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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name: Salmeterol Xinafoate
CAS-number: 94749-08-3

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	Repr. 2 Acute Tox. 4	H361d, H302,
H Statements	Suspected of damaging the unborn child. Harmful if swallowed.	

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2.2. Label elements

Hazard Pictograms



Signal word

Warning

H Statements

H361d Suspected of damaging the unborn child.
H302 Harmful if swallowed.

P Statements

P308+P313 IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Salmeterol Xinafoate	94749-08-3	-	NA

Other information

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions

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

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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 skin with water/shower.
Eye contact	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
Ingestion	Rinse mouth. Get immediate medical advice/attention.

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

Data not available.

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

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	Water CO2 Alcohol resistant foam Powder
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5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters	Isolating breathing apparatus eg. compressed breathing apparatus and isolating protective
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clothing.

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.

Provide sufficient ventilation.

6.4. Reference to other sections

See Section 8 and 13

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space.

Avoid contact during pregnancy/while nursing.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well ventilated place. Keep container tightly closed.

Store in a dry place.

Protect from sunlight.

Keep cool.

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

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International OEL values -
DNELs -
PNECs -

8.2. Exposure controls

Appropriate engineering controls

Accessible emergency shower.

Emergency eye-wash

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).

Eye protection

Use protective goggles.

Skin protection

In dust making work use disposal overalls and extra throwaway sleeves.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state	Powder
Colour	Nearly white
Odour	Odourless
Odour threshold	-

9.1. Information on basic physical and chemical properties

pH Value	6,6 - 6,7
Melting point	134 - 140 °C
Boiling point	403,5 °C 101,3 kPa

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Flash point 180,8 °C -

Water solubility Partially soluble

9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Stable in normal conditions.

10.2. Chemical stability

Stable when stored and handled according to instructions of use.

10.3. Possibility of hazardous reactions

Not expected to occur.

10.4. Conditions to avoid

Avoid dust formation.
Light

10.5. Incompatible materials

Strong oxidants

10.6 Hazardous decomposition products

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

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed.
LD50: > 1000 mg/kg rat, oral

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Skin irritation and corrosion	May irritate the skin.
Skin sensitization	Data not available.
Serious eye damage and irritation	May irritate eyes.
Respiratory irritation	Data not available.
Respiratory sensitization	Data not available.
Carcinogenicity	There is no evidence of carcinogenicity.
Germ cell mutagenicity	There is no evidence of mutagenicity.
Reproductive toxicity	Suspected of damaging the unborn child. Empirical data. Laboratory experiments have shown teratogenic effects.
STOT-single exposure	Data not available.
STOT-repeated exposure	Data not available.
Aspiration hazard	Data not available.
Repeated dose toxicity	Data not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Data not available.

Toxic effects on other organisms

Data not available.

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Octanol-water partition coefficient Data not available.

Bioconcentration factor Data not available.

12.4. Mobility in soil

Data not available.

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.

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SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

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14.2. UN Proper shipping name

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

This product is not regulated under the transport regulations.

14.4. Packing group

-

14.5. Environmental hazard

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14.6. Special precautions for user

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

Not applicable

SECTION 15: REGULATORY INFORMATION

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

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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

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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:

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