

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



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

1.1. Product identifier

Trade name

Donepezil hydrochloride

CAS number

120011-70-3

EC number

620-543-2

Synonyms

1H-Inden-1-one, 2,3-dihydro-5,6-dimethoxy-2-((1-(phenylmethyl)-4-piperidiny)methyl)-, hydrochloride

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

Relevant identified uses

Research and development. Laboratory Chemicals. Manufacture of substances.

Not suitable for use in

Not suitable for human consumption or veterinary purposes.

1.3. Details of the supplier of the safety data sheet

Supplier

Molekula Group

Address

Molekula Ltd, Lingfield Way, Darlington,
DL1 4XX Darlington
United Kingdom

Telephone

+44 (0) 3302 000 333

Email

info@molekula.com

Web site

www.molekula.com

Contact person

Kevin Banks

Email

+44 (0) 7769276927

1.4. Emergency telephone number

Poison center/Additional emergency number

0344 892 0111 - National Poisons Information Service (Newcastle Centre)

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Classification

Eye irritation, hazard category 2

Acute toxicity, oral, hazard category 3

Hazard statements

H301, H319

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Danger

Hazard statements

H301 Toxic if swallowed.

H319 Causes serious eye irritation.

Precautionary statements

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.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No data available

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical name	CAS No. EC No. REACH No. Index No.	Concentration	Classification	H-phrases M factor acute M factor chronic	Note
Donepezil hydrochloride	120011-70-3 620-543-2 - -	100%	Acute Tox. 3 - oral, Eye Irrit. 2	H301, H319 - -	-

Molecular weight

415.95

Substance additional information

For the complete text of H- / EUH-statements mentioned in this section, see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

IF exposed or concerned: Get medical advice/attention. First aiders/ medical personnel need to protect themselves. Show this Safety Data Sheet (SDS) to medical personnel.

Inhalation

Toxic if inhaled. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor. If breathing stops, provide artificial respiration. For breathing difficulties oxygen may be necessary.

Skin contact

In case of skin contact: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Immediately call a POISON CENTER/doctor. The casualty should be transferred to hospital for further treatment.

Eye contact

Remove contact lenses if present. Rinse eyes with water. Continue to rinse for at least 15 minutes and seek medical attention.

Ingestion

IF SWALLOWED: give water to drink (two glasses at most). Seek medical advice immediately. In exceptional cases only, if medical care is not available within one hour, induce vomiting (only if the persons are fully conscious and awake). Administer activated charcoal (20 - 40g in a 10% slurry) and consult a doctor as quickly as possible. Do not attempt to neutralise.

Information for doctors

No data available.

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



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

The severity of the symptoms described will vary dependant of the concentration and the length of exposure. See section 11 for more detailed information on health effects and symptoms.

Inhalation

Single exposure may cause the following adverse effects: Difficulty in breathing. Unconsciousness, possibly death.

Skin contact

Single exposure may cause the following adverse effects: Unconsciousness, possibly death.

Eye contact

Single exposure may cause the following adverse effects: Severe irritation. Unconsciousness, possibly death.

Ingestion

Single exposure may cause the following adverse effects: Severe abdominal pain. May cause severe internal injury. Unconsciousness, possibly death.

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

Treat symptomatically. No special treatment requirement.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish.

Unsuitable extinguishing media

No specific fire fighting procedure given.

5.2. Special hazards arising from the substance or mixture

Specific hazards: Toxic. Combustible.

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

Development of hazardous combustion gases or vapours possible in the event of fire.

Carbon monoxide (CO). Carbon dioxide (CO₂).

Nitrous gases (NO_x).

Hydrogen Chloride gas

5.3. Advice for firefighters

Special protective equipment for fire-fighters

Evacuate area. Avoid breathing gas, fume, vapours or spray. Cool containers exposed to heat with water spray and remove container, if no risk is involved.

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid breathing dust/fume/gas/mist/vapours/spray. Provide adequate ventilation. Avoid contact with skin and eyes. Avoid dust formation. For personal protection, see section 8.

6.2. Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Collect spillage with shovel, broom or the like and reuse, if possible. Dispose of large amounts of spillage/waste according to agreement with local authorities.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Preventive handling precautions

For precautions see section 2.2. Do not handle until all safety precautions have been read and understood. Do not handle broken packages without protective equipment. This product is toxic. Keep containers tightly closed. Immediate first aid is necessary. Wear protective clothing, gloves, eye and face protection. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid ingestion and inhalation. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Do not reuse empty containers.

General hygiene

Observe good chemical hygiene practices. Remove contaminated clothing immediately and wash skin with soap and water. Remove contaminated clothing and launder thoroughly before re-use. Wash skin thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Store at room temperature. Store in a dry place. Store in a closed container.

Storage class : Toxic storage.

7.3. Specific end use(s)

No specific usage precautions noted.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

According to Regulation (EC) No 1907/2006

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Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



8.2. Exposure controls

Personal Protective Equipment Symbols



Eye / face protection

Wear eye protection.

Hand protection

Wear protective gloves. Recommended gloves: Nitrile.

Glove Thickness: 0.11mm

Breakthrough time: 8 hours

Always inspect gloves before use. If signs of wear and tear are noticed then the gloves should be replaced.

No specific hygiene procedures noted, but good personal hygiene practices are always advisable, especially when working with chemicals. Wash contaminated skin thoroughly after handling.

Other skin protection

Wash skin thoroughly after handling.

Respiratory protection

Provide adequate ventilation. If ventilation is insufficient, suitable respiratory protection must be provided.

Environmental exposure controls

Avoid discharge into drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Solid

Colour

White.

Odour

No data available

Melting point / freezing point

211 - 231 °C

Boiling point or initial boiling point and boiling range

No data available

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



Flammability

No data available

Lower and upper explosion limit

No data available

Flash point

No data available

Auto-ignition temperature

No data available

Decomposition temperature

No data available

pH

No data available

Kinematic viscosity

No data available

Solubility

No data available

Partition coefficient n-octanol/water

No data available

Vapour pressure

No data available

Density and/or relative density

No data available

Relative vapour density

No data available

Particle characteristics

No data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stable under normal temperature conditions. Stable under the prescribed storage conditions.

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



10.3. Possibility of hazardous reactions

There are no known conditions that are likely to result in a hazardous situation.

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

See section 5.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Product / Substance name CAS / EC no.	Dose descriptor	Value / Dose	Exposure route	Test animals
Donepezil hydrochloride 120011-70-3 / 620-543-2	LD50	32.6 mg/kg	Oral	Rat

Germ cell mutagenicity

Product / Substance name CAS / EC no.	Result	Species	Method / Guideline
Donepezil hydrochloride 120011-70-3 / 620-543-2	Negative.	Salmonella typhimurium	Ames test

Carcinogenicity

Product / Substance name CAS / EC no.	Other
Donepezil hydrochloride 120011-70-3 / 620-543-2	No evidence of carcinogenicity in animal studies

Aspiration hazard

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

11.2. Information on other hazards

No data available

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

This product does not contain any known or suspected endocrine disruptors.

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal considerations

Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

14.1. UN number

2811

14.2. UN proper shipping name

ADR / RID / ADN proper shipping name

TOXIC SOLID, ORGANIC, N.O.S. (Donepezil hydrochloride)

IMDG proper shipping name

TOXIC SOLID, ORGANIC, N.O.S. (Donepezil hydrochloride)

IATA proper shipping name

Toxic solid, organic, n.o.s. (Donepezil hydrochloride)

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1

Issued: 2024-03-22



14.3. Transport hazard class(es)

Label

ADR/RID/ADN



6.1

IMDG



6.1

IATA



6.1

ADR / RID Class

6.1

ADR / RID Classification code

T2

ADR / RID hazard identification number

60

IMDG Class

6.1

IATA Class

6.1

ADN Class

6.1

ADN Class Code

T2

14.4. Packing group

ADR / RID / ADN: II

IMDG: II

IATA: II

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

Donepezil hydrochloride

Version number: 1
Issued: 2024-03-22



14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Special precautions for user

Tunnel restriction code: D/E

Transport category: 2

IMDG EmS

F-A, S-A

14.7. Maritime transport in bulk according to IMO instruments

IBC Instruction: IBC08

SECTION 15: Regulatory information

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

EU regulations

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

This material safety data sheet complies with the requirements of Regulation (EU) 2020/878.

National regulations

Directive: 2012/18/EU: ACUTE TOXIC

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Phrase meaning

Eye Irrit. 2 - Eye irritation, hazard category 2

Acute Tox. 3 - oral - Acute toxicity, oral, hazard category 3

H301 Toxic if swallowed.

H319 Causes serious eye irritation.