	:	No data available
BOD/ThOD	:	No data available
Dissolved organic carbon (DOC)	:	No data available
Physico-chemical removability	:	No data available
Stability in water	:	No data available
Impact on Sewage Treatment	:	No data available
Photodegradation	:	No data available

### **12.3 Bioaccumulative potential**

Bioaccumulation	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 2,6 According to logP value this compound is not bioaccumulative.

### **12.4 Mobility in soil**

Mobility	:	No data available
Distribution among environmental compartments	:	No data available
Stability in soil	:	No data available

### **12.5 Results of PBT and vPvB assessment**

Assessment	:	No data available
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### **12.6 Endocrine disrupting properties**

No data available

### **12.7 Other adverse effects**

Environmental fate and pathways	:	No data available
Adsorbed organic bound halogens (AOX)	:	No data available
Ozone-Depletion Potential	:	No data available
Additional ecological information	:	No data available

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### **SECTION 13: Disposal considerations**

#### **13.1 Waste treatment methods**

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

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### **SECTION 14: Transport information**

#### **14.1 UN number**

ADR/RID: UN 2811

IMDG: UN 2811

IATA: UN 2811

#### **14.2 UN proper shipping name**

TOXIC SOLID, ORGANIC, N.O.S. (Formoterol fumarate dihydrate)

#### **14.3 Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)**

ADR/RID: 6.1

IMDG: 6.1

IATA: 6.1

#### **14.4 Packing group**

ADR/RID: II

IMDG: II

IATA: II

#### **14.5 Environmental hazards**

ADR/RID: -

IMDG: -

IATA: -

#### **14.6 Special precautions for user**

Tunnel restriction code : No data available

Further information for transport : No data available

#### **14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code**

Not applicable

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### **SECTION 15: Regulatory information**

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

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#### **15.2 Chemical Safety Assessment**

No

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### **SECTION 16: Other information**

#### **Full text of H-Statements**

H370

Causes damage to organs.

H372

Causes damage to organs through prolonged or repeated

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H412	exposure.
H330	Harmful to aquatic life with long lasting effects.
H361d	Fatal if inhaled.
	Suspected of damaging the unborn child.

### Full text of other abbreviations

STOT SE	: Specific target organ toxicity - single exposure
STOT RE	: Specific target organ toxicity - repeated exposure
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Acute Tox.	: Acute toxicity
Repr.	: Reproductive toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

AIIC - Australian Inventory of Industrial Chemicals

ASTM - American Society for the Testing of Materials

bw - Body weight

CLP - Classification Labelling Packaging Regulation

Regulation (EC) No 1272/2008

CMR - Carcinogen, Mutagen or Reproductive Toxicant

DIN - Standard of the German Institute for Standardisation

DSL - Domestic Substances List (Canada)

ECHA - European Chemicals Agency

EC-Number - European Community number

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

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)

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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  
NO(A)EC - No Observed (Adverse) Effect Concentration  
NO(A)EL - No Observed (Adverse) Effect Level  
NOELR - No Observable Effect Loading Rate  
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  
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail  
SADT - Self-Accelerating Decomposition Temperature  
SDS - Safety Data Sheet  
SVHC - substance of very high concern  
TCSI - Taiwan Chemical Substance Inventory  
TECI - Thailand Existing Chemicals Inventory  
TRGS - Technical Rule for Hazardous Substances  
TSCA - Toxic Substances Control Act (United States)  
UN - United Nations  
vPvB - Very Persistent and Very Bioaccumulative

### **Further information**

Other information : No data available

Sources of key data used to compile the Material Safety Data Sheet : Information provided by the supplier

Information which has been added, deleted or revised : Updated section / sections:  
1

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the spe-

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cific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.