

Fluoxetine hydrochloride

Safety Data Sheet

900618

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)
2015/830
Issue date: 19/10/2020

Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Fluoxetine hydrochloride
IUPAC name : (3RS)-N-Methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]-propan-1-amine hydrochloride
EC-No. : 260-101-2
CAS-No. : 56296-78-7
Product code : 900618
Formula : C17H19ClF3NO
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
Function or use category : Antidepressant

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4	H302
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 1	H318
Hazardous to the aquatic environment — Acute Hazard, Category 1	H400

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H400 - Very toxic to aquatic life.

Precautionary statements (CLP)

: P280 - Wear eye protection, face protection, protective gloves, protective clothing.
P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.
P310 - Immediately call a POISON CENTER/doctor.
P302+P352 - IF ON SKIN: Wash with plenty of water.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Fluoxetine hydrochloride	(CAS-No.) 56296-78-7 (EC-No.) 260-101-2	100	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : If medical advice is needed, have product container or label at hand.
- First-aid measures after inhalation : Obtain medical attention if breathing difficulty persists
Allow affected person to breathe fresh air.
- First-aid measures after skin contact : Wash skin with plenty of water
Seek medical attention if ill effect or irritation develops.
- First-aid measures after eye contact : Rinse immediately with plenty of water
Seek medical advice.
- First-aid measures after ingestion : Rinse mouth.
Never give anything by mouth to an unconscious person
Do NOT induce vomiting.
Seek medical attention immediately.

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

No additional information available

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

Give activated charcoal.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray.
Foam
Dry powder
Carbon dioxide.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Chlorine. Fluorine. Nitrogen oxides.
- Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Protective equipment : Use the personal protective equipment as indicated in chapter 8.
- Emergency procedures : Ensure adequate air ventilation. Avoid raising dust. Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. Absorb with liquid binding material: Sand, silica, acid binder, saw dust. On land, sweep or shovel into suitable containers.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
- Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Safety glasses. Dust/aerosol mask with filter type P3. Gloves.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 345.8 g/mol
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: 4.5 - 6.5 (c=0,1%)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 193 - 197 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Solubility	: Moderately soluble in water Soluble in methanol.
Log Pow	: 1.8 (pH 7)
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

High temperature.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides

Chlorine

Fluorine.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

Fluoxetine hydrochloride (56296-78-7)	
LD50 oral rat	625 mg/kg
LD50 dermal rabbit	1250 mg/kg

Skin corrosion/irritation	: Causes skin irritation. pH: 4.5 - 6.5 (c=0,1%)
Serious eye damage/irritation	: Causes serious eye damage. pH: 4.5 - 6.5 (c=0,1%)
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life.

Fluoxetine hydrochloride (56296-78-7)	
LC50 fish 1	1.57 mg/l
EC50 Daphnia 1	0.94 mg/l

12.2. Persistence and degradability

Fluoxetine hydrochloride (56296-78-7)	
Persistence and degradability	Not readily biodegradable.

12.3. Bioaccumulative potential

Fluoxetine hydrochloride (56296-78-7)	
Log Pow	1.8 (pH 7)
Bioaccumulative potential	Slightly or not bioaccumulative.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN



ADR	IATA
14.1. UN number	
3077	3077
14.2. UN proper shipping name	
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Not applicable

Fluoxetine hydrochloride

900618

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

ADR	IATA
14.3. Transport hazard class(es)	
9	9
	
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available	

14.6. Special precautions for user

. Overland transport

Classification code (ADR) : M7

Excepted quantities (ADR) : E1

Hazard identification number (Kemler No.) : 90

Orange plates : 


Tunnel restriction code (ADR) : E

EAC code : 2Z

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Fluoxetine hydrochloride is not on the REACH Candidate List

Fluoxetine hydrochloride is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.2	Function or use category	Added	
-----	--------------------------	-------	--

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

4.2	Symptoms/effects	Removed	
7.2	Maximum storage period	Removed	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : Supplier.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

SDS EU (REACH Annex II) duchefa nieuwe logo

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.