

Salmeterol Xinafoate

Version: 7.2

Revision Date: 22.01.2025

SDS Number: 100000000272

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

1.1 Product identifier

Trade name : Salmeterol Xinafoate
REACH Registration Number : NA
CAS-No. : 94749-08-3
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 on use : No data available

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 responsible for the SDS : chemicalsafety@orion.fi
VAT Reg. No: : FI18552129

1.4 Emergency telephone number

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture


Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 H302: Harmful if swallowed.
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 : 

Signal Word : Warning

Hazard Statements

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

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Precautionary Statements

General:

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

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

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Salmeterol Xinafoate	94749-08-3		

Other information : No data available

3.2 Mixtures

Not applicable

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice	:	Helpers should ensure their own protection. Symptoms of poisoning may be delayed. Exposed should be monitored for at least 48 hours.
If inhaled	:	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention.
In case of skin contact	:	Remove/ Take off immediately all contaminated clothing. IF ON SKIN: Wash with soap and water. Rinse skin with water/shower.
In case of eye contact	:	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
If swallowed	:	Rinse mouth. Get immediate medical advice/ attention.

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4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No data available

Risks : No data available

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Carbon dioxide (CO₂)
Alcohol-resistant foam
Water
Powder

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 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 : No data available

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.

6.3 Methods and material for containment and cleaning up

Methods for 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

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Handle in well-ventilated space.
Avoid contact during pregnancy and while nursing.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Store in a well ventilated place.
Keep container tightly closed.
Keep in a dry place.
Protect from sunlight.
Keep cool.
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.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures : 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.

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 : In dust making work use disposal overalls and extra throw-away sleeves.

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	:	powder
Physical state	:	solid
Color	:	Nearly white
Odor	:	odorless
Odor Threshold	:	No data available
Melting point/range	:	134 - 140 °C
Boiling point/boiling range	:	403,5 °C (101,3 kPa)
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	180,8 °C
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	6,6 - 6,7
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Solubility(ies)		
Water solubility	:	partly soluble
Solubility in other solvents	:	No data available
Dissolution Rate	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Dispersion Stability	:	No data available
Vapor pressure	:	No data available

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Relative density	:	No data available
Density	:	No data available
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
Molecular weight	:	603,75 g/mol
Hygroscopic properties	:	No data available
Henry's Constant	:	No data available
Further information	:	No data available

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

Hazardous reactions : Not expected to occur.

10.4 Conditions to avoid

Conditions to avoid : Avoid dust formation.
Light

10.5 Incompatible materials

Materials to avoid : 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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Health hazard information : Harmful if swallowed.

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Acute oral toxicity : LD50 (Rat): > 1 000 mg/kg

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : No data available

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 : There is no evidence of mutagenicity.

Genotoxicity in vivo : No data available

Carcinogenicity

Remarks : There is no evidence of carcinogenicity.

Reproductive toxicity

Effects on fertility : Suspected of damaging the unborn child.
Empirical data.

Effects on fetal development : Laboratory experiments have shown teratogenic effects.

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

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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 : No data available

Other Health Hazards

No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : No data available

Toxicity to daphnia and other aquatic invertebrates : No data available

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

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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 : No data available

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

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- : No data available

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octanol/water

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

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

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

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

-

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

ADR/RID: This product is not regulated under the transport regulations.

IMDG: This product is not regulated under the transport regulations.

IATA: This product is not regulated under the transport regulations.

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14.4 Packing group

ADR/RID: -

IMDG: -

IATA: -

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

SECTION 15: Regulatory information

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

-

15.2 Chemical Safety Assessment

No

SECTION 16: Other information

Full text of H-Statements

H361d

Suspected of damaging the unborn child.

H302

Harmful if swallowed.

Full text of other abbreviations

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

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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)
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

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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 specific 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.