

Tramadol hydrochloride

Safety Data Sheet

843180

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 03/10/2016 Revision date 08/01/2020
 Supersedes 17/05/2017

Version: 3.0

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

1.1. Product identifier

Product form : Substance
 Substance name : Tramadol hydrochloride
 IUPAC name : trans-(±)-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol hydrochloride
 EC-No. : 252-950-2
 CAS-No. : 36282-47-0
 Product code : 843180
 Formula : C₁₆H₂₅NO₂ · HCL
 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 : Professional use
 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@duchefa.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)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

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 3

H301

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

Full text of 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] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP) :



GHS06



GHS09

Signal word (CLP) : Danger

Hazard statements (CLP) : H301 - Toxic if swallowed.
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P273 - Avoid release to the environment.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P330 - Rinse mouth.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tramadol hydrochloride	(CAS-No.) 36282-47-0 (EC-No.) 252-950-2	100	Acute Tox. 3 (Oral), H301 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

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First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 15 minutes If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Get medical advice/attention. Rinse mouth.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: dry chemical powder, alcohol-resistant foam, carbon dioxide (CO ₂) Water spray.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: The product is not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon dioxide Carbon monoxide Nitrogen oxides Hydrogen chloride.

5.3. Advice for firefighters

Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
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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	: Evacuate unnecessary personnel. Avoid raising dust. Ensure adequate air ventilation.

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

For containment : Avoid raising dust.
Methods for cleaning up : Sweep up, shovel or vacuum.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Take all necessary technical measures to avoid or minimize the release of the product on the workplace.
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.
Store in dry, cool, well-ventilated area
Protect from light.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

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 ISO 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	: 299.8 g/mol
Colour	: White to off-white.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
pH solution	: 5 - 6 (1 % solution in water)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 178 - 181 °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)	: The product is not flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Freely soluble in water.
Log Pow	: No data available
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

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

High temperature.

10.5. Incompatible materials

Strong oxidizers

Strong acids

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Strong bases.

10.6. Hazardous decomposition productsCarbon oxides (CO, CO₂)

Nitrogen oxides

Hydrogen chloride.

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

Acute toxicity : Toxic if swallowed.

Tramadol hydrochloride (36282-47-0)	
LD50 oral rat	228 mg/kg
LD50 oral	270 mg/kg mouse

Skin corrosion/irritation : Slight skin irritant.

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

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

Tramadol hydrochloride (36282-47-0)	
LC50 fish 1	6.2 mg/l <i>Carassius auratus</i> (goldfish)

12.2. Persistence and degradability

Tramadol hydrochloride (36282-47-0)	
Persistence and degradability	Moderately biodegradable.

12.3. Bioaccumulative potential

Tramadol hydrochloride (36282-47-0)	
Bioaccumulative potential	Not established.

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.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
14.3. Transport hazard class(es)	
6.1	6.1
	
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) : T2

Special provisions (ADR) : 274, 614

Limited quantities (ADR) : 5kg

Excepted quantities (ADR) : E1

Packing instructions (ADR) : P002, IBC08, LP02, R001

Special packing provisions (ADR) : B3

Mixed packing provisions (ADR) : MP10

Portable tank and bulk container instructions (ADR) : T1

Portable tank and bulk container special provisions (ADR) : TP33

Tank code (ADR) : SGAH, L4BH

Tank special provisions (ADR) : TU15, TE19

Vehicle for tank carriage : AT

Transport category (ADR) : 2

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Special provisions for carriage - Bulk (ADR) : VC1, VC2, AP7

Special provisions for carriage - Loading, unloading and handling (ADR) : CV13, CV28

Special provisions for carriage - Operation (ADR) : S9

Hazard identification number (Kemler No.) : 60

Orange plates : 

Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

PCA Excepted quantities (IATA) : E1

PCA Limited quantities (IATA) : Y645

PCA limited quantity max net quantity (IATA) : 10kg

PCA packing instructions (IATA) : 670

PCA max net quantity (IATA) : 100kg

CAO packing instructions (IATA) : 677

CAO max net quantity (IATA) : 200kg

Special provisions (IATA) : A3, A5

ERG code (IATA) : 6L

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

Tramadol hydrochloride is not on the REACH Candidate List

Tramadol hydrochloride is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1		Modified	Change of Logo
7.1	Hygiene measures	Added	

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7.2	Storage conditions	Added	
8.2	Respiratory protection	Modified	
11.1	LD50 oral	Added	

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 : Supplier.

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
H301	Toxic if swallowed.
H411	Toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II) ducheфа nieuwe logo

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.