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

#### 1.1. Product identifier

Trade name: Fluoxetine hydrochloride  
CAS-number: 59333-67-4

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. 4 Eye Dam. 1 Aquatic Acute 1	H302, H318, H400,
H Statements	Harmful if swallowed. Causes serious eye damage. Very toxic to aquatic life.	

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### 2.2. Label elements

#### Hazard Pictograms



Signal word

Danger

#### H Statements

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

#### P Statements

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection.

P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do, continue rinsing.

### 2.3. Other hazards

-

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Fluoxetine hydrochloride	59333-67-4	260-101-2	NA

Other information

-

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## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Special instructions</b>	Helpers should ensure their own protection.
<b>Inhalation</b>	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.
<b>Skin contact</b>	Remove/Take off immediately all contaminated clothing. IF ON SKIN: Wash with soap and water. If skin irritation occurs: Get medical advice/attention.
<b>Eye contact</b>	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
<b>Ingestion</b>	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

See section 11 for symptoms of exposure.

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

Data not available.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

<b>Suitable extinguishing media</b>	Powder Foam
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Carbon dioxide  
Water

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

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.

### 5.3. Advice for fire-fighters

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

### 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.  
Avoid dust formation.  
Avoid breathing dust/fume/gas/mist/vapours/spray.  
All exposure must be avoided.

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

Keep container tightly closed.  
Keep cool.  
Store in a dry place.  
Protect from sunlight.  
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	-
DNELs	-
PNECs	-

#### 8.2. Exposure controls

##### Appropriate engineering controls

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.

##### Respiratory protection

In open handling use respirator (A2B2E2K2-P3) with a minimum protection factor of 20.  
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

Use normal working clothes.

### Environmental exposure controls

Do not put into water system, drain or soil.

## 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 5 % w/V
Melting point	158 °C
Water solubility	Slightly soluble
Partition coefficient: n-octanol/water (logP)	1,8

### 9.2. Other information

-

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

-

### 10.2. Chemical stability

Stable when stored and handled according to instructions of use.

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### 10.3. Possibility of hazardous reactions

Not expected to occur.

### 10.4. Conditions to avoid

Oxidizing conditions

### 10.5. Incompatible materials

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 toxicological effects

<b>Acute toxicity</b>	Harmful if swallowed. Symptoms of exposure: dizziness headache fatigue muscular weakness drowsiness LD50 = 452 mg/kg (rat, oral) LD50 = 120 mg/kg (mouse, intraperitoneal)
<b>Skin irritation and corrosion</b>	Non-irritant (rabbit)
<b>Skin sensitization</b>	Data not available.
<b>Serious eye damage and irritation</b>	Causes serious eye damage. Severe eye irritation (rabbit)
<b>Respiratory irritation</b>	May be harmful if inhaled. May cause respiratory irritation.
<b>Respiratory sensitization</b>	Data not available.

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<b>Carcinogenicity</b>	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.
<b>Germ cell mutagenicity</b>	Data not available.
<b>Reproductive toxicity</b>	<p>Reproductive toxicity (rabbit, oral) =&gt; maternal effects, effects on newborn</p> <p>Developmental toxicity (rat, subcutaneous), specific developmental abnormalities: Central nervous system</p> <p>Developmental toxicity (rat, oral), specific developmental abnormalities: Skin and skin appendages</p> <p>Developmental toxicity (human, oral), specific developmental abnormalities: Central nervous system</p>
<b>STOT-single exposure</b>	Data not available.
<b>STOT-repeated exposure</b>	Data not available.
<b>Aspiration hazard</b>	Data not available.
<b>Repeated dose toxicity</b>	Gastrointestinal disturbances such as nausea, vomiting, dyspepsia and diarrhea. Neurological effects as anxiety, nervousness, drowsiness, headache and dizziness.



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## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Aquatic toxicity

Very toxic to aquatic life.

Toxicity to fish:

LC50 (96 h): 1,57 mg/l (Oncorhynchus mykiss, rainbow trout)

Toxicity to aquatic invertebrates:

EC50 (48 h): 0,94 mg/l (Daphnia magna, water flea)

#### Toxic effects on other organisms

Data not available.

### 12.2. Persistence and degradability

Data not available.

### 12.3. Bioaccumulative potential

**Octanol-water partition coefficient** Not expected to be bioaccumulative.

**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

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disposal for this material. Observe all local and national regulations when disposing of this material.

#### SECTION 14: TRANSPORT INFORMATION

##### 14.1. UN Number

UN 3077

##### 14.2. UN Proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

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

9

##### 14.4. Packing group

III

##### 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

#### SECTION 15: REGULATORY INFORMATION

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

The product has not been fully tested.

##### 15.2. Chemical Safety Assessment

No

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## 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

Update of the Product identifier.