Fluoxetine hydrochloride

Version: 4.5 **Revision Date:** 22.01.2025 **SDS Number:** 100000000623

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

1.1 Product identifier

Trade name	:	Fluoxetine hydrochloride
REACH Registration Number	:	NA
CAS-No.	:	59333-67-4
EC-No.	:	260-101-2
Unique Formula Identifier	:	-

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

Use of the Substance/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.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.

For explanation of abbreviations see section 16.

2.2 Label elements

Labeling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal Word : Danger

Hazard Statements

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Precautionary Statements

General:

P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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
Fluoxetine hydrochloride	59333-67-4 260-101-2 NA		

Other information : -

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.
If inhaled	:	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If appropriate, give oxygen. If appropriate, give artificial respiration. Get medical advice/attention.

In case of skin contact	:	Remove/ Take off immediately all contaminated clothing. IF ON SKIN: Wash with soap and water. If skin irritation occurs: Get medical advice/ attention.
In case of eye contact	:	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
If swallowed	:	Do NOT induce vomiting. If the patient is conscious, give plenty of water (2 - 4 glasses), and let the charcoal (approximately 20 tablets), or give activated charcoal slurry (2 - 4 glasses). Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms	:	See section 11 for symptoms of exposure.
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	:	Powder Foam Carbon dioxide (CO2) Water
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 hydrogen chloride and oxides of carbon and nitrogen during heating or fire. May emit toxic fumes of hydrogen fluoride and 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	:	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.

6.4 Reference to other sections

See Section 8 and 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	Handle in well-ventilated space. Avoid dust formation. Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. All exposure must be avoided.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep container tightly closed. Keep cool. Keep in a dry place. Protect from sunlight. 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	:	Handle in well-ventilated space. 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 20. 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	:	Use normal working clothes.
Protective measures	:	No data available

Environmental exposure controls

Air	:	Do not put into water system, drain or soil.

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
Melting point/range	:	158 °C
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	:	No data available
Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	6 Concentration: 5 % w/V
Viscosity		
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	:	No data available
Dissolution Rate	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 1,8
Dispersion Stability	:	No data available
Vapor pressure	:	No data available
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	:	345,79 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

No data available

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 : Oxidizing conditions

10.5 Incompatible materials

Materials to avoid : Oxidants

10.6 Hazardous decomposition products

May emit toxic fumes of hydrogen chloride and oxides of carbon and nitrogen during heating or fire.
May emit toxic fumes of hydrogen fluoride and oxides of carbon and nitrogen 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.
Acute oral toxicity	:	LD50 (Rat): 452 mg/kg
Acute inhalation toxicity	:	No data available
Acute dermal toxicity	:	No data available
Acute toxicity (other routes of administration)	:	LD50 (Mouse): 120 mg/kg Target Organs: Intraperitoneal Symptoms: Symptoms of exposure:, Dizziness, Headache, Fatigue, muscular weakness, Drowsiness

Skin corrosion/irritation

Result	:	Non-irritant (rabbit)

Serious eye damage/eye irritation

Species	:	Rabbit
Remarks	:	Causes serious eye damage. Severe eye irritation

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Genotoxicity in vitro	:	No data available
Genotoxicity in vivo	:	No data available

Carcinogenicity

Remarks	:	No component of this product present at levels greater than or equal to 0,1 % is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Effects on fertility	:	No data available
Effects on fetal development	:	Reproductive toxicity (rabbit, oral) => maternal effects, effects on newborn Developmental toxicity (rat, subcutaneous), specific developmental abnormalities: Central nervous system Developmental toxicity (rat, oral), specific developmental abnormalities: Skin and skin appendages Developmental toxicity (human, oral), specific developmental abnormalities: Central nervous system

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Repeated dose toxicity

Remarks	:	Gastrointestinal disturbances such as nausea, vomiting, dyspepsia and diarrhea. Neurological effects as anxiety, nervousness, drowsiness, headache and dizziness.

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.
May be harmful if inhaled.

Other Health Hazards

No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 1,57 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,94 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	:	Very toxic to aquatic life.
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-octanol/water	:	log Pow: 1,8 Not expected to be 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

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: UN 3077 IMDG: UN 3077 IATA: UN 3077

14.2 UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluoxetine hydrochloride)

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

ADR/RID: 9 IMDG: 9 IATA: 9

14.4 Packing group

ADR/RID: III IMDG: III IATA: III

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

The product has not been fully tested.

15.2 Chemical Safety Assessment

No

SECTION 16: Other information

Full text of H-Statements

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Eye Dam.	:	Serious eye damage
Aquatic Acute	:	Short-term (acute) aquatic hazard

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)

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	:	Information provided by the supplier

compile the Material Safety Data Sheet

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

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