

SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Isathal® (10 mg/g eye drops, suspension)
<b>Synonyms:</b>	Previously known as Fucithalamic Also known as Conoptal [IT]
<b>Proper Shipping name:</b>	Not Available
<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>	<p><u>Dog:</u> For the topical treatment of conjunctivitis associated with <i>Staphylococcus aureus</i> and in particular the biotype <i>Staphylococcus intermedius</i>.</p> <p><u>Cat:</u> For the topical treatment of conjunctivitis associated with secondary staphylococcal infections.</p> <p><u>Rabbit:</u> For the topical treatment of conjunctivitis associated with staphylococcal infections.</p>
<b>Uses advised against:</b>	<ul style="list-style-type: none"> <li>• The veterinary medicinal product should not be used in conjunctivitis cases associated with <i>Pseudomonas</i> spp.</li> <li>• Do not use in cases of known hypersensitivity to the active substance or any of the excipients.</li> <li>• Official, national and regional antimicrobial policies should be taken into account when the product is used.</li> </ul>
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</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>Email:</b>	Not available
<b>Distributor name (Canada):</b>	Dechra Veterinary Products



<b>Address:</b>	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada
<b>Telephone:</b>	+1 (855) 332 9334
<b>Website:</b>	www.dechra.ca
<b>Email:</b>	Not Available

#### 1.4 Emergency Telephone Numbers

<b>Dechra (US):</b>	+1 (866) 933 2472
<b>Dechra (CA):</b>	+1 (855) 332 9334

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

<b>DSD Classification:</b>	Not Available
<b>DPD Classification:</b>	Not Available
<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	Not Available

### 2.2 Label Elements

<b>Signal Word:</b>	Not Available
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#### Hazard Statement(s)

Not Available

#### Additional Statement(s)

None

#### Precautionary Statement(s) Prevention:

<b>P264</b>	Wash hands thoroughly after handling.
<b>P270</b>	Do not eat, drink or smoke when using this product.

#### Precautionary Statement(s) Response:

<b>P301 + P310</b>	IF SWALLOWED: immediately call a POISON CENTER/doctor
<b>P330</b>	Rinse mouth.

#### Precautionary Statement(s) Storage:

<b>P405</b>	Store locked up
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#### Precautionary Statement(s) Disposal:

<b>P501</b>	Dispose of contents / packaging according to local regulations
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### 2.3 Other Hazard Information

<b>SECTION 3: INFORMATION ON THE INGREDIENTS</b>			
<b>3.1 Substances</b>			
See section below for composition of mixtures			
<b>3.2 Mixtures</b>			
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. 6990-06-3 2. Not Available 3. Not Available 4. Not Available	1%	Fusidic acid	Acute toxicity (oral) category 4; H302 <sup>1</sup>
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a
<b>Legend:</b> 1. Classified by Chemwatch			

<b>SECTION 4: FIRST AID MEASURES</b>	
<b>4.1 Description of first aid measures</b>	
<b>Eye contact:</b>	In case of accidental contact of the product with the eyes rinse with fresh water. Seek medical attention if irritation persists.
<b>Skin contact:</b>	In case of accidental contact of the product with the skin, wash with soap and water. Seek medical attention if irritation persists.
<b>Inhalation:</b>	Due to physical form of this product, inhalation exposure is unlikely. However, if this product is accidentally inhaled, seek fresh air.
<b>Ingestion:</b>	In case of accidental ingestion, wash out mouth thoroughly and drink 1-2 glasses of water in small sips. Seek medical advice in case of persistent discomfort.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
See Section 11	
<b>4.3 Indication of immediate medical attention and special treatment needed</b>	
N/a.	

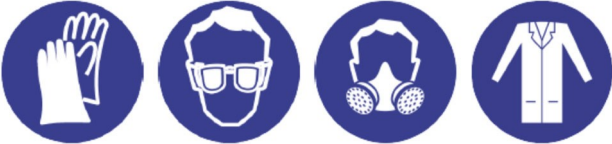
<b>SECTION 5: FIRE FIGHTING MEASURES</b>	
<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Water spray, carbon dioxide, dry chemical and foam, as appropriate for surrounding fire and materials.
<b>Unsuitable:</b>	None.
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	None known
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.
<b>Fire / explosion hazard:</b>	Incineration products contain: <ul style="list-style-type: none"> <li>• Carbon dioxide (CO<sub>2</sub>)</li> <li>• Carbon monoxide (CO)</li> <li>• Hydrogen chloride (HCl; hydrochloric acid)</li> <li>• Phosgene</li> <li>• Nitrogen oxides (NO<sub>x</sub>)</li> <li>• other pyrolysis products typical of burning organic material.</li> </ul> May emit toxic fumes.

<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>	
Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water.	
<b>6.3 Methods and material for containment and cleaning up</b>	
<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. Wipe up minor spills with a cloth.
<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. Large spills should be collected into an appropriate container for waste disposal.
<b>SECTION 7: HANDLING AND STORAGE</b>	
<b>7.1 Precautions for safe handling</b>	
<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. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Do not store above 25°C. Keep out of the reach and sight of children.
<b>7.2 Conditions for safe storage, including any incompatibilities</b>	
<b>Suitable Container:</b>	Replace the cap between applications. Following withdrawal of first dose, use the product within 1 month
<b>Storage incompatibility:</b>	Unknown.
<b>7.3 Specific end uses</b>	
Not available	

<b>SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION</b>				
<b>8.1 Control parameters</b>				
<b>DERIVED NO EFFECT LEVEL - DNEL (EU)</b>				
Not Available				
<b>PREDICTED NO EFFECT LEVEL - PNEC (EU)</b>				
Not Available				
<b>OCCUPATIONAL EXPOSURE LIMITS (OEL)</b>				
<b>INGREDIENT DATA:</b>				
Not Available				
<b>EMERGENCY LIMITS:</b>				
<b>Ingredient</b>	<b>Material Name</b>	<b>TEEL-1</b>	<b>TEEL-2</b>	<b>TEEL-3</b>

Not Available	
<b>8.2 Exposure controls</b>	
<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
<b>8.3 Environmental exposure controls</b>	
See Section 12	

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance:</b> Isathal®:	Sterile, white to off-white, viscous formulation.	
<b>Container:</b>	Sterilized aluminium tube laminated on both sides of tube wall with high density polyethylene, with a high density polyethylene nozzle closed with a high density polyethylene screw cap.	
<b>Physical state:</b> Isathal®:	eye drops, suspension.	
<b>Odour:</b>	Not available	
<b>Odour Threshold:</b>	Not available	
<b>pH (as supplied):</b>	Not available	
<b>Melting point / freezing point (degrees C):</b>	192°C -193°C	
<b>Initial boiling point and boiling range:</b>	Not available	
<b>Flash Point:</b>	Not available	
<b>Evaporation rate:</b>	Not available	
<b>Flammability:</b>	Not available	
<b>Upper/lower flammability or explosive limits:</b>	Not available	
<b>Vapour pressure:</b>	Not available	
<b>Relative Density (at degrees C):</b>	Not available	
<b>Solubility in water and solvents (mg/l):</b>	Soluble	
<b>Vapour density:</b>	Not available	
<b>Auto ignition temperature (degrees C):</b>	Not available	
<b>Decomposition temperature (degrees C):</b>	Not available	
<b>Viscosity: (degrees C):</b>	Not available	
<b>Explosive properties:</b>	Not available	
<b>Oxidising properties:</b>	Not available	
<b>Partition Coefficient:</b>	Not available	
<b>Molecular weight :</b>	Fusidic acid: 516.709	
<b>Taste:</b>	Not available	
<b>Surface tension:</b>	Not available	
<b>Volative component:</b>	Not available	
<b>Gas group:</b>	Not available	
<b>pH as a solution:</b>	Not available	
<b>VOC g/L:</b>	Not available	

### 9.2 Other information

Not Available

## 10: REACTIVITY AND STABILITY

<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>	See Section 7.

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

SECTION 11: TOXICOLOGICAL INFORMATION		
<b>Inhalation:</b>	The product does not release hazardous vapours. Due to physical form of this product, inhalation exposure is unlikely.	
<b>Ingestion:</b>	Ingestion may cause discomfort.	
<b>Skin contact:</b>	The product may very rarely produce slight skin irritation in some persons.	
<b>Eye contact:</b>	The product may very rarely produce eye irritation in some persons.	
<b>Chronic:</b>	Allergic reactions or hypersensitivity to the active substance or the excipients might occur. Discontinue use if hypersensitivity to the product develops.	
<b>Isathal®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Fusidic acid:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (mouse) LD <sub>50</sub> : 1500 mg/kgd <sup>2</sup>	Not Available
<i>1. * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</i>		
<b>Skin corrosion/ irritation:</b>		
Not Available		
<b>Serious eye damage/ irritation:</b>		
Not available		
<b>Respiratory or skin sensitization:</b>		
Not available		
<b>Germ cell mutagenicity:</b>		
Not available		
<b>Carcinogenicity:</b>		
Not available		
<b>Reproductive toxicity:</b>		



**SECTION 11: TOXICOLOGICAL INFORMATION**

The product may be used safely in pregnant and lactating animals.

**STOT – single exposure:**

Not available

**STOT–repeated exposure:**

Not available

**Aspiration hazard:**

Not available

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 Toxicity**

Fusidic Acid	Endpoint	Duration of test (hr)	Type	Value	Source
	LC <sub>50</sub>	96	Fish	2.249mg/L	3
	EC <sub>50</sub>	96	Not available	0.213mg/L	3

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

**Legend:** EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated)

**12.2 Persistence and degradability**

Ingredient	Persistence: Water/Soil	Persistence: Air
Fusidic Acid	HIGH	HIGH

**12.3 Bioaccumulative potential**

Ingredient	Bioaccumulation
Fusidic Acid	HIGH (LogKOW = 6.7525)

**12.4 Mobility in Soil**

Ingredient	Mobility
Fusidic Acid	LOW (KOC = 4505)

**12.5 Results of PBT and vPvB assessment**

Not Available

**12.6 Other adverse effects**

Not Available

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<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 country, state and/ or territory. Each user must refer to laws operating in their area.  Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b>	None	
<b>Marine pollutant:</b>	NO	
<b>Hazchem:</b>	Not Applicable	
<b>Land transport (ADR):</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
	Classification code	N/a
	Hazard Label	N/a
	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):</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):</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):</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 MARPOL73/78 and the IBC Code</b>	N/a		

<b>SECTION 15: REGULATORY INFORMATION</b>			
<b>15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture</b>			
<b>FUSIDIC ACID (6990-06-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS:</b>			
<ul style="list-style-type: none"> <li>• European Customs of Chemicals ECICS (English)</li> <li>• European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)</li> </ul>			
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			
<b>15.2 Chemical Safety Assessment</b>			
<b>ECHA SUMMARY</b>			
<b>Ingredient</b>	<b>CAS number</b>	<b>Index Number</b>	<b>ECHA Dossier</b>
Fusidic acid	6990-06-3	Not Available	Not Available
<b>Harmonization (C&amp;L Inventory)</b>	<b>Hazard Class and Category Code(s)</b>	<b>Pictograms Signal Word Code(s)</b>	<b>Hazard Statement Code(s)</b>
1	Acute Tox. 4	GHS07, Wng	H302
2	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3	GHS07, Wng	H302, H315, H319, H335
Harmonization Code 1 = The most prevalent classification.			
Harmonization Code 2 = The most severe classification			

Australia - AICS	N (Fusidic acid)
Canada - DSL	Y
Canada - NDSL	N (Fusidic acid)
China - IECSC	N (Fusidic acid)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Fusidic acid)
Korea - KECI	N (Fusidic acid)
New Zealand - NZIoC	Y
Philippines - PICCS	N (Fusidic acid)
USA - TSCA	N (Fusidic acid)
<b>Legend:</b>	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)

## SECTION 16: OTHER INFORMATION

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

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

### 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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