

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078926799

N/A



SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Zycortal® (Suspension for Injection)
<b>Synonyms:</b>	Desoxycortone Pivalate
<b>Proper Shipping name:</b>	Not applicable
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	For use as replacement therapy for the mineralocorticoid deficit in dogs with primary hypoadrenocorticism (Addison's disease).
<b>Uses advised against:</b>	Not for human use. Do not use in case of hypersensitivity to the active substance or to any of the excipients. Pregnant and breastfeeding women should avoid administration of the product.
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name (UK):</b>	Dechra Ltd
<b>Address:</b>	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
<b>Telephone:</b>	+44 (0) 1756 791311
<b>Fax:</b>	+44 (0) 1756 798604
<b>Website:</b>	www.dechra.com
<b>Email:</b>	Not available
<b>Registered company name (US):</b>	Dechra Veterinary Products
<b>Address:</b>	Dechra Pharmaceutical Products 7015 College Blvd Suite 525 Overland Park KS 66211 USA
<b>Telephone:</b>	866-933-2472



<b>Fax:</b>	Not available
<b>Website:</b>	www.dechra.com
<b>Email:</b>	Not available
<b>1.4 Emergency Telephone Numbers</b>	
<b>Dechra (US):</b>	866-933-2472

**SECTION 2: HAZARDS IDENTIFICATION**

**2.1 Classification of the substance or mixture**  
 Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).  
 Considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes (US).

<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	H361: Reproductive Toxicity Category 2
<b>Classification (US):</b>	Reproductive Toxicity Category 2

**2.2 Label Elements**

<b>GHS Label Elements:</b>	
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**Signal Word:** WARNING

**Hazard statement(s):**  
 None

**Supplementary Statement(s) EU:**

<b>EUH208</b>	Contains 4-chloro-m-cresol. May produce an allergic reaction.
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**Precautionary Statement(s) Prevention:**

<b>P201</b>	Obtain special instructions before use.
<b>P264</b>	Wash all exposed external body areas thoroughly after handling.
<b>P281</b>	Use personal protective equipment as required.

**Precautionary Statement(s) Response:**

<b>P308 + P313</b>	IF exposed or concerned: Get medical advice/attention.
<b>P305 + P351 + P338</b>	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.



<b>Precautionary Statement(s) Storage:</b>	
<b>P405</b>	Store locked up.
<b>Precautionary Statement(s) Disposal:</b>	
<b>P501</b>	Dispose of contents/container in accordance with local regulations.
<b>2.3 Other Hazard Information</b> REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	

### SECTION 3: INFORMATION ON THE INGREDIENTS

#### 3.1 Substances

See section below for composition of mixtures

#### 3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 808-48-0 2. 212-366-0 3. Not Available 4. Not Available	2.5	Desoxycortone Pivalate	Acute Toxicity (Oral) Category 4, Acute Toxicity (Dermal) Category 4, Acute Toxicity (Inhalation) Category 4, Carcinogenicity Category 2, Reproductive Toxicity Category 2; H302, H312, H332, H351, H361 <sup>1</sup>
1. 59-50-7 2. 200-431-6 3. 604-014-00-3 4. 01-2119938953-25-XXXX	<0.1	4-chloro-m-cresol	Acute Toxicity (Dermal) Category 4, Acute Toxicity (Oral) Category 4, Serious Eye Damage Category 1, Skin Sensitizer Category 1, Acute Aquatic Hazard Category 1; H312, H302, H318, H317, H400 <sup>2</sup>
	Balance	Ingredients determined not to be hazardous	
<b>Legend:</b>	1. Classified by Chemwatch; 2 Classification drawn from EC Directive 1272/2008 – Annex VI		

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

<b>Eye contact:</b>	Accidental spillage on the eyes should be washed off with plenty
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	of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Skin contact:</b>	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
<b>Ingestion:</b>	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
<b>Self-injection:</b>	Care should be taken when handling the product to avoid self-injection, especially by pregnant women. Read the package leaflet before use for full instructions and user warnings.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
<b>Eye contact:</b>	The material may be irritating to the eye, with prolonged contact causing inflammation.
<b>Skin contact:</b>	Hypersensitivity to the active substance or excipients may occur after prolonged or repeated exposure. Entry into the blood-stream, through cuts, abrasions or lesions, may produce systemic injury with harmful effects.
<b>Ingestion:</b>	Overdose of Desoxycortone Pivalate may produce excessive sodium and water retention leading to hypertension, edema, pulmonary congestion and signs and symptoms of congestive heart-failure. Other symptoms of overdose include polyuria, polydipsia, increased blood volume and cardiac enlargement.
<b>Self-injection:</b>	Product may cause pain and swelling at the injection site if accidentally self-administered.
See Section 11 for more detailed information	
<b>4.3 Indication of immediate medical attention and special treatment needed</b>	
Treat symptomatically. 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. The adverse effects of corticosteroids are almost always due to their use in excess of physiological requirements. Symptomatic treatment is called for. Where possible the dose should be withdrawn or reduced. Acute renal insufficiency should be treated with intravenous hydrocortisone sodium succinate with infusions of 0.9% dextrose. <sup>1</sup>	



<b>Legend:</b>	<i>MARTINDALE, The Extra Pharmacopoeia, 29th Ed.</i>
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<b>SECTION 5: FIRE FIGHTING MEASURES</b>	
<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Select extinguishing media suitable for surrounding area
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	None known
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	Use water delivered as a fine spray to control fire and cool adjacent area. <b>Do not</b> approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
<b>Fire / explosion hazard:</b>	Non-combustible. Not considered a significant fire risk, however containers may burn.

<b>SECTION 6: ACCIDENTAL RELEASE MEASURES</b>	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
For information on protective equipment, see section 8	
<b>6.2 Environmental Precautions</b>	
See section 12	
<b>6.3 Methods and material for containment and cleaning up</b>	
Spills are unlikely due to the nature of the product and how it is packaged	
<b>Minor Spills:</b>	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
<b>Major Spills:</b>	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite.



	Prevent, by any means available, spillage from entering drains or water course.
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## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

<b>Safe Handling:</b>	Wear suitable protection gloves and clothing when handling the product. When handling, <b>DO NOT</b> eat, drink or smoke. Always wash hands with water after handling. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Store at a temperature of 25°C. Excursions permitted between 15°C and 30°C. Do not store above 30°C. Protect from light. Do not freeze. Keep out of the reach and sight of children.

### 7.2 Conditions for safe storage, including any incompatibilities

<b>Suitable Container:</b>	Check that containers are clearly labelled. Shelf life after first opening the immediate packaging: 120 days. Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
<b>Storage incompatibility:</b>	No known incompatibilities.

### 7.3 Specific end uses

Not available

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters


#### DERIVED NO EFFECT LEVEL – DNEL (EU)

Not Available

#### PREDICTED NO EFFECT LEVEL – PNEC (EU)

Not Available

#### OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA				
Not Available				
EMERGENCY LIMITS (EU/US):				
Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
4-chloro-m-cresol	Chloro-m-cresol, 4-	5.5 mg/m <sup>3</sup>	60 mg/m <sup>3</sup>	360 mg/m <sup>3</sup>
Ingredient		Original IDLH		Revised IDLH
Desoxycortone Pivalate		Not Available		Not Available
4-chloro-m-cresol		250ppm		250 [Unch] ppm
Water		Not Available		Not Available
8.2 Exposure controls				
<b>Appropriate engineering controls:</b>		The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.		
<b>Personal protection:</b>				
<b>Eye and face protection:</b>		Safety glasses with side shields / chemical goggles		
<b>Skin protection:</b>		See hand protection below		
<b>Hands/ feet protection:</b>		No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves		
<b>Body protection:</b>		Wear appropriate clothing		
<b>Other protection:</b>		No special equipment needed when handling small quantities		
<b>Thermal hazards:</b>		Not applicable		
<b>Respiratory protection:</b>		Not applicable		
8.3 Environmental exposure controls				
See Section 12				





**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

**Appearance:** Zycortal: Opaque white suspension  
 Desoxycortone Pivalate: White crystalline powder  
**Container:** Cardboard box containing one Type I clear glass vial (containing 4 ml) with a coated chlorobutyl rubber stopper and aluminium seal with a plastic flip off cap.  
**Physical state:** Liquid  
**Odour:** Not available  
**Odour Threshold:** Not available  
**pH (as supplied):** Desoxycortone Pivalate: 5.0 - 7.0  
**Melting point / freezing point (degrees C):** Desoxycortone Pivalate: 200-206°C  
**Initial boiling point and boiling range:** Not available  
**Flash Point:** In water – no flash point  
**Evaporation rate:** Not available  
**Flammability:** Not available  
**Upper/lower flammability or explosive limits:** Not available  
**Vapour pressure:** Not available  
**Relative Density (at degrees C):** Not available  
**Solubility in water and solvents (mg/l):** Water: not soluble  
 Methanol: sparingly soluble  
**Vapour density:** Not available  
**Auto ignition temperature (degrees C):** Not available  
**Decomposition temperature (degrees C):** Not available  
**Viscosity: (degrees C):** Not available  
**Explosive properties:** Not available  
**Oxidising properties:** Not available  
**Partition Coefficient:** Not available  
**Molecular weight:** Desoxycortone Pivalate: 414.58  
**Taste:** Not available  
**Surface tension:** Not available  
**Volative component:** Not available  
**Gas group:** Not available  
**pH as a solution:** Not available  
**VOC g/L:** Not available

**9.2 Other information**  
 Not Available

**SECTION 10: STABILITY AND REACTIVITY**

<b>10.1 Reactivity:</b>	See Section 7.
<b>10.2 Chemical stability:</b>	Product is considered stable. Hazardous polymerisation will not occur.
<b>10.3 Possibility of hazardous reactions:</b>	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
<b>10.4 Conditions to avoid:</b>	Protect from light.



<b>10.5 Incompatible materials:</b>	See section 7.
<b>10.6 Hazardous decomposition:</b>	See Section 5.

<b>SECTION 11: TOXICOLOGICAL INFORMATION</b>	
<b>Inhalation:</b>	Not normally a hazard due to non-volatile nature of product.
<b>Ingestion:</b>	Overdose of Desoxycortone Pivalate may produce excessive sodium and water retention leading to hypertension, edema, pulmonary congestion and signs and symptoms of congestive heart-failure. Other symptoms of overdose include polyuria, polydipsia, increased blood volume and cardiac enlargement.
<b>Skin contact:</b>	<p>The material may cause skin irritation after prolonged or repeated exposure. Hypersensitivity to the active substance or excipients may occur.</p> <p>Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material.</p> <p>Entry into the blood-stream, through cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
<b>Eye contact:</b>	The material may be irritating to the eye, with prolonged contact causing inflammation./ Repeated or prolonged exposure to irritants may produce conjunctivitis.
<b>Chronic:</b>	<p>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.</p> <p>There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.</p> <p>Chronic exposure to glucocorticoids can lead to changes in hormone production, a change in fat distribution (central obesity with wasting of limbs), susceptibility to infections, osteoporosis, cataracts, glaucoma, mental disturbance, high blood sugar and sugar in the urine. There may be muscular weakness and fatigue, acne, period disturbances in women and peptic ulcers.</p> <p>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.</p>



SECTION 11: TOXICOLOGICAL INFORMATION		
<b>Self-injection:</b>	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>Zycortal:</b>	<b>Toxicity</b>	<b>Irritation</b>
	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.	User safety studies conducted with the final formulation of Zycortal in acute dermal and eye irritation studies in the rabbit showed that Zycortal was a minimal irritant to the rabbit eye and a mild irritant to rabbit skin. Zycortal is considered to be a non-sensitiser in a local lymph node assay in the mouse.



<b>Desoxycortone Pivalate:</b>	<b>Toxicity</b>	<b>Irritation</b>
	<p>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.</p> <p>CEL TWA: 0.02 mg/m<sup>3</sup>          (CEL=Chemwatch Exposure Limit)          (compare Merck, Sharp and Dohme recommendation for dexamethasone).</p> <p>All corticosteroids have numerous and varied pharmacological actions. In humans, single dose or short term (several days) use is virtually without harmful effects. However, prolonged therapeutic use of corticosteroids may result in suppression of pituitary function. The daily threshold dose for this effect is approximately 0.5 mg for a 50 kg individual. Therefore typical exposure limits of about 0.02 mg/m<sup>3</sup> have been calculated from the threshold dose. This is thought to provide about a two-fold safety factor.</p>	May cause irritation to eye and skin
<b>4-chloro-m-cresol:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (rat) LD <sub>50</sub> : 1830 mg/kg <sup>1</sup>	Not Available
<p><i>1. * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</i></p>		
<b>Skin corrosion/irritation:</b>		
May cause irritation		



<b>Serious eye damage/irritation:</b>
May cause irritation
<b>Respiratory or skin sensitization:</b>
Not expected to be a respiratory sensitization. Not a skin sensitizer.
<b>Germ cell mutagenicity:</b>
Not mutagenic in Ames, in vitro or in vivo tests
<b>Carcinogenicity:</b>
Not expected to be carcinogenic.
<b>Reproductive toxicity:</b>
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.
<b>STOT – single exposure:</b>
Not available
<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity**

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Desoxycortone Pivalate	LC <sub>50</sub>	96	Fish	0.404mg/L	1
Desoxycortone Pivalate	EC <sub>50</sub>	96	Algae or other aquatic plants	0.127mg/L	1
Desoxycortone Pivalate	EC <sub>50</sub>	96	Algae or other aquatic plants	0.354mg/L	1
4-chloro-m-cresol	LC <sub>50</sub>	96	Fish	0.917mg/L	4
4-chloro-m-cresol	EC <sub>50</sub>	48	Crustacea	1.5mg/L	4
4-chloro-m-cresol	EC <sub>50</sub>	72	Algae or other aquatic plants	4.2mg/L	2



4-chloro-m-cresol	EC <sub>50</sub>	48	Crustacea	1.5mg/L	3
4-chloro-m-cresol	NOEC	96	Fish	0.366mg/L	2
<b>Legend:</b>			1. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 2. US EPA, Ecotox database - Aquatic Toxicity Data 2. IUCLID Toxicity data 3. Europe ECHA Registered Substances – Ecotoxicological Information – Aquatic Toxicity 4. US EPA, Ecotox database – Aquatic Toxicity Data		

**DO NOT** discharge into sewer or waterways.

### 12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Desoxycortone Pivalate	HIGH	HIGH
4-chloro-m-cresol	LOW (Half-life = 49 days)	LOW (Half-life = 0.67 days)

### 12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
Desoxycortone Pivalate	HIGH (LogKOW = 5.0693)
4-chloro-m-cresol	LOW (BCF = 13)

### 12.4 Mobility in Soil

Ingredient	Mobility
Desoxycortone Pivalate	LOW (KOC = 17560)
4-chloro-m-cresol	LOW (KOC = 717.6)

### 12.5 Results of PBT and vPvB assessment

Not Available

### 12.6 Other adverse effects

Not Available

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

<b>Product / packaging disposal:</b>	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.  Legislation addressing waste disposal requirements may differ by
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	<p>country, state and/or territory. Each user must refer to laws operating in their area.</p> <p>Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal.          Bury residue in an authorised landfill.          Recycle containers if possible, or dispose of in an authorised landfill.</p> <p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

SECTION 14: TRANSPORT INFORMATION		
<b>Labels required:</b>		
<b>Marine pollutant:</b>	NO	
<b>Hazchem:</b>	Not Applicable	
<b>Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	Class	N/a
	Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	



<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Limited quantity	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	





<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	IMDG Class	N/a
	IMDG Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	N/a	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazard</b>	N/a	
<b>14.6 Special precautions for user</b>	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
<b>14.7 Transport in bulk according to Annex II of</b>	N/a	



<b>MARPOL73/78 and the IBC Code</b>	
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**SECTION 15: REGULATORY INFORMATION**

**15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture**

**DESOXYCORTONE PIVALATE (808-48-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS:**

- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
- EU REACH Regulation (EC) No 1907/2006 - Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles
- European Customs Inventory of Chemical Substances ECICS (English)

**4-CHLORO-M-CRESOL (59-50-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS:**

- EU REACH Regulation (EC) No 1907/2006 - Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles
- European Customs Inventory of Chemical Substances ECICS (English)
- European Trade Union Confederation (ETUC) Priority List for REACH Authorisation
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
- European Union (EU) Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances - updated by ATP: 31

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments.

**FEDERAL REGULATIONS:**

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Section 311/312 Hazard Categories**

Immediate (acute) health hazard	NO
Delayed (chronic) health hazard	YES
Fire hazard	NO
Pressure hazard	NO
Reactivity hazard	NO

**US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4)**  
 None reported



<b>STATE REGULATIONS:</b>
<b>US. CALIFORNIA PROPOSITION 65</b> None reported
<b>15.2 Chemical Safety Assessment</b>

<b>ECHA SUMMARY</b>
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Ingredient	CAS number	Index Number	ECHA Dossier
Desoxycortone Pivalate	808-48-0	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4	GHS07, Wng	H302, H312, H332
2	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Repr.2	Wng, GHS08	H302, H312, H332, H315, H319, H335, H361
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS Number	Index Number	ECHA Dossier
4-chloro-m-cresol	59-50-7	604-014-00-3	01-2119938953-25-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Index Number	ECHA Dossier
1	Acute Tox. 4, Skin Corr. 1C, Skin Sens. 1, Eye Dam. 1, Aquatic Acute 1	GHS07, GHS09, GHS05, Dgr	H314, H317, H318, H302+H312
2	Acute Tox. 4, Skin Sens. 1, Eye Dam. 1, Aquatic Acute 1, Skin Corr. 1C	GHS09, GHS05, Dgr, GHS03	H302, H312, H317, H318, H314
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS Number	Index Number	ECHA Dossier
Water	7732-18-5	Not Available	Not Available



Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	GHS06, GHS05, Dgr, GHS02, Wng	H301, H226, H314
2	Acute Tox. 3, Skin Corr. 1A, Acute Tox. 2, Flam. Liq. 3	GHS06, GHS05, Dgr, GHS02, Wng	H301, H226, H314
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

National Inventory	Status
Australia - AICS	N (desoxycortone pivalate)
Canada - DSL	N (desoxycortone pivalate)
Canada - NDSL	N (desoxycortone pivalate; 4-chloro-m-cresol; water)
China - IECSC	N (desoxycortone pivalate)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (desoxycortone pivalate, water)
Korea - KECI	N (desoxycortone pivalate)
New Zealand - NZIoC	N (desoxycortone pivalate)
Philippines - PICCS	N (desoxycortone pivalate)
USA - TSCA	N (desoxycortone pivalate)
<b>Legend:</b>	<i>Y = All ingredients are on the inventory        N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>

**SECTION 16: OTHER INFORMATION**

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

**Full text Risk and Hazard codes:**

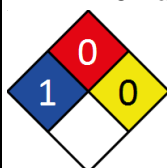
<b>H226</b>	Flammable liquid and vapour
<b>H301</b>	Toxic if swallowed
<b>H302 + H312</b>	Harmful if swallowed or in contact with skin
<b>H314</b>	Causes severe skin burns and eye damage
<b>H315</b>	Causes skin irritation
<b>H317</b>	May cause an allergic skin reaction
<b>H318</b>	Causes serious eye damage
<b>H319</b>	Causes serious eye irritation
<b>H332</b>	Harmful if inhaled
<b>H335</b>	May cause respiratory irritation
<b>H361</b>	Suspected of damaging fertility or the unborn child.
<b>H400</b>	Very toxic to aquatic life.

**Other Information**

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

**NFPA 704 diamond (US):**



Blue = Health, Red = Fire, Yellow = Reactivity, White = Special (Oxidizer or water reactive substances)

**Definitions and abbreviations**

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations



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