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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
CAS-number: 183814-30-4

Reach registration number: NA

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

The uses of the chemical: Active pharmaceutical ingredients
Classification of the economic activities (NACE): 212
Use categories (UC62): 41

1.3.Details of the supplier of the safety data sheet:

Manufacturer/importer: Fermion Oy
Street address: Koivu-Mankkaan tie 6 A
Post-office box: P.O. Box 28
Postcode: 02101 Espoo, Finland
Telephone number: +358 10 4261
Telefax: +358 9 452 1764
E-mail address: chemicalsafety@orion.fi
VAT Reg. No: FI18552129

1.4. Emergency telephone number

Poison Center: +358 9 471 977

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008	Acute Tox. 2 STOT SE 1 STOT RE 1 Repr. 2 Aquatic Chronic 3	H330, H370, H372, H361d, H412,
H Statements	Fatal if inhaled. Causes damage to organs. Causes damage to organs through prolonged or	

	repeated exposure. Suspected of damaging the unborn child. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazard Pictograms

Signal word Danger

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

P Statements
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P260 Do not breath dust/fume/gas/mist/vapours/spray.
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.

2.3. Other hazards

-

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:

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Formoterol fumarate dihydrate	183814-30-4	-	NA

Other information -

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions
Symptoms of poisoning may be delayed. Exposed should be monitored for at least 48 hours.
Helpers should ensure their own protection.

Inhalation
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Get medical advice/attention.

Skin contact
Remove/Take off immediately all contaminated clothing.
IF ON SKIN: Wash with soap and water.
Rinse continuously with water for several minutes.

Eye contact
IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

Ingestion
Rinse mouth.
Get medical advice/attention.

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

nausea
spasm
tachycardia

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

Treat symptomatically.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Water spray
Carbon dioxide
Powder
Large fires: water or alcohol-resistant foam

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters

Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

Other instructions

Avoid breathing dust/fume/gas/mist/vapours/spray.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.

6.2. Environmental precautions

Do not put into water system, drain or soil.

6.3. Methods and material for containment and 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

Handle in well-ventilated space.
Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

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.

7.3. Specific end use(s)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values	0,0002 mg/m3 (8 h)
DNELs	-
PNECs	-

8.2. Exposure controls

Appropriate engineering controls
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.

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.

Hand protection
Use protective gloves (e.g. nitrile or neopren gloves).

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Eye protection
Use protective goggles.

Skin protection
Wear protective clothing.

Environmental exposure controls
Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state	Crystalline
Colour	White
Odour	Odourless
Odour threshold	-

9.1. Information on basic physical and chemical properties

pH Value	6 0,1 % w/V 20 °C
Water solubility	Slightly soluble
Solubility	Soluble in methanol
Partition coefficient: n-octanol/water (logP)	2,6
Auto-ignition temperature	400 °C

9.2. Other information

Density: 200 g/l (+20 °C)
Melting point:
137–143 °C (determined by DSC)
138-140 °C (Merck index)
135-142 °C (also reported as 154-155 °C)(USP reference standard MSDS)

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SECTION 10: STABILITY AND REACTIVITY

10.1.Reactivity

-

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4. Conditions to avoid

Light
Keep away from heat/sparks/open flames/hot surfaces - No smoking.

10.5. Incompatible materials

Strong oxidants

10.6 Hazardous decomposition products

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

SECTION 11: TOXICOLOCIGAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

Fatal if inhaled.
Swallowing of the substance may induce:
nausea
mouth dryness
feeling of thirst
Potential impacts of exposure include:
muscular spasms
nervousness
headache
tremble
dizziness
fatigue
hypokalemia
hyperglycemia
angina pectoris
hypotension

hypertension
tachycardia
aryhtmia
LD50 : 3130 mg/kg (rat, oral)
LD50: 1000 mg/kg (rat, subcutaneous)
LD50: 98 mg/kg (rat, intravenous)
LD50: 170 mg/kg (rat, intraperitoneal)
LC50: 0,26-1,25 mg/l (rat, inhalation, 4 h)
LDLo: 156 mg/kg (rat, inhalation)

Skin irritation and corrosion

May irritate the skin.

Skin sensitization

Data not available.

Serious eye damage and irritation

May irritate eyes.

Respiratory irritation

May cause respiratory irritation.

Respiratory sensitization

Data not available.

Carcinogenicity

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.
Germ cell mutagenicity	The product was not mutagenic or clastogenic in the following tests: mutagenicity test in 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.
Reproductive toxicity	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.
STOT-single exposure	Causes damage to organs.
STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	Data not available.
Repeated dose toxicity	Data not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Harmful to aquatic life with long lasting effects.
LC50(96h): 268 mg/l (zebra fish)
EC50(48h): 54 mg/l (Daphnia magna)

Toxic effects on other organisms

Data not available.

12.2.Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Octanol-water partition coefficient	According to logP value this compound is not bioaccumulative.
Bioconcentration factor	Data not available.

12.4. Mobility in soil

Data not available.

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12.5. Results of PBT and vPvB assessment

Data not available.

12.6. Other adverse effects

Data not available.

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.

SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

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)

6.1

14.4. Packing group

II

14.5. Environmental hazard

-

14.6. Special precautions for user

-

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 substance or mixture

-

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION

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. Fermion Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Information provided by the supplier

Information which has been added, deleted or revised

Updated section / sections:
1