Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FLUOXETINI HYDROCHLORIDUM

Publication: 21/03/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Fluoxetine hydrochloride Fluoxetini hydrochloridum Fluoxetine hydrochloride Fluoxétine (chlorhydrate de) Fluoxetinhydrochlorid
N° CAS:	56296-78-7
N° EC:	260-101-2

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Eye Dam. 1	H318
Aquactic Acute 1	H400

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Danger

Irritant

Harmful to the environment

Corrosive

Hazard statements:	
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
Precautionary statements:	
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.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Fluoxetine hydrochloride
IUPAC name:	N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]propan-1-amine;hydrochloride
Synonyms:	Fluoxetine HCl Prozac Sarafem Fluoxeren
N° CAS:	56296-78-7
N° EC:	260-101-2
Molecular Formula:	$C_{17}H_{19}ClF_3NO$
Content:	98.0 per cent to 102.0 per cent (anhydrous substance)

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

Emits toxic fumes in case of fire.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a face mask with full face shield covering the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure proper ventilation.

For emergency responders

Wear personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure proper ventilation.

6.2 Environmental precautions

Prevent further leakage or spillage if this can be done safely. Do not allow product to enter sewage system. Discharge into the environment should be avoided.

6.3 Methods and material for containment and cleaning up

Collect and prepare for disposal without causing dust. Store in suitable, closed containers for disposal.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	Not available.
Technical protective measures:	Avoid the formation of dust and aerosols. Adequate extraction must be provided where dust is formed. Normal fire prevention provisions.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store in a cool place. Keep container tightly closed in a dry and well-ventilated place.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Does not contain substances with personal exposure limit values.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection:	Protective face shields and safety goggles according to EN166.
Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the resulting EN 374 standard.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Slight.
Odour threshold:	Not available.
pH:	(0.1 % in water): 4.5 - 7.0
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	0.393 g/ml (20 °C)
Solubility:	Freely soluble in methanol, sparingly soluble in methylene chloride. Soluble in chloroform, insoluble in diethyl ether.
Solubility in water:	Sparingly soluble in water.
Partition coefficient (n-octanol/water):	Log P(o/w) = 1.8 (25 °C)
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 345.83 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions: carbon oxides (CO_x), nitrogen oxides (NO_x), hydrogen chloride and hydrogen fluoride.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD_{50}, rat): 452 mg/kg	
Skin corrosion/irritation:	Not a skin irritant.	
Serious eye damage/irritation:	Serious eye irritation.	
Respiratory/skin sensitisation:	Not available.	
Germ cell mutagenicity:	Not available.	
Carcinogenicity:	No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1 %.	
Reproductive toxicity:	Oral (rabbit):	Effects on the reproductive system: Other effects.
	Oral (rat):	Effects on the neonate: Stillbirth effects on the neonate: Viability index (no live individuals at day 4/no live births) Effects on the neonate: Growth statistics.
Summary of evaluation of the CMR properties:	Not available.	
STOT-single exposure:	Not available.	
STOT-repeated exposure:	Not available.	
Aspiration Hazard:	Not available.	
Other:	**Developmental toxicity**	
	Subcutaneous (rat):	Specified developmental abnormalities: Central nervous system neonatal effects: Growth statistics.
	Oral (rat):	Specified developmental abnormalities: Skin and skin appendages.
	Oral (human):	Specific developmental abnormalities: Central nervous system.
	Signs and symptoms of exposure	
	Headache, dizziness, fatigue, muscle weakness, drowsiness and in extreme cases, loss of consciousness. Based on our information, we believe that the chemical, physical and toxicological properties have not been adequately investigated.	
	N° RTECS	
	UI4050000	

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation. Causes serious eye damage.
Skin contact:	May be harmful if absorbed through skin. May cause skin irritation.

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

LC_{50} (fish):	1.57 mg/l/96 hours (*Oncorhynchus mykiss*)
EC_{50} (aquatic invertebrates):	0.94 mg/l/48 hours (*Daphnia magna*)

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Based on available data, the product does not contain PBT or vPvB substances above 0.10 %.

12.6 Other adverse effects

Very toxic to aquatic organisms.

The product must be considered as hazardous to the environment and has a high toxicity to aquatic organisms with long term adverse effects on the aquatic environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	It is not dangerous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.6 Special precautions for user

It is not dangerous in transport.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant Corrosive Harmful to the environment

Risk phrases:

R22 Harmful if swallowed.

R41 Risk of serious damage to eyes.

R50 Very toxic to aquatic organisms.

Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization

IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.
https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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