

Citalopram hydrobromide

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 20/10/2016 Revision date: 09/03/2017

900857

Version: 1.1

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

1.1. Product identifier

Product form : Substance
Substance name : Citalopram hydrobromide
IUPAC name : 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-2-benzofuran-5-carbonitrile hydrobromide
EC No : 261-890-6
CAS No : 59729-32-7
Product code : 900857
Formula : C₂₀H₂₁FN₂O · BrH
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 industry
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

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 - Nederland
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)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

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
Reproductive toxicity, Category 2 H361f

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Hazardous to the aquatic environment — Chronic Hazard, Category 2 H411

Full text of hazard classes and 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]

Hazard pictograms (CLP)



Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed
H361f - Suspected of damaging fertility
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP)

: P273 - Avoid release to the environment
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P308+P313 - IF exposed or concerned: Get medical advice/attention

2.3. Other hazards

Other hazards not contributing to the classification : Exposure may produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Citalopram hydrobromide	(CAS No) 59729-32-7 (EC No) 261-890-6	100	Acute Tox. 4 (Oral), H302 Repr. 2, H361f Aquatic Chronic 2, H411

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 after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

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- First-aid measures after skin contact : Wash with plenty of soap and water.
First-aid measures after eye contact : Immediately rinse with plenty of water.
First-aid measures after ingestion : Rinse mouth. Get medical advice/attention.

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

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- 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 : Only qualified personnel equipped with suitable protective equipment may intervene.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up, shovel or vacuum. Hose down area with water.

6.4. Reference to other sections

See Heading 13.

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.
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep container tightly closed. Protect from light.
Incompatible products : Strong oxidizing agent.
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

8.2. Exposure controls**Appropriate engineering controls:**

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

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 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	: 405.3 g/mol
Colour	: White to off-white.
Odour	: No data available
Odour threshold	: No data available
pH	: 5.5 - 6.5 0.5% solution
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 185 - 188 °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
Solubility	: Soluble in ethanol. Soluble in chloroform.

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Log Pow : 4.22
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**

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Direct sunlight.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

On heating/burning: release of harmful/irritant gases/vapours.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Oral: Harmful if swallowed.

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LD50 oral rat	800 mg/kg
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Skin corrosion/irritation : Not classified
pH: 5.5 - 6.5 0.5% solution

Serious eye damage/irritation : Not classified
pH: 5.5 - 6.5 0.5% solution

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Suspected of damaging fertility.

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Citalopram hydrobromide (59729-32-7)	
LC50 fish 1	3.9 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Citalopram hydrobromide (59729-32-7)	
Log Pow	4.22

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) : Disposal must be done according to official regulations.
Waste disposal recommendations : Dispose of contaminated material at an authorized site.

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.	Environmentally hazardous substance, solid, n.o.s.
14.3. Transport hazard class(es)	
9	9
	
14.4. Packing group	
III	III
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
Special provisions (ADR) : 274, 335, 601, 375
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P002, IBC08, LP02, R001

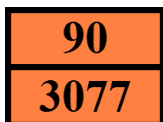
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Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	:



Tunnel restriction code (ADR)	: E
EAC code	: 2Z

- Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197
ERG code (IATA)	: 9L

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

Citalopram hydrobromide is not on the REACH Candidate List

Citalopram hydrobromide is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

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 : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Supplier.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Repr. 2	Reproductive toxicity, Category 2
H302	Harmful if swallowed
H361f	Suspected of damaging fertility
H411	Toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II) Version 2017

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