

SAFETY DATA SHEET

According to JIS Z 7253:2019
Revision date 07-Feb-2023
 Revision Number 2.02

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	Donepezil Hydrochloride
Product Code	045-32321,041-32323

Manufacturer	FUJIFILM Wako Pure Chemical Corporation 1-2 Doshomachi 3-Chome Chuo-ku, Osaka 540-8605, Japan Phone: +81-6-6203-3741 Fax: +81-6-6203-5964
Supplier	FUJIFILM Wako Pure Chemical Corporation 1-2 Doshomachi 3-Chome, Chuo-ku, Osaka 540-8605, Japan Phone: +81-6-6203-3741 Fax: +81-6-6203-2029
Emergency telephone number	+81-6-6203-3741 / +81-3-3270-8571
Recommended uses and restrictions on use	For research use only

Section 2: HAZARDS IDENTIFICATION

GHS classification**Classification of the substance or mixture**

Acute toxicity - Oral

Category 2

Pictograms**Signal word**

Danger

Hazard statements

H300 - Fatal if swallowed

Precautionary statements-(Prevention)

- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product

Precautionary statements-(Response)

- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
- Rinse mouth

Precautionary statements-(Storage)

- Store locked up

Precautionary statements-(Disposal)

- Dispose of contents/container to an approved waste disposal plant

Others**Other hazards**

Not available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Single Substance or Mixture Substance

Formula C₂₄H₂₉NO₃·HCl

Chemical Name	Weight-%	Molecular weight	ENCS	ISHL No.	CAS RN
Donepezil hydrochloride	90.0	415.95	N/A	8-(1)-4069	120011-70-3

Note on ISHL No.: * in the table means announced chemical substances.

Impurities and/or Additives: Not applicable

Section 4: FIRST AID MEASURES

Inhalation

Remove to fresh air. If symptoms persist, call a physician.

Skin contact

Wash off immediately with soap and plenty of water. If symptoms persist, call a physician.

Eye contact

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediate medical attention is required.

Ingestion

Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician or poison control center immediately. Do not induce vomiting without medical advice.

Protection of first-aiders

Use personal protective equipment as required.

Section 5: FIRE FIGHTING MEASURES

Suitable extinguishing media

Water spray (fog), Carbon dioxide (CO₂), Foam, Extinguishing powder, Sand

Unsuitable extinguishing media

No information available

Specific hazards arising from the chemical product

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

Special extinguishing method

No information available

Special protective actions for

fire-fighters

Use personal protective equipment as required. Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Section 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

For indoor, provide adequate ventilation process until the end of working. Deny unnecessary entry other than the people involved by, for example, using a rope. While working, wear appropriate protective equipments to avoid adhering it on skin, or inhaling the gas. Work from windward, and retract the people downwind.

Environmental precautions

To be careful not discharged to the environment without being properly handled waste water contaminated.

Methods and materials for contaminant and methods and materials for cleaning up

Sweep up and gather scattered particles, and collect it in an empty airtight container.

Recovery, neutralization

No information available

Secondary disaster prevention measures

Clean contaminated objects and areas thoroughly observing environmental regulations.

Section 7: HANDLING AND STORAGE

Handling**Technical measures**

Avoid contact with strong oxidizing agents. Use with local exhaust ventilation.

Precautions

Do not rough handling containers, such as upsetting, falling, giving a shock, and dragging Prevent leakage, overflow, and scattering. Not to generate steam and dust in vain. Seal the container after use. After handling, wash hands and face, and then gargle In places other than those specified, should not be smoking or eating and drinking Should not be brought contaminated protective equipment and gloves to rest stops Deny unnecessary entry of non-emergency personnel to the handling area

Safety handling precautions

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Storage**Safe storage conditions**

Storage conditions Keep container protect from light tightly closed. Store in a cool (2-10 °C) place.

Safe packaging material Glass

Incompatible substances Strong oxidizing agents

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**Engineering controls**

In case of indoor workplace, seal the source or use a local exhaust system. Provide the safety shower facility, and hand- and eye-wash facility. And display their position clearly.

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Personal protective equipment

Respiratory protection Dust mask

Hand protection Protection gloves

Eye protection protective eyeglasses or chemical safety goggles

Skin and body protection Long-sleeved work clothes

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES**Form**

Color White - slightly brown

Appearance crystals - powder

Odor no data available

Melting point/freezing point no data available

Boiling point, initial boiling point and boiling range no data available

Flammability no data available

Evaporation rate: no data available

Flammability (solid, gas): no data available

Upper/lower flammability or explosive limits

Upper: no data available

Lower: no data available

Flash point no data available

Auto-ignition temperature: no data available

Decomposition temperature: no data available

pH no data available

Viscosity (coefficient of viscosity) no data available

Dynamic viscosity no data available

Solubilities water : soluble .

n-Octanol/water partition coefficient:(log Pow) 4.27

Vapour pressure no data available

Specific Gravity / Relative density no data available

Vapour density no data available
 Particle characteristics no data available

Section 10: STABILITY AND REACTIVITY

Stability

Reactivity no data available
 Chemical stability May be altered by light.

Hazardous reactions

None under normal processing

Conditions to avoid

Extremes of temperature and direct sunlight

Incompatible materials

Strong oxidizing agents

Hazardous decomposition products

Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Hydrogen chloride (HCl) gas, Halides

Section 11: TOXICOLOGICAL INFORMATION

Acute toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Donepezil hydrochloride	32.6 mg/kg (Rat, female) 36.9 mg/kg (Rat, male)	N/A	N/A

Skin irritation/corrosion no data available
 Serious eye damage/ irritation no data available
 Respiratory or skin sensitization no data available
 Reproductive cell mutagenicity no data available
 Carcinogenicity no data available
 Reproductive toxicity no data available
 STOT-single exposure no data available
 STOT-repeated exposure no data available
 Aspiration hazard no data available

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity No information available

Other data no data available

Persistence and degradability No information available
 Bioaccumulative potential No information available
 Mobility in soil No information available
 Hazard to the ozone layer No information available

Section 13: DISPOSAL CONSIDERATIONS

Waste from residues

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated container and contaminated packaging

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Section 14: TRANSPORT INFORMATION

ADR/RID

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Donepezil hydrochloride)
UN classification	6.1
Subsidiary hazard class	
Packing group	II
Marine pollutant	Not applicable

IMDG

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Donepezil hydrochloride)
UN classification	6.1
Subsidiary hazard class	
Packing group	II
Marine pollutant (Sea)	Not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

IATA

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Donepezil hydrochloride)
UN classification	6.1
Subsidiary hazard class	
Packing group	II
Environmentally Hazardous Substance	Not applicable

Section 15: REGULATORY INFORMATION

International Inventories

EINECS/ELINCS	-
TSCA	-

Japanese regulations

Fire Service Act	Not applicable
Poisonous and Deleterious Substances Control Law	Not applicable
Industrial Safety and Health Act	Not applicable
Regulations for the carriage and storage of dangerous goods in ship	Toxic Substances - Poison (Ordinance Art.3, Ministry of Transportation Ordinance Regarding Transport by Ship and Storage, Attached Table 1)
Civil Aeronautics Law	Toxic and Infectious Substances (Ordinance Art.194, MITL Notification for Air Transportation of Explosives etc., Attached Table 1)
Pollutant Release and Transfer Register Law (~2023.3.31)	Not applicable
Pollutant Release and Transfer Register Law (2023/4/1~)	Not applicable
Export Trade Control Order	Not applicable

Section 16: OTHER INFORMATION

Key literature references and sources for data etc.

NITE: National Institute of Technology and Evaluation (JAPAN)
<http://www.safe.nite.go.jp/japan/db.html>
 IATA dangerous Goods Regulations
 RTECS:Registry of Toxic Effects of Chemical Substances
 Japan Industrial Safety and Health Association GHS Model SDS
 Dictionary of Synthetic Organic Chemistry, SSOCJ, Koudansha Scientific Co.Ltd.
 Chemical Dictionary, Kyouritsu Publishing Co., Ltd.

etc

Disclaimer

This SDS is according to JIS Z 7253: 2019. The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

GHS Classification is according to JIS Z7252(2019). *JIS: Japanese Industrial Standards

End of Safety Data Sheet