

## HEALTH AND SAFETY DATA SHEET

<b>1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY</b>		
<b>COMPANY ADDRESS:</b>  Dechra Pharmaceuticals PLC 24 Cheshire Avenue Cheshire Business Park Lostock Gralam Northwich CW9 7UA UK  Tel: +44 (0) 1606 814730 Fax: +44 (0) 1606 814731  US Technical Support: (866) 933-2472	<b>PRODUCT NAME:</b>  <b>ZYCORTAL® SUSPENSION            (desoxycorticosterone            pivalate injectable            suspension)</b>  NADA 141-444	<b>ISSUE DATE:</b> 25 November 2015  <b>PHYSICAL FORM:</b> Suspension for injection  <b>PRODUCT TYPE:</b> Rx; Mineralocorticoid Hormone  <b>CONTAINER:</b> Type I glass vial (containing 4ml) with a coated chlorobutyl rubber stopper and aluminium seal with a plastic flip-off cap.
<b>2. HAZARDS IDENTIFICATION:</b>		
<p>May cause eye and skin irritation.            Product may cause pain and swelling at the injection site if accidentally self-administered. This product may cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates. Pregnant and breast-feeding women should avoid administration of the product.</p>		
<b>3. COMPOSITION/INFORMATION ON ACTIVE INGREDIENTS</b>		
<u>NAME</u>	<u>mg/ml</u>	<u>HAZARD</u>
Desoxycorticosterone pivalate	25	May cause eye and skin irritation. May cause adverse effects on male reproductive organs and, as a result, fertility. May cause adverse developmental effects on unborn children and neonates. Pregnant and breast-feeding women should avoid administration of the product.

#### 4. FIRST-AID MEASURES

EYE CONTACT:	In case of accidental spillage onto eyes, wash the affected area with water. If irritation occurs, seek medical advice immediately and show the package leaflet or the label to the physician.
DERMAL CONTACT:	In case of accidental spillage onto skin, wash the affected area with water. If irritation occurs, seek medical advice immediately and show the package leaflet or the label to the physician.
INGESTION:	Remove material and flush mouth with water. Seek medical attention: treatment is symptomatic and includes replacement of fluid and electrolytes.
INHALATION:	Not applicable.
ACCIDENTAL INJECTION:	In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
EQUIPMENT AT WORKPLACE:	Eye and skin washing facilities.

#### 5. FIRE-FIGHTING MEASURES (BULK ACTIVE)

FLAMMABILITY: Not flammable.

SUITABLE EXTINGUISHERS:  
Water spray, carbon dioxide, dry chemical and foam, as appropriate for surrounding fire and materials.

EXTINGUISHERS NOT TO BE USED:  
None.

SPECIAL PROTECTIVE EQUIPMENT:  
Evacuate area. Wear self-contained breathing apparatus and protective clothing.

EXPLOSIVE HAZARDS:  
None known.

HAZARDOUS COMBUSTION PRODUCTS:  
None

## 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PROTECTION:	Wear adequate eye protection and gloves.
SPILLAGE CLEAN-UP:	Cover with an absorbent material, sweep up and place in an approved chemical waste container. Wash the area with water containing a strong detergent, absorb with an absorbent material, sweep up and place in chemical container. Flush the area with water to remove any residue. Avoid contamination of sewers and waterways.

## 7. HANDLING AND STORAGE

HANDLING:	Handle with normal precautions as with any drug product.
STORAGE:	Do not store above 30°C. Do not freeze. Keep out of the reach and sight of children.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION:

Not required under normal conditions of therapeutic administration and uses.

## 9. PHYSICAL AND CHEMICAL PROPERTIES OF PRODUCT

APPEARANCE (Zycortal Suspension): Opaque white suspension	MELTING POINT °C: Not applicable
SOLUBILITY IN WATER (DOCP): Not available	BOILING POINT °C: Not available
MOLECULAR FORMULA (DOCP): $C_{26}H_{36}O_4$	MOLECULAR MASS (DOCP): 414.58

## 10. STABILITY AND REACTIVITY:

Stable under normal conditions and pressures.

<b>11. TOXICOLOGICAL INFORMATION</b>	
EYE CONTACT:	May cause irritation.
DERMAL CONTACT:	May cause irritation.
INGESTION:	Not known to cause any significant effects if ingested.
INHALATION:	Not applicable.
ACCIDENTAL INJECTION:	Product may cause pain and swelling at the injection site if accidentally self-administered. This product may cause adverse effects on male reproductive organs and, as a result, fertility. This product may cause adverse developmental effects on unborn children and neonates. Pregnant and breast-feeding women should avoid administration of the product.
<b>12. ECOLOGICAL INFORMATION:</b>	Not expected to reach the environment in significant amounts under normal circumstances.
<b>13. DISPOSAL CONSIDERATIONS:</b>	Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
<b>14. TRANSPORT INFORMATION:</b>	Not regulated for domestic transport.
<b>15. REGULATORY INFORMATION:</b>	
<b>16. OTHER INFORMATION</b>	
Prepared by Dechra Pharmaceuticals PLC on the basis of the best available data. No representation is given that the information provided is complete in all respects.	