

SAFETY DATA SHEET

Print date February 8, 2021

Section 1. Identifications

Product name: Duloxetine Impurity 16 (Mixture of Isomers)
TLC ID: D-1144
Product Use: For laboratory use only. Not for use in humans or animals, drug, household or other use.
Supplier/Manufacturer:

TLC Pharmaceutical Standards Ltd.
130 Pony Drive
Newmarket, ON, L3Y 7B6, Canada
Telephone: (905)-898-3645 Fax: (905)-898-0595
Website: www.tlcstandards.com

Section 2. Hazards identifications

Physical state: liquid
Warning: Combustible. Harmful if swallowed. Suspected of causing cancer.
Routes of entry: Inhalation, skin, eyes

GHS classification:

Acute toxicity, Oral (Category 4), H302
Carcinogenicity (Category 2), H351
Acute toxicity, oral (Category 4)

GHS Label elements, including precautionary statements

Pictogram(s):



Signal word: DANGER

Hazards statements:

H302 +H312 +H332 Harmful if swallowed, in contact with skin or if inhaled.
H351 Suspected of causing cancer

Precautionary statements:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P405 Store locked up.
P501 Dispose of contents/ container to an approved waste disposal plant.

Section 3. Composition/ Information on Ingredients

CAS No.: N/A
Molecular Formula: C₁₈H₁₈N₂O₂S
Molecular Weight: 326.41
Synonyms: (S)-N-methyl-N-(3-(naphthalen-1-yloxy)-3-(thiophen-2-yl)propyl)nitrous amide

Section 4. First-aid measures

General

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Section 5. Firefighting measures

Conditions of flammability

COMBUSTIBLE. Avoid use of metal spatula.

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Hazardous combustion products

Hazardous decomposition products formed under fire conditions: carbon oxides, sodium oxides, nitrogen oxides

Special firefighting procedures

Wear self-contained breathing apparatus and protective clothing.

Section 6. Accidental release measures

Personal precautions

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

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Method and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

Section 7. Handling and storage

Handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. For precautions see section 2.2.

Storage

Keep refrigerated as specification of Certificate of Analysis. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Section 8. Exposure controls/personal protection

Engineering controls

Use mechanical exhaust or laboratory fumehood to avoid exposure. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

Hand Protection

Handle with chemical-resistant gloves, solvent-resistant gloves. Gloves must be inspected prior to use. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye Protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Section 9. Physical and chemical properties

Physical property: liquid

Colour: brown

Odour: No data available

Density: No data available

Melting Point/Freezing Point(°C): No data available

Flash Point (°C): No data available

Explosive Properties: No data available

Oxidizing Properties: No data available

Water solubility: No data available

Solubility (other solvents): Methanol, DMSO, Acetonitrile

Section 10. Stability and reactivity

Reactivity: No data available.

Chemical stability: Stable under recommended storage conditions.

Conditions to avoid: Heat, flames and sparks. Extremes of temperature and direct sunlight.

Materials to avoid: strong oxidizing agents.

Hazardous decomposition products: formed under fire conditions: Carbon oxides, Nitrogen oxides (NO_x)

Section 11. Toxicological information

Acute toxicity

Oral LD50: No data available

LC50: No data available.

Dermal LD50: No data available.

Skin Corrosion/Irritation: Toxic if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Carcinogenicity

Limited evidence of carcinogenicity in animal studies

IARC: 2B - Group 2B: Possibly carcinogenic to humans (1-Nitrosopyrrolidine)

Acute and Chronic Health hazards: TLV: None verified.

Effects of Overexposure: May causes eye, respiratory, and skin irritation. May be harmful by inhalation, ingestion, or skin absorption.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated

Section 12. Ecological information

No data available.

Section 13. Disposal considerations

Product

Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra care in igniting as this material is highly flammable. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging

Dispose of as unused product.

Section 14. Transport information

Classification DOT/IMDG/IATA label:

Shipping name: Environmentally hazardous substance, liquid, n.o.s. (1-Nitrosopyrrolidine)

UN number: no data available

Class: 9

Packaging group: III

Additional information: None

Not dangerous goods by IATA

Section 15. Regulatory information

This product has been classified in accordance with the hazard criteria of the Occupational Health and Safety (OSH) and the SDS contains all the information required by the OSH.

Section 16. Other information

This product is not bioactive, not radioactive. It is for R&D use only. Not for drug, household or other uses.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. TLC Pharmaceutical Standards Ltd. extends no warranties with respect hereto and disclaims all liabilities from reliance thereon. All judgments as to the suitability of the data presented with respect to the use of this product are the responsibility of the purchaser and intended user.