

SAFETY DATA SHEET (According to EC-Regulations 1907/2006 (REACH) & 1272/2008 (CLP))	
TRAMADOL HYDROCHLORIDE	

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

- 1.1 Product identifier**
Product Number 67
Chemical Name: (±)-cis-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride;
OR
(1RS,2SR)-2-[(Dimethylamino) methyl]-1-(m-methoxyphenyl) cyclohexanol hydrochloride.
Trade name: Tramadol
CAS No.: 36282-47-0
EINECS No.: No information available
REACH Registration No.: No information available
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s): Pharmaceutical Product : Analgesic
- 1.3 Details of the supplier of the Safety Data Sheet**
Company Identification: Sun Pharmaceutical Industries Ltd.
Ahmednagar, Maharashtra state, India.
- 1.4** **Telephone:** 91-(0241) 2777329 / 330 / 359
Fax: (0241) 2777231
E-Mail : api@sunpharma.com

2. HAZARD IDENTIFICATION

- 2.1 Classification of the substance or mixture**
According to Regulation (EC) No. 1272/2008 (CLP):
Acute toxicity, oral Category 3
STOT, single exposure Category 3 narcotic effects
Specific target organ toxicity, repeated exposure Category 1
According to Directive 67/548/EEC & Directive 1999/45/EC:
- 2.2.1 Label elements**
According to Regulation (EC) No. 1272/2008 (CLP)

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Hazard pictogram(s):



Signal word(s):

Danger

Hazard statement(s):

H302:Harmful if swallowed.
H317:May cause an allergic skin reaction.
H334:May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H340:May cause genetic defects.
H350:May cause cancer.
H360:May damage fertility or the unborn child.
H372:Causes damage to organs (bone marrow) through prolonged or repeated exposure

Precautionary statement(s):

P264: Wash skin thoroughly after handling.
P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312: IF SWALLOWED:Call a doctor/physician if you feel unwell.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338: IF IN EYES: Rinse continuously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313: If exposed or concerned: Get medical advice/attention.
P332+P313: IF SKIN irritation occurs: Get medical advice/attention.
P337+P313: IF eye irritation persists: Get medical advice/attention.
P501: Dispose of contents in accordance with local, state or national legislation.

2.2.2 Label elements

According to Directive 67/548/EEC & Directive 1999/45/EC

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Hazard pictogram(s): No information available
 Hazard Symbol: No information available
 Risk Phrases: R22: Harmful if swallowed.
 R36/38: Irritating to eyes and skin.
 R40: Limited evidence of a carcinogenic effect.
 R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 R63: Possible risk of harm to the unborn child.

Safety Phrases: S22: Do not breathe dust.
 S24/25: Avoid contact with skin and eyes.
 S36/37: Wear suitable protective clothing and gloves.
 S61: Avoid release to the environment. Refer to special instructions/Safety Data Sheets.

2.3 Other hazards No information available

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

EC Classification No. 1272/2008

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	Hazard symbol(s) and hazard statement(s)
Tramadol	100	-	-	See section 2.

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	EC Classification and Risk Phrases
Tramadol	100	-	-	See section 2.

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4. FIRST AID MEASURES

4.1 Description of first aid measures.

Inhalation:	Remove patient from exposure, keep warm and at rest. If symptoms persist, obtain medical attention.
Skin Contact:	Remove contaminated clothing immediately and drench affected skin with plenty of water, then wash with soap and water. If symptoms persist, obtain medical attention.
Eye Contact:	If substance has got into the eyes, immediately wash out with plenty of water for at least 15 minutes. If symptoms persist, obtain medical attention.
Ingestion:	Do not induce vomiting. Provided the patient is conscious, wash out mouth with water. Obtain immediate medical attention.

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

4.3 Indication of any immediate medical attention and special treatment needed In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE FIGHTING MEASURES

5.1	Extinguishing media	
	Suitable Extinguishing Media:	Water spray, foam, dry powder or CO ₂ .
	Unsuitable Extinguishing Media:	No information available
5.2	Special hazards arising from the substance or mixture:	No unusual fire or explosion hazards noted.

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| <p>5.1 Extinguishing media</p> <p>5.3 Advice for fire-fighters</p> | <p>A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Keep fire exposed containers cool by spraying with water.</p> |
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6. ACCIDENTAL RELEASE MEASURES

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| <p>6.1 Personal precautions, protective equipment and emergency procedures</p> | <p>Eliminate sources of ignition. Avoid contact with skin and eyes. Avoid inhalation of dusts. Wear suitable protective clothing and gloves. Provide adequate ventilation.</p> |
| <p>6.2 Environmental precautions</p> | <p>Avoid release to the environment.</p> |
| <p>6.3 Methods and material for containment and cleaning up</p> | <p>Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up.</p> |
| <p>6.4 Reference to other sections</p> <p>Other advice</p> | <p>See Section: 8.</p> <p>Spillages or uncontrolled discharges into watercourses must be alerted to the Environment Agency or other appropriate regulatory body.</p> |

7. HANDLING AND STORAGE

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| <p>7.1 Precautions for safe handling</p> | <p>Eliminate sources of ignition. Provide adequate ventilation. Avoid inhalation of vapours. Avoid contact with skin and eyes. Wear suitable protective clothing. See Section: 8.</p> |
| <p>7.2 Conditions for safe storage, including any incompatibilities</p> | <p>Preserve in tight, light resistant, cool & well ventilated place between 15 ° C and 30 ° C. This material should be handled and stored as per label instructions to ensure product integrity</p> |

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1	Control parameters :	Tramadol
8.2	Exposure Control:	No information available
8.2.1	Appropriate engineering controls	Provide adequate ventilation, including appropriate local extraction if dusts, fumes or vapours are likely to be evolved.
8.2.2	Personal Protection	
	Eye/face protection	Goggles giving complete protection to eyes.
		
	Skin / Body protection	Wear suitable gloves and suitable protective clothing.
		
	Respiratory protection	In case of insufficient ventilation or workplace exposure limits are exceeded wear suitable respiratory equipment.
		
8.2.3	Environmental Exposure Controls	Avoid release to the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1	Information on basic physical and chemical properties	
	Appearance:	A white crystalline powder.
	Colour:	White
	Chemical Formula:	<chem>C16H25NO2.HCl</chem>
	Molecular weight:	299.84
	pH (Value):	Between 4.5 and 6.0
	Melting Point (°C):	Between 180° C and 184° C
	Solubility (Water):	Freely soluble in water
	Solubility (Other):	Freely soluble in methanol and in ethanol; slightly

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		soluble in isopropanol; very slightly soluble in acetone
9.2	Partition Coefficient:	No information available
	Other information	
	Auto-ignition temperature	No information available
	Explosive limit - lower (%)	No information available
	Explosive limit - upper (%)	No information available

10 . STABILITY AND REACTIVITY

10.1	Reactivity	No information available.
10.2	Chemical stability	Stable under normal conditions.
10.3	Possibility of hazardous reactions	No information available.
10.4	Conditions to avoid	Avoid friction, sparks, or other means of ignition. Keep away from heat and direct sunlight.
10.5	Incompatible materials	Strong oxidizing agents. Aluminum
10.6	Hazardous Decomposition Product(s)	NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

	Acute toxicity	LD50 Rat Oral 228 mg/kg
	Ingestion:	Toxic if swallowed..
	Inhalation:	No information available.
	Skin Contact:	May causes skin irritation
	Eye Contact	May causes eye irritation.
	Skin corrosion/irritation	No information available.
	Serious eye damage/irritation	No information available.
	Respiratory or skin sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
11.2	Mutagenicity	No information available.
11.3	Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

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11.4	Reproductive toxicity	No information available.
11.5	STOT - single exposure	No information available.
11.6	STOT-repeated exposure	Narcotic effects
11.7	Aspiration hazard	No information available.
11.8	Other information	No information available.

12. ECOLOGICAL INFORMATION

12.1	Toxicity	No information available.
12.2	Persistence and degradability	No information available.
12.3	Bioaccumulative potential	No information available.
12.4	Mobility in soil	No information available.
12.5	Results of PBT and VPVB assessment	No information available.
12.6	Additional Information	No information available.

13. DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point. To be disposed of as hazardous waste. Disposal should be in accordance with local, state or national legislation.
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14. TRANSPORT INFORMATION

14.1	UN number	2811
14.2	Proper Shipping Name	Toxic solids, organic, n.o.s. (Tramadol Hydrochloride)
14.3	Transport hazard class(es):	6.1
14.3.1	Land transport (UN):	Toxic solid, organic, n.o.s. (Tramadol Hydrochloride)
14.3.2	Air transport (ICAO-IATA / DGR):	Toxic solid, organic, n.o.s. (Tramadol Hydrochloride)
14.3.3	Sea transport (IMDG-Code / GGVSee):	Toxic solid, organic, n.o.s. (Tramadol Hydrochloride)
14.4	Packing Group	III

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|-------------|--|----------------------------------|
| 14.5 | Environmental hazards | No information available. |
| 14.6 | Special precautions for user | Avoid release to the environment |
| 14.7 | Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | No information available |

15. REGULATORY INFORMATION

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|-------------|---|---|
| 15.1 | Safety, health and environmental regulations/legislation specific for the substance or mixture | This Safety Data Sheet was prepared in accordance with EC Regulation (EC) No. 1907/2006., Regulation (EC) No. 1272/2008 (CLP), Directive 67/548/EEC & Directive 1999/45/EC. |
| 15.2 | Chemical Safety Assessment | No information available |
| 15.3 | Superfund Amendments and Reauthorization Act of 1986 (SARA) | Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No |

16. OTHER INFORMATION

Full text of Hazard statements and Risk phrases for pure substances listed in section 3.

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| 16.1 | Issue date : | 15 April 2018 |
| 16.4 | Further information : | No information available |

LEGEND

CAS = Chemical Abstracts Service;
 CNS = Central Nervous System;
 EINECS = European Inventory of Existing Commercial Chemical Substances;
 EC50 = Effective Concentration 50%;
 EPA = Environmental Protection Agency;
 IARC = International Agency for Research on Cancer;
 IC50 = Inhibitory Concentration 50%;
 LC50 = Lethal Concentration 50%;

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LD50 = Lethal Dose 50%;
LTEL = Long Term Exposure Limit;
STEL = Short Term Exposure Limit;
TWA = Time Weighted Average;
STOT = Specific target organ toxicity

Disclaimer:

The above information and recommendations are believed to be correct as on date but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Sun Pharmaceutical shall not be held liable for any damage resulting from handling or from contact with the above product. Sun Pharmaceutical reserves the right to revise this MSDS.