



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 Cervidil

Other Names Dinoprostone, Prostaglandin E2, PGE2, 11 α -15S-dihydroxy-9-oxo-prosta-5Z,13E-dien-1-oic acid

Manufacturer's Product Code 0853 0001 (1 x 10mg)

Use Vaginal pessary

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 SWA
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>
Prostaglandin E2	363-24-6	98%

4. FIRST AID MEASURES

- Eye** Immediately flush eyes with water for at 2-3 minutes, occasionally lifting the upper and lower eyelids.
- Ingestion** Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water.
- Skin** Wash with soap and water for at least 2-3 minutes while removing contaminated clothing and shoes.
- Inhaled** Remove from exposure and move to fresh air immediately.

5. FIRE FIGHTING MEASURES

- Fire/Explosion Hazard** As in any fire, wear a self-contained breathing apparatus in pressure-demand, and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.
- Fire Extinguishing Media** In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam.
- Hazchem Code** -

6. ACCIDENTAL RELEASE MEASURES

- Minor Spills** Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up, then place into a suitable container for disposal.

7. HANDLING AND STORAGE

Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.

Store in a freezer below -18 °C. Keep container closed when not in use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Exposure Standards** -
- Engineering Controls** -
- Personal Protection** Eyes: Wear safety glasses or chemical goggles if exposure is possible.
Skin: Wear appropriate protective gloves and clothing to prevent skin exposure.
Clothing: Wear appropriate protective clothing to minimize contact with skin.
Respirators: None required

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance** Thin, flat, polymeric pessary (vaginal insert) rectangular in shape with rounded corners
- Odour** -
- pH** -

Melting Point	65-69 °C
Vapour Pressure	-
Vapour Density	-
Specific Gravity	-
Flashpoint	-
Flammability Limits	-
Solubility in Water	-

10. STABILITY AND REACTIVITY

Reactivity Strong oxidizing agents, acids, bases.

Stability Stable under normal temperatures and pressures.

Decomposition Products Carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

11. TOXICOLOGICAL INFORMATION

Skin Moderate Irritant

Eyes Moderate Irritant

Inhalation -

Ingestion -

Chronic Health Effects Long-term carcinogenicity and fertility studies have not been conducted with CERVIDIL. No evidence of mutagenicity has been observed with PGE₂ in the Micronucleus Test, or Ames Test. PGE₂ did induce chromosomal aberrations in Chinese hamster lung fibroblasts in culture but only at an unphysiologically high concentration.
Exposure to PGE₂ at the dosage and administration recommended for induction of labour is not considered to be of toxicological concern.

Long term clinical use of chemically related polymers such as those used in the hydrogel and retrieval system has not identified any concerns regarding genotoxicity.

12. ECOLOGICAL INFORMATION

No data available

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with prevailing country, federal, state and local regulations

14. TRANSPORT INFORMATION

UN Number Not applicable

Proper Shipping Name Not applicable

Transport Hazard Class Not applicable

Packing Group Not applicable

Hazchem Code Not applicable

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Last Revised 18 December 2012

Reason for Revision Original SDS

Abbreviations

SWA Safe Work Australia

ADG Code Australian Dangerous Goods Code

UN Number United Nations Number

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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