



IMPORTANT NOTICE This Material Safety Data Sheet (MSDS) is prepared by CSL Limited in accordance with the Australian National Occupational Health & Safety Commission National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(2003)]. The information contained herein must not be altered or deleted. Additional information may be appended to the MSDS, 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 Vesicare®

Other Names Flomin (5mg,10mg), Solifenacina (10mg), Solfenacina Yamanouchi (5mg), Uriclin (5mg, 10mg), Vesicare (5mg, 10mg), Vesikur (5mg, 10mg), Vesitirim (5mg, 10mg).

Manufacturer's Product Code 80692005 - Vesicare 5mg 30 PACK Tabs, 80692006 - Vesicare 10mg 30 PACK Tabs, 80693005 - Vesicare 5mg 10 PACK Tabs SAMPLE

Use To treat the symptoms of overactive bladder.

Supplier's Name CSL Limited (ABN 99 051 588 348)

Address 45 Poplar Road, Parkville, Victoria 3052, Australia

Telephone +61 03 9389 1911

Emergency Telephone +61 03 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

**Not classified as hazardous according to the criteria of Safe Work Australia
Not classified as a dangerous good by the criteria of the ADG Code**

3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical name:</i>	<i>CAS Number:</i>	<i>Proportion:</i>
Sollifenacin succinate	242478-38-2	Min 5mg, Max 10 mg
Excipients (non hazardous ingredients)	Unassigned	

4. FIRST AID MEASURES

Eye Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek immediate medical attention.

Ingestion DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. If hypersensitivity occurs, seek medical attention.

Skin Wash affected thoroughly with water. Seek medical attention if skin reaction occurs.

Inhaled Physical form suggests that risk of inhalation exposure is negligible.

First Aid Facilities Ensure water is available at point of use.

Advice to Doctor Solifenacin is a potent, selective muscarinic M3 antagonist. Treat according to standard protocols for antimuscarinics. Show this Material Safety Data Sheet.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard Not expected for the product, although the packaging is combustible.

Fire Extinguishing Media Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding materials.

Hazchem Code None allocated

6. ACCIDENTAL RELEASE MEASURES

Minor Spills Wear proper PPE. Prevent eye and skin contact with powder. Prevent dust formation and ensure ventilation. Contain all tablets in dry sealed materials and dispose according to relevant regulatory requirements.

Major Spills Wear proper PPE. Prevent eye and skin contact with powder.. Prevent dust formation and ensure ventilation. Contain all tablets in dry sealed materials and dispose according to relevant regulatory requirements.

7. HANDLING AND STORAGE

- Handle in accordance with good occupational hygiene and safety practices.
- Keep out of reach of children.
- Avoid breaking or crushing tablets.
- Store in a dry place at temperature below 25°C.
- Store as per Schedule 4 Pharmaceutical.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards Not established

Engineering Controls Well ventilated area

Personal Protection Safety glasses, gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance 5 mg tablets – light yellow tablets marked with the company logo and “150” on the same side.
10mg tablets – light pink tablets marked with the company logo and “151” on the same side.

Odour Not determined

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 REACTIVITY

Reactivity None for normal handling of this product

Stability Stable under normal conditions

Decomposition Products May produce CO, CO₂ and NO_x on combustion

11. TOXICOLOGICAL INFORMATION

Eye Causes severe irreversible eye damage, which is only slightly alleviated by washing immediately.

Ingestion Vomiting, mydriasis, salivation, reduction in spontaneous activity, tremor, ataxia, palpitations and changes in the ECG were observed in animal studies.

Skin No Skin irritant.

Inhalation No studies have been conducted.

Chronic Health Effects Solifenacin is a selective M3 antagonist that shows potent activity at low doses. In case of human exposure to amounts higher than present in the tablets, effects may occur that are directly related to the pharmacological action on the muscarinic receptor. The effects that were observed most frequently in patients were: constipation, nausea, dyspepsia, abdominal pain, blurred vision, somnolence and dry nose and skin.

12. ECOLOGICAL INFORMATION

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- No data available.
 - For good environmental practice avoid discharge to waterways.

13. DISPOSAL CONSIDERATIONS

In accordance with state land and waste management authority.

14. TRANSPORT INFORMATION

UN Number	None allocated
DG Class	None allocated
Subsidiary Group	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 Original MSDS

Abbreviations

SWA	Safe Work Australia
NOHSC	National Occupational Health and Safety Commission
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

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