Tramal®
(50mg Capsules)

SAFETY DATA SHEET

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.**

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name	Tramal® 50mg Capsules
Other Names	Not Applicable
Manufacturer's Product Code	50mg x 10 - 80680001; 50mg x 20 - 80680006; 50mg x 30 - 80680002; 50mg x 50 – 80680019
Use	Analgesic
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)

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name:	*CAS Number:*	*Proportion:*
Tramadol Hydrochloride	36282-47-0	36%
Microcrystalline cellulose	9004-34-6	20%
Non-Hazardous Ingredients	-	Up to 100%

Capsule shells contain gelatine, titanium dioxide and food grade dyes.

4. FIRST AID MEASURES

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

Swallowed Seek medical attention. After accidental ingestion of tramadol hydrochloride empty the stomach by vomiting (conscious patient) or gastric lavage.

Skin Wash area immediately with water.

Inhaled If dust is present remove person from exposure. Administer medical oxygen if available by trained personnel. Apply artificial respiration if not breathing and seek medical attention.

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 capsules 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 overdosage 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.

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 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

6. ACCIDENTAL RELEASE MEASURES

Minor Spills

- Clean up spill immediately.
- Wear protective gloves and safety glasses.
- Take care to avoid inhaling dust during clean up.
- Wear dust mask (filter P3) if dusts are generated.
- 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.
- Take care to avoid creating excessive dust during clean up.
- Wear dust mask (filter P3) if dusts are generated.
- 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.

7. HANDLING AND STORAGE

- Store capsules below 30°C in dry conditions.
- Store as per Schedule 4 pharmaceutical.
- Avoid puncturing or crushing capsules.
- Always wash hands with soap and water after handling.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by SWA or ACGIH

Engineering Controls None under normal operating conditions.

Personal Protection

No special equipment needed when handling unbroken capsules. Otherwise, for potentially moderate exposure or if the powder has spilled from damaged capsules:

- Protective gloves
- Safety Glasses
- Dust mask (P3 filter grade)

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White to pale yellow, odourless powder contained within a green and yellow bicolour gelatine capsule.
Odour	Odourless
pH	Not determined
Boiling Point/Melting Point	Not determined
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	Not determined
Flashpoint	Not determined
Flammability Limits	Not determined
Solubility in Water	Not determined

10. STABILITY AND REACTIVTY

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

11. TOXICOLOGICAL INFORMATION

Eye	May cause irritation following direct contact with powder.
Swallowed	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 overdosage are respiratory depression and seizure. Serious and rarely fatal anaphylactoid reactions have been reported in patients receiving tramadol hydrochloride.

Skin Not irritating to the skin.

Inhaled Not an expected route of exposure unless dust is present. May be harmful if dust is inhaled.

Chronic Health Effects No chronic health effects known.

Toxicity Data

Acute toxicity LD50 oral: 228mg/kg (Species: rat) (Tramadol Hydrochloride)
LC50: >500mg/kg (Species: rabbit) (Tramadol Hydrochloride)

Sub-acute to chronic toxicity
Teratogenicity rat: Normal
Teratogenicity rabbit: Normal

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)

Evaluation Toxic to aquatic organisms “N” R51/53 (Tramadol Hydrochloride)

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.

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

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Last Revised 15 November 2016

Reason for Revision
- Period review
- Update to SWA Code of Practice version

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