


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | FLUOXETINE HYDROCHLORIDE, USP/EP |
| PRODUCT CODE | 0013 |
| SUPPLIER | MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020 |
| EMERGENCY PHONE | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670 |
| RECOMMENDED USES | Pharmaceutical Manufacturing |
| RESTRICTIONS ON USE | Not applicable |

SECTION 2: HAZARDS IDENTIFICATION

| | |
|---|---|
| GHS CLASSIFICATION | Acute Toxicity - Oral (Category 4) Eye Damage (Category 1) Skin Irritation (Category 2) Specific Target Organ Toxicity - Repeated Exposure (Category 1) Chronic Aquatic Toxicity (Category 1) |
| PICTOGRAM |  |
| SIGNAL WORD | Danger |
| HAZARD STATEMENT(S) | Harmful if swallowed. Fatal if inhaled and toxic in contact with skin Causes serious eye damage. Causes skin irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects. |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | Not Applicable |

PRECAUTIONARY STATEMENT(S)
Prevention

Wash hands thoroughly after handling. Do not touch eyes.
 Do not eat, drink or smoke when using this product.
 Do not breathe dust/fume/gas/mist/ vapors/spray.
 Use only outdoors or in a well-ventilated area.
 In case of inadequate ventilation, wear respiratory protection.
 Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Wear protective gloves, protective clothing, eye protection, face protection.
 Avoid release to the environment.

Response

IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.
 IF ON SKIN (HAIR): Wash with plenty of water; Call a poison center or medical professional; Take off immediately all contaminated clothing and wash it before reuse.
 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center or medical professional; Treatment is urgent.
 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help; Immediately call a poison center or medical professional.
 COLLECT SPILLAGE
 Get medical help if you feel unwell.

Storage

Store in a well-ventilated place.
 Keep container tightly closed.
 Store locked up.

Disposal

Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION
Health Hazard

2

Flammability

0

Reactivity

0

Personal Protection

G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

(±)-N-Methyl-3-phenyl-3-[(α,α,α-trifluoro-p-tolyl)oxy]propylamine, hydrochloride

BOTANICAL NAME

Not applicable

SYNONYM

(3RS)-N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]-propan-1-amine hydrochloride; Methyl-[3-phenyl-3-[4-(trifluoromethyl)phenoxy]-propyl]ammonium chloride

CHEMICAL FORMULA
 $C_{17}H_{18}F_3NO.HCl$
CHEMICAL FAMILY

Cyclic propylamine derivative

CAS NUMBER

56296-78-7

ALTERNATE CAS NUMBER

59333-67-4 (alternate EC number: 611-817-2)

MOLECULAR WEIGHT

345.79

COMPOSITION

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|--------------------------|------------|-----------|-------------|
| FLUOXETINE HYDROCHLORIDE | 56296-78-7 | 260-101-2 | 100 |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES
IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable.

FLAMMABLE PROPERTIES

May be combustible at high temperature.

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: FLUOXETINE HYDROCHLORIDE CAS #: 56296-78-7

| | Country | Limit value-8 hours | | Limit value-Short Term | | IDLH | REL | Advisory | Notes |
|--------|-------------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
| | | ppm | mg/m ³ | ppm | mg/m ³ | | | | |
| OSHA | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| ACGIH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| NIOSH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| WEEL | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSIS | Australia | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSE | UK | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| GESTIS | Add Country | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

 USP: ELV: Industrial: STEL: 12 hours: 30 micrograms/m³.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White to off-white crystalline powder.

SOLUBILITY

Sparingly soluble in water and in dichloromethane; freely soluble in alcohol and in methanol; practically insoluble in ether.

ODOR

Characteristic odor or odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

| | | | | | |
|-------------------------------------|-------------------|---|---------------------|---|------------------------------|
| EVAPORATION RATE | Not available | EXPLOSIVE LIMIT | Not available | FLASH POINT | Not available |
| log P (OCTANOL-WATER) | 1.8 (pH 7) (20°C) | LOWER FLAMMABLE/EXPLOSIVE LIMIT(S) | Not available | MELTING/FREEZING POINT | (158-163)°C, (316.4-325.4)°F |
| PARTICLE CHARACTERISTICS | Not available | OXIDIZING PROPERTY | Not available | pH | 4.5 - 6.5 (1%) |
| RELATIVE DENSITY (WATER = 1) | 0.3 - 0.6 mg/mL | SPECIFIC GRAVITY | 0.3 - 0.6 | UPPER FLAMMABLE/EXPLOSIVE LIMIT(S) | Not available |
| VAPOR DENSITY (AIR = 1) | Not available | VAPOR PRESSURE | 0.000003 kPa (25°C) | VISCOSITY | Not available |

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

| | |
|--|--|
| REACTIVITY | Not established. |
| CHEMICAL STABILITY | Stable under recommended storage conditions. |
| INCOMPATIBLE MATERIALS | Strong oxidants and acids. Strong bases. |
| HAZARDOUS DECOMPOSITION PRODUCTS | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur. |
| HAZARDOUS POLYMERIZATION | Will not occur. |
| POSSIBILITY OF HAZARDOUS REACTION | Not established. |
| CONDITIONS TO AVOID | Moisture, sunlight and extreme temperatures. |

SECTION 11: TOXICOLOGICAL INFORMATION

| | |
|--|---|
| ACUTE TOXICITY | Oral: Rat: LD50: (mg/kg): 452 Dermal: Rabbit: LD50: (mg/kg): > 500 Inhalation: Rat: LC50: (mg/L/4hr): Not available |
| SKIN CORROSION/IRRITATION | Causes skin irritation. pH: 4.5 - 6.5 (1%) Irritancy test: Rabbit: Skin: Non-irritant. |
| SERIOUS EYE DAMAGE/EYE IRRITATION | Causes serious eye damage. Irritancy test: Rabbit: Eye: Corrosive. pH: 4.5 - 6.5 (1%) |
| RESPIRATORY SENSITIZATION | Due to lack of data the classification is not possible. |
| SKIN SENSITIZATION | Due to lack of data the classification is not possible. |

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.
 Bacterial mutation assay: Negative.
 DNA repair assay in cultured rat hepatocytes: Negative.
 Lymphoma assay: Mouse: Negative.
 Suspected mutagen: KNN Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability)

CARCINOGENICITY

OSHA FLUOXETINE HYDROCHLORIDE is not listed.
NTP FLUOXETINE HYDROCHLORIDE is not listed.
IARC FLUOXETINE HYDROCHLORIDE is not evaluated.
California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.
 Carcinogenicity test: Rat: Not carcinogenic (in high doses).

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.
 Studies in animals have not shown that fluoxetine causes birth defects. In humans, some adverse effects, including poor neonatal adaptation and reduced birth weight at term, have occurred in some newborns exposed to fluoxetine during the third trimester.
 Reproductivity test (12 mg/kg body weight per day): Rat: Impaired pup survival and decreased birth weight.
 Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction; CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value)

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Causes damage to organs through prolonged or repeated exposure.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE

ROUTES OF EXPOSURE:
 Oral, Dermal, Inhalation, Eye contact
EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:
 Not available
DELAYED HEALTH EFFECT FROM EXPOSURE:
 Not available

Symptoms related to the physical, chemical, and toxicological characteristics:
 Restlessness. Anxiety. Diarrhea. Drowsiness. Headache. Sweating. Trouble sleeping. Nausea. Chills. Fever. Joint pain. Skin rash. Abnormal thoughts or dreams. Taste changes. Changes in vision. Chest pain. Constipation. Dizziness. Dry mouth. Frequent, painful, or difficult urination. Loss of appetite. Cramps. Skin sensitivity to sunlight. Tremor. Hair loss. Weight gain. Weight loss. Vomiting. Agitation. Excitement. Fast heartbeat. Seizures.

Medical conditions aggravated by exposure:
 Diabetes. Impaired kidney function. Impaired liver function. Mental disorders. Seizure disorders.

POTENTIAL HEALTH EFFECTS

Inhalation Fatal if inhaled. May cause respiratory tract irritation.
Ingestion Harmful if swallowed.
Skin Toxic if absorbed through skin. Causes skin irritation.
Eyes Causes serious eye damage.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea (Daphnia magna): (mg/L): 0.94
 LC50: 96 Hr: Fish: (mg/L): 1.57
 EC50: 96 Hr: Green Algae (or other aqua plants): (mg/L): <1*

| | |
|--------------------------------------|--|
| PERSISTENCE AND DEGRADABILITY | Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR platform predicts that the chemical is NON Readily Biodegradable (moderate reliability) The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable |
| BIOACCUMULATIVE POTENTIAL | Log Pow: 1.8 (pH 7) (20°C) |
| MOBILITY IN SOIL | Sparingly soluble in water. Henry's Law constant (H) in Pa m ³ /mol or dimensionless Pa m ³ /mol: [9.02x10 ⁻³] (25°C) |
| OTHER ADVERSE EFFECTS | Not available |
| NOTES | This product is not intended to be released into the environment *Danish QSAR database |

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

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|---|--|
| UN PROPER SHIPPING NAME | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| UN NUMBER | 3077 |
| CLASS | 9 |
| PACKING GROUP | III |
| <u>AUSTRALIA</u> | |
| HAZCHEM | 2Z |
| <u>EU</u> | |
| TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE | Not Listed |
| ENVIRONMENTAL HAZARDS | Not available |
| SPECIAL SHIPPING INFORMATION | Not applicable |

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

| Chemical Name & CAS | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.65 | EPA 40 CFR Part 355 | | Right-to-know | | |
|----------------------------|--------------------------|-------------------------------------|---------------------|------------|---------------|------------|---------------|
| | | | Appendix A | Appendix B | Pennsylvania | New Jersey | Massachusetts |
| FLUOXETINE HCl, 56296-78-7 | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

| Chemical Name & CAS | Poisons and Therapeutic Goods Regulation | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|----------------------------|--|-----------------------|---|------------------------------------|-----------------------------------|
| FLUOXETINE HCl, 56296-78-7 | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed

EU REGULATIONS

| Chemical Name & CAS | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | PIC - Prior Informed Consent Regulation | EC 2012/18 |
|----------------------------|------------------|-----------------|--------------|-------------|---|------------|
| FLUOXETINE HCl, 56296-78-7 | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

NOTES

*Listed as the base.

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** – Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

10/2024

SUPERSEDES

03/2023

 For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com
DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. 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. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.