


SAFETY DATA SHEETS

This SDS packet was issued with item:

078949271

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).


078949270

	VIRUPAKSHA ORGANICS LIMITED	MATERIAL SAFETY DATA SHEET
Name of the product		TRAMADOL HYDROCHLORIDE

1. Material Identification

Name of the product	:	TRAMADOL HYDROCHLORIDE
Trade name	:	TRAMADOL HYDROCHLORIDE
Application of the substance/ Product identification	:	Active Pharma Ingredient / CAS No. [36282-47-0]
Chemical name	:	(1RS, 2RS) -2-[(Dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride.
Manufacturer	:	VIRUPAKSHA ORGANICS LIMITED Survey No. 10, Gaddapotharam Village, Jinnaram Mandal, Sangareddy District – 502319, Telangana, INDIA.
Further Information:	:	Fax : +91-40- 23720738
Emergency number	:	+91-40- 23075816/ 64555689

2. Hazard(s) Identification



Hazard description & Symbol	:	Xn, N 
Risk phrases	:	R22 Harmful if swallowed. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases	:	S22 Do not breathe dust. S36/37 Wear suitable protective clothing and gloves. S60 This material and its container must be disposed of as hazardous waste. S61 Avoid release to the environment. Refer to special instructions/safety data sheets.


Classification (REGULATION (EC) No 1272/2008


Acute toxicity, category 4	:	R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Eye irritation, category 2	:	H319 Causes serious eye irritation.
Specific target organ toxicity - single	:	No data available
Skin irritation, Category 2	:	No data available


Classification

Adverse Effects	:	Adverse effects may include back pain; dizziness; drowsiness; painful menstruation; fatigue; headache; indigestion; nausea; and sinusitis, cold, or flu. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.
Overdose Effects	:	Overdose may cause dizziness, drowsiness, or dry mouth.
Acute	:	Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.
Chronic	:	Possible hypersensitization.

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Medical Conditions Aggravated by Exposure	:	Hypersensitivity to material, diabetes mellitus, enlarged prostate or urinary problems, glaucoma or increased pressure in the eye, heart or blood vessel disease or high blood pressure, kidney disease, and overactive thyroid.	
Cross Sensitivity	:	No data available	
Target Organs	:	No data available	
Label elements			
Hazard Pictogram	:		
Single word	:	Warning	
Hazard statement(s)	:	H301 : Toxic if swallowed. H302 Harmful if swallowed. H319 Causes serious eye irritation. H336: May cause drowsiness or dizziness H411 Toxic to aquatic life with long lasting effects	
Precautionary statement(s)	:	P261 : Avoid breathing dust P280 : Wear protective gloves/protective clothing/eye protection/face protection P285 : In case of inadequate ventilation wear respiratory protection P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P321: Specific treatment (see on this label). P362: Take off contaminated clothing and wash before reuse. P405: Store locked up. P501: Dispose of contents/container in accordance with local/regional/national/international regulations. P302+352 : IF ON SKIN: Wash with soap and water P304+340 : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+351+338 : IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing P312 : Call a POISON CENTER or doctor/physician if you feel unwell	
3. Composition/ Information on ingredients			
Name	*CAS No.	*EINECS No.	Composition
Tramadol Hydrochloride	[36282-47-0]	252-950-2	---
4. First-aid measures			
General information	:	In case of reactions described in hazards identification / toxicological information or other severe, immediate or persisting symptoms seek medical advice and call the	

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		nearest poison centre. Show the label and this safety data sheet.
After Inhalation	:	Remove to fresh air. If breathing becomes difficult, call a physician. If Breathing stops, give oxygen.
After Skin contact	:	Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothing and shoes.
After Eye contact	:	Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.
After swallowing	:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.
5. Fire fighting measures		
Suitable extinguishing Media	:	Carbon dioxide, dry chemical powder or appropriate foam. Water spray. Avoid spill into drains, surface and groundwater and soil. Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Emits toxic fumes under fire conditions. Risk of dust explosion cannot be excluded.
For safety reason unsuitable extinguishing agents	:	Water with full jet.
Unusual fire and explosion hazards	:	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.
Specific hazards in case of fire	:	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.
Special protective equipment and precaution for fire fighters	:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
6. Accident release measures		
Personal related precautions	:	Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing and equipment consistent with the degree of hazard. Vapour-suppressing foam or water spray may be used to control vapours as appropriate.
Environmental related precautions	:	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Methods and materials for containment and clean up	:	Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by

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		<p>spreading water on the contaminated surface and dispose of according to local and regional authority requirements.</p> <p>Large Spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.</p>
7. Handling and storage		
Precautions for safe handling	:	Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Avoid use with incompatible materials.
Conditions for safe storage, Including : incompatibilities	:	Preserve in tight containers, and store at controlled room temperature.
Storage	:	Preserve in tight containers, and store at controlled room temperature.
8. Exposure controls/ personal protection		
Information on the system design	:	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit
Exposure limits	:	No data available
Ventillation	:	No data available
General protective and Hygienic measures	:	The usual precautionary measures are to be adhered to when handling chemicals. Do not drink, eat and smoke while working. Avoid contact with the eye and skin. Keep away from food stuffs, feed and beverages.
Respiratory protection	:	Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.
Eye protection	:	Safety glasses or goggles
Skin protection	:	Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.
9. Physical and chemical properties		
Appearance	:	White or almost white crystalline powder.
Melting Point	:	180°C to 184°C
Solubility	:	Freely soluble in water and in methanol, very slightly soluble in acetone.
Flash point	:	No data available.
pH	:	5 – 6 (1% aqueous solution).
Log Pow	:	3.01 (calculated).

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10. Stability and reactivity

Chemical stability	:	This product is expected to be stable.
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	Avoid exposure to heat.
Materials to avoid	:	Excess, incompatible materials.
Hazardous decomposition products	:	When heated to decomposition, material emits toxic fumes of NO _x and HF. Emits toxic fumes under fire conditions.

11. Toxicological Information

Acute Toxicity:

RTECS No	:	GV8940000
LD ₅₀ (Oral toxicity)	:	>50 but ≤300 mg/kg
LD ₅₀ (Dermal toxicity)	:	>200 but ≤1000 mg/kg
LC ₅₀ (Inhalation toxicity by dust and mists)	:	>2.0 but ≤4.0 mg/L




Completely absorbed following ingestion. Crosses the blood-brain barrier and the placenta barrier. Harmful if swallowed. May cause headache and gastro-intestinal disturbances. May cause slow heart rate. May affect central nervous system. May cause allergic skin reactions. May cause dependence. Risk of carcinogenicity, mutagenicity, reproductive toxicity and sensitisation cannot be excluded.




Sub chronic/Chronic Toxicity:


Chronic Toxicity	:	No data available
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12. Ecological information

Persistence and degradability	:	No data available
Bio - accumulative potential	:	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain. Bioconcentration Factor: 1
Mobility	:	Solubility: This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in methanol. Volatility: This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance. Adsorption: This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment. Partitioning: This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

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Aquatic Toxicity	:	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	
13. Disposal Considerations			
Waste disposal	:	Dispose of waste in accordance with all applicable Federal, State, and local laws.	
Recommendation	:	Disposal must be made according to official regulations.	
14. Transport Information			
UN Number	:	UN 2811	
UN proper shipping Name	:	TOXIC SOLID, ORGANIC, N.O.S. (TRAMADOL HYDROCHLORIDE)	
Transport hazard class	:	Class 6.1 – PG III	
Packing group	:	670	
Marine Pollutant	:	Yes	
Additional information	:	Not dangerous according to the above specifications.	
15. Regulatory Information			
Hazard description & Symbol	:	Xn, N 	
Risk phrases	:	R22 Harmful if swallowed. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	
Safety phrases	:	S22 Do not breathe dust. S36/37 Wear suitable protective clothing and gloves. S60 This material and its container must be disposed of as hazardous waste. S61 Avoid release to the environment. Refer to special instructions/safety data sheets.	
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Label elements			
Hazard Pictogram	:		
Single word	:	Warning	

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Other Regulatory information		
*DSCL (EEC):	:	R36/38- Irritating to eyes and skin. S2- Keep out of the reach of children. S46- If swallowed, seek medical advice immediately and show this container or label.
*HMIS (U.S.A.):	:	
National Fire Protection Association (U.S.A.):	:	 <p> Health : 2 Flammability : 1 Reactivity : 0 </p>
16. Other Information		

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Reason for update:

Revision according to Regulation (EC) No 1907/2006. New name and address of the EDQM.
R22 Harmful if swallowed.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Warning! Reference Standards - important notice.

Information applies only to the CRS/BRP for its intended use. The EDQM staff assembles the MSDSs by using the information available at the time from sources considered reliable, such as, the European Chemical Substances Information System, approved Summaries of Product Characteristics, RTECS and the MSDS of the suppliers, manufacturers or importers.

The Ph. Eur does not independently verify the information. The accuracy of the information cannot therefore be guaranteed, nor does it constitute any expression of opinion by the Ph. Eur. concerning the substance/preparation.

This information is accordingly not to be regarded as a representation or statement concerning the quality or safety of the substance, the presence of any defect in it, or its fitness for any particular purpose except that of use as a Ph. Eur. CRS/BRP by professional persons having technical skill and at their own discretion and risk. The downstream users have the responsibility to manage the risks arising from their uses of the Ph. Eur. Reference Standards and for use of any information provided in this MSDS.

People working with any reference materials should apply regional and national laws, good practices and state-of-the-art precautions.