

# Tramal<sup>®</sup> Oral Drops



## SAFETY DATA SHEET

Page 1 of 6

Date of Issue: 27 October 2021

**IMPORTANT NOTICE** This Safety Data Sheet (SDS) is prepared by Seqirus Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (July 2020). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

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### 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

**Product Name** Tramal<sup>®</sup> Oral Drops 100 mg / mL  
Tramadol hydrochloride

**Other Names** Not Applicable

**Manufacturer's Product Code** 80860020

**Use** Analgesic TRAMAL<sup>®</sup> is used to relieve severe pain.

**Supplier Name** Seqirus Pty Ltd (ABN 26 160 735 035)

**Address** 63 Poplar Road, Parkville, Victoria 3052, Australia

**Telephone** +61 3 9389 2000

**Emergency Telephone** +61 3 9389 1984 (24hr)

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### 2. HAZARDS IDENTIFICATION

**Not classified as a hazardous chemical according to Australian WHS Regulations**

**GHS Classification(s)** None Allocated

**Signal Word** No Signal Word

**Pictogram(s)** No Pictogram(s)

**Hazard Statement(s)** None Allocated

**Prevention statement(s)** None Allocated

**Response** None Allocated

**Storage** None Allocated

**Disposal** None Allocated

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical Name:</i>	<i>CAS Number:</i>	<i>Proportion:</i>	<i>Classification</i>
Tramadol Hydrochloride	36282-47-0	10%	Acute Tox 4; H302 Aqua Chr 2; H411
Other ingredients	non-hazardous -	Up to 100%	

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### 4. FIRST AID MEASURES

**Eye** Wash eye thoroughly with running water for at least 15 minutes and seek medical attention.

**Swallowed** Seek medical attention following accidental ingestion.

**Skin** Wash area immediately with water.

**Aggravated Medical Conditions**

- Individuals with hypersensitivity to tramadol hydrochloride or any excipients
- Acute intoxication with alcohol, hypnotics, analgesics, opioids or psychotropic drugs
- Patients who are receiving MAO inhibitors or who have taken them within the last 14 days
- Individuals with sensitivity to opioids
- Individuals at risk of respiratory depression
- Individuals with epilepsy or those susceptible to seizures

**Advice to Doctor** If large volumes of solution have been swallowed the patient should be observed for signs of respiratory depression for at least 2 hours.

Naloxone will reverse respiratory depression, but not all symptoms caused by over dosage with tramadol hydrochloride. Adequate ventilation should be maintained. Haemodialysis is not expected to be helpful because it removes only a small percentage of the administered dose. Convulsions occurring in mice following the administration of toxic doses of tramadol hydrochloride could be suppressed with barbiturates or benzodiazepines, but were increased with Naloxone. Naxolone did not change the lethality of an overdose in mice.

Serious anaphylactoid reaction may require treatment with adrenaline, oxygen, intravenous steroids and airway management including intubation.

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### 5. FIRE FIGHTING MEASURES

**Fire/Explosion Hazard** Toxic gases (carbon monoxide and hydrochloric acid) may be emitted from fires involving this product, therefore self-contained breathing apparatus and full protective equipment are

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recommended for fire fighters. Prevent fire-fighting water from entering waterways as material may cause long term adverse effects in the aquatic environment.

- Fire Extinguishing Media**
- Dry chemical powder
  - Water spray or fog
  - Foam
  - Carbon dioxide

**Hazchem Code** None allocated

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## 6. ACCIDENTAL RELEASE MEASURES

- Minor Spills**
- Clean up spill immediately.
  - Wear protective gloves and safety glasses.
  - Place spilled material in clean, dry, sealed container for disposal.
  - Wash area with copious amounts of water.
- Major Spills**
- Clean up spill immediately.
  - Wear protective gloves and safety glasses.
  - Do not allow material to enter sewage system or surface/ground water.
  - Place spilled material in clean, dry, sealed container for disposal.
  - Wash area with copious amounts of water.
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## 7. HANDLING AND STORAGE

- Store below 30°C.
  - Protect from light.
  - Store as per Schedule 4 pharmaceutical or per state scheduling requirements.
  - Always wash hands with soap and water after handling.
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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Exposure Standards** No exposure limits set by SWA or ACGIH
- Engineering Controls** None under normal operating conditions.
- Personal Protection** The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.
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## 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance** Clear, slightly viscous liquid. Free from visible impurities. Colourless to weakly yellow (not exceeding Colour Reference Solution B9 of Ph.Eur.)
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<b>Odour</b>	Distinct peppermint and weak anise odour
<b>pH</b>	Not determined
<b>Boiling Point/Melting Point</b>	Not determined
<b>Vapour Pressure</b>	Not determined
<b>Vapour Density</b>	Not determined
<b>Specific Gravity</b>	Not determined
<b>Flashpoint</b>	Not determined
<b>Flammability Limits</b>	Not determined
<b>Solubility in Water</b>	Miscible

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## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not known to be incompatible with any other material.
<b>Stability</b>	Stable under anticipated storage and handling conditions (refer section 7).
<b>Decomposition Products</b>	Formation of carbon monoxide and hydrochloric acid is possible in the event of fire.

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## 11. TOXICOLOGICAL INFORMATION

<b>Eye</b>	May cause irritation following direct contact.
<b>Swallowed</b>	May be harmful if swallowed. Symptoms include nausea, vomiting, dizziness, drowsiness, sweating and headache. Machinery must not be operated if dizziness or drowsiness occurs.  Serious potential consequences of overdose are respiratory depression and seizure. Serious and rarely fatal anaphylactoid reactions have been reported in patients receiving tramadol hydrochloride.
<b>Skin</b>	Not irritating to the skin.
<b>Inhaled</b>	Not an expected route of exposure.
<b>Chronic Health Effects</b>	No chronic health effects known.
<b>Toxicity Data</b>	
<i>Acute toxicity</i>	LD50 oral: 228mg/kg (Species: rat) (Tramadol Hydrochloride) LC50: >500mg/kg (Species: rabbit) (Tramadol Hydrochloride)

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*Sub-acute to chronic toxicity*  
Teratogenicity rat: Normal  
Teratogenicity rabbit: Normal  
*Genotoxicity*  
Ames test: Negative  
Chromosome aberration test: Negative

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## 12. ECOLOGICAL INFORMATION

### Elimination data

(persistence and degradability)

Analysis method

(closed bottle test OECD 31 D)

*Elimination degree* <5% BOR of COR after 28 days (Tramadol Hydrochloride)

*Classification* Not easily biodegradable (Tramadol Hydrochloride)

*Evaluation* Difficult to eliminate from water (Tramadol Hydrochloride)

### Aquatic Toxicity OECD 203

*Acute Fish Toxicity* LC50: 6.2mg/L/96 hours (Species: golden orfe) (Tramadol Hydrochloride)  
LC100: 7.5mg/L/96 hours (Species: golden orfe) (Tramadol Hydrochloride)

*Acute Bacterial Toxicity* LC50: 8.1 g/L (Pseudomonas putida)

*Evaluation* Toxic to aquatic organisms "N" R51/53 (Tramadol Hydrochloride)

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## 13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.
  - Disposal of this material should only be undertaken by a licensed chemical disposal company.
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## 14. TRANSPORT INFORMATION

**Not Classified as a dangerous good by the criteria of the ADG Code**

**UN Number** None allocated

**DG Class** None allocated

**Subsidiary Risk** None allocated

**Packing Group** None allocated

**Hazchem Code** None allocated

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## 15. REGULATORY INFORMATION

**Poisons Schedule Number** Schedule 4 (S4) – Prescription only medicine

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**16. OTHER INFORMATION****Last Revised** 15 November 2016**Reason for Revision**

- Updated year of SDS Code of Practice reference
- Regulatory review

**Abbreviations**

SWA	- Safe Work Australia
GHS	- Globally Harmonised System
WHS	- Work, Health and Safety
ADG Code	- Australian Dangerous Goods Code
UN Number	- United Nations Number
DG Class	- Dangerous Goods Class
CAS Number	- Chemical Abstract Service Number

**Contact Point**

Company Contact:	+61 3 9389 1984 (24hr)
Australian Poisons Information Centre, 24 hour service:	13 11 26
Australian Police, Fire Brigade or Ambulance:	000

New Zealand Poisons Information Centre, 24 hour service:	0800 764 766
New Zealand Police, Fire Brigade or Ambulance:	111

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