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# CONTROLLED THERAPEUTICS (SCOTLAND) LTD

Standard Operating Procedure

SOP/SFT/013

Material Safety Data Sheet

Dinoprostone Hydrogel Polymer Slices - (Cervidil/Propess)

Effective Date 10 December 2001

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Supersedes \_\_\_\_\_

Revision No. 00

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Prepared by *JH* Date 10 Dec 2001  
 Departmental Approval *JH* Date 10 Dec 2001  
 Quality Approval *S...* Date 10 Dec 2001

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#### 1. Product and Company Identification

Product Code: Cervidil/Propess

Product Name: Dinoprostone Hydrogel Polymer Slices (0.8mm/1.1mm)

Manufacturer/Supplier: Controlled Therapeutics (Scotland) Ltd

Address: 1 Redwood Place  
Peel Park Campus  
East Kilbride  
Glasgow  
G74 5PB

Telephone Number: +44 (0)1355 239166

Fax Number: +44 (0)1355 263661

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#### 2. Composition

Trivial Name: Dinoprostone Pessary Slice

Formal Name: Cervidil/Propess

Chemical Family: Active: Prostaglandins  
Carrier: Polyurethane Polymer

CAS Number: None

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#### 3a. Hazard Identification- Hydrogel Polymer Slice (carrier)

Health effects: Eyes - Dust may cause transient irritation  
Skin - None  
Ingestion - May cause digestive problems  
Inhalation - None

#### 3b. Hazard Identification - Prostaglandin E<sub>2</sub> (active)

Health effects: Eyes - May cause eye irritation  
Skin - May cause skin irritation  
Ingestion - Gastrointestinal disturbances  
Inhalation - NA

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#### 4. First Aid Measures

Eyes: Irrigation with copious amounts of water, obtain medical attention if symptoms persist.

Skin: Wash skin with water.

Ingestion: Seek medical advice.

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#### 5. Fire Fighting Measures

Flash Point: NA  
Lower Explosion Limit (LEL): NA  
Upper Explosion Limit (UEL): NA  
Extinguishing media: Water, carbon dioxide or dry chemical.  
Special Hazards: This product may give rise to hazardous fumes in a fire.

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#### 6. Accidental Release Measures

Spillages: Sweep up into suitable containers for disposal as special waste.

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#### 7. Handling and Storage

Handling: Gloves should be worn when handling this product.  
Storage: Store in sealed air and water tight container at -10°C to -20°C.

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#### 8. Exposure Controls/Personal Protection

UK Occupational Exposure Standards: None assigned  
Respiratory Protection: Not required  
Body Protection: Gloves required

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#### 9. Physical and Chemical Properties

Physical State: Thin polymeric slabs  
Colour: Yellow/Off White.  
Odour: None  
Boiling Point: NA  
Melting Temp: Softens above 23°C  
Solubility in Water: Swells in water, does not dissolve.  
pH: NA  
Flash Point: NA

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## 10. Stability and Reactivity

Stability: Stable under normal conditions. Oxidises slowly in air and active degrades at temperatures greater than 0°C.

Conditions to Avoid: High temperatures >200°C.

Materials to Avoid: None known.

Hazardous Decomposition: In the presence of temperatures above 200°C toxic fumes may be generated.

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## 11a. Toxicological Information - (PGE<sub>2</sub> - Active)

Active Studies: Intravenous LD50 (Rat): 59,500µg/kg  
Intravenous LD50 (Mouse): 23,200µg/kg  
Oral LD50 (Rat): 500mg/kg  
Oral LD50 (Mouse): 750mg/kg  
Intra peritoneal LD50 (Hamster): 1mg/kg  
Subcutaneous LD50 (Rat): 31,600µg/kg  
Subcutaneous LD50 (Mouse): 19,700µg/kg

## 11b. Toxicological Information - (Hydrogel Polymer - carrier)

### Chronic Studies:

Non Toxic: 100mg/kg/day in rats for 25 days  
1.4g/kg/day in dogs for 18 days

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## 12. Ecological Information

Mobility: This material is non-volatile and insoluble.

Resistance/Degradability: The product degrades slowly.

Bio-accumulation: Not expected to accumulate.

Ecotoxicity: The product is expected to be non-hazardous to aquatic species.

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## 13. Disposal Consideration

Dispose of waste in a certified landfill, in accordance with local regulations and available facilities.

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## 14. Transport Information

UK: Not classified.

UN: Not classified.

ADR/RID: Not classified.

IMDG: Not classified.

IATA: Not classified.

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15. Regulatory Information

Not classified.

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16. Other Information

None.

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The above information corresponds to our present state of knowledge and expertise. The safety data sheet serves as a description of the product in terms of safety requirements. The MSDS sheet does not guarantee specifications or properties.