



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 Prolia™

Other Names Denosumab, AMG 162

Manufacturer's Product Code 55530001(Prolia™ 60mg/1.0mg syringe X1)

Use Treatment of post-menopausal osteoporosis

Manufacturer Amgen Inc.

Address One Amgen Center Drive
Thousand Oaks, California, 91320-1799

Emergency Telephone 1-805-47-7233
1-805-447-1000

Supplier Name CSL Limited (ABN 99 051 588 348)

Address 45 Poplar Road, Parkville, Victoria 3052, Australia

Telephone +61 03 9389 1911

Emergency Telephone 03 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

Not classified as hazardous according to the criteria of SWA
Not classified as a dangerous good by the criteria of the ADG Code

3. COMPOSITION/INFORMATION ON INGREDIENTS

Each 1mL single-use vial of Prolia™ contains 60mg denosumab (60 mg/ml solution) and the following:

<i>Chemical Name:</i>	<i>CAS number:</i>	<i>Proportion:</i>
Sorbitol	50-70-4	4.7%
Sodium acetate	127-09-3	17 mM
Water for injection	7732-18-8	---

Each 1mL single-use prefilled syringe of Prolia™ contains 60mg denosumab (60 mg/ml solution) and the following:

<i>Chemical Name:</i>	<i>CAS number:</i>	<i>Proportion:</i>
Sorbitol	50-70-4	4.7%
Sodium acetate	127-09-3	17 mM
Polysorbate 20	9005-64-5	0.01%
Water for injection	7732-18-8	---

4. FIRST AID MEASURES

Accidental injection Rinse injection site with water. Seek medical attention. Treat symptomatically.

Eye Flush with water for at least 15 minutes. If symptoms persist seek medical attention.

Swallowed DO NOT INDUCE VOMITING. Wash out mouth with water and give water to drink. If symptoms persist seek medical attention.

Skin Remove contaminated clothing. Wash affected area with soap and water for at least 15 minutes. If symptoms persist seek medical attention.

Inhaled Remove to fresh air. Give oxygen if breathing is difficult and seek medical attention.

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

Advice to Doctor Treat symptomatically.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard This is an aqueous solution. Not considered a fire risk.

Fire Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazchem Code None allocated.

6. ACCIDENTAL RELEASE MEASURES

Minor Spills

- Wear protective gloves and safety glasses.
- Soak up spills with absorbent material i.e. paper towels or vermiculite.
- Place spilled material in clean, dry, sealed container for disposal.
- Clean the spill area thoroughly with appropriate cleaning materials.

Major Spills

- Wear protective gloves and safety glasses.
- Contain and absorb spills using earth, sand or inert absorbent.
- Prevent material entering open drains and waterways.
- Collect residues and seal in labelled drums for disposal.

7. HANDLING AND STORAGE

- Provide sufficient absorbent material for potential spillage due to damage to transport container.
- Handle in accordance with good hygiene and safety practice.
- Store this product protected from light.
- Transport and store at 2 to 8 degrees C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by NOHSC or ACGIH

Engineering Controls None under normal operating conditions.

Personal Protection Protective gloves and safety glasses should be worn when handling this product. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance A clear colourless to slightly yellow liquid

Odour Odourless

pH 5.2

Boiling Point/Melting Point As for water.

Vapour Pressure As for water (3.17kPa at 25° C)

Vapour Density Not determined

Specific Gravity Not determined

Flashpoint Not determined

Flammability Limits Not determined

Solubility in Water Aqueous solution

10. STABILITY AND REACTIVITY

Reactivity None.

Stability Stable under anticipated storage and handling conditions (refer section 7).

Decomposition Products None known.

11. TOXICOLOGICAL INFORMATION

Eye No information.

Swallowed No information.

Skin No information.

Inhaled No information.

Chronic Health Effects Adverse drug reactions associated with repeated dose of Prolia™ treatment include transient hypocalcaemia and potential increased risk of skin infections; potential higher incidence of eczema (includes dermatitis, allergic dermatitis, atopic dermatitis and contact dermatitis), which were observed in postmenopausal women with osteoporosis, and potential higher incidence of cataracts in males with prostate cancer receiving androgen deprivation therapy.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.
- Dispose via a licensed waste facility.

14. TRANSPORT INFORMATION

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 Not scheduled

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
New Zealand Poisons Information Centre, 24 hour service:	(03) 4747 000
New Zealand Police, Fire Brigade or Ambulance:	111

Whilst the information contained in this document is based on data which, to the best of our knowledge, was accurate and reliable at the time of preparation, no responsibility can be accepted by us for errors and omissions. Users are advised to make their own determination as to the suitability of this information in relation to their particular purposes and specific circumstances. Since the information contained in this document may be applied under conditions beyond our control, we can accept no responsibility for any loss or damage by any person acting or refraining from action as a result of this information.