

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Isathal® (10 mg/g eye drops, suspension)
Synonyms:	Previously known as Fucithalamic Also known as Conoptal [IT]
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	<u>Dog:</u> For the topical treatment of conjunctivitis associated with <i>Staphylococcus aureus</i> and in particular the biotype <i>Staphylococcus intermedius</i> . <u>Cat:</u> For the topical treatment of conjunctivitis associated with secondary staphylococcal infections. <u>Rabbit:</u> For the topical treatment of conjunctivitis associated with staphylococcal infections.
Uses advised against:	<ul style="list-style-type: none"> • The veterinary medicinal product should not be used in conjunctivitis cases associated with <i>Pseudomonas</i> spp. • Do not use in cases of known hypersensitivity to the active substance or any of the excipients. • Official, national and regional antimicrobial policies should be taken into account when the product is used.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
Telephone:	+44 (0) 1756 791311
Fax:	+44 (0) 1756 798604
Email:	Not available
1.4 Emergency Telephone Numbers	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
DSD Classification:	Not Available
DPD Classification:	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	Not Available
2.2 Label Elements	
Signal Word:	Not Available
Hazard Statement(s)	
Not Available	
Additional Statement(s)	
None	
Precautionary Statement(s) Prevention:	
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
Precautionary Statement(s) Response:	
P301 + P310	IF SWALLOWED: immediately call a POISON CENTER/doctor
P330	Rinse mouth.
Precautionary Statement(s) Storage:	
P405	Store locked up
Precautionary Statement(s) Disposal:	
P501	Dispose of contents / packaging according to local regulations
2.3 Other Hazard Information	

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. 6990-06-3 2. Not Available 3. Not Available 4. Not Available	1%	Fusidic acid	Acute toxicity (oral) category 4; H302 ¹
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a
Legend: 1. Classified by Chemwatch			

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	In case of accidental contact of the product with the eyes rinse with fresh water. Seek medical attention if irritation persists.
Skin contact:	In case of accidental contact of the product with the skin, wash with soap and water. Seek medical attention if irritation persists.
Inhalation:	Due to physical form of this product, inhalation exposure is unlikely. However, if this product is accidentally inhaled, seek fresh air.
Ingestion:	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.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3 Indication of immediate medical attention and special treatment needed

N/a.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media	
Suitable:	Water spray, carbon dioxide, dry chemical and foam, as appropriate for surrounding fire and materials.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.
Fire / explosion hazard:	Incineration products contain: <ul style="list-style-type: none"> • Carbon dioxide (CO₂) • Carbon monoxide (CO) • Hydrocgen chloride (HCl; hydrochloric acid) • Phosgene • Nitrogen oxides (NO_x) • other pyrolysis products typical of burning organic material. May emit toxic fumes.


SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8.	
6.2 Environmental Precautions	
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.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	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.
Major Spills:	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.
SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Wear suitable protection gloves and clothing when handling the product. When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Do not store above 25°C. Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Replace the cap between applications. Following withdrawal of first dose, use the product within 1 month.
Storage incompatibility:	Unknown.
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:				
Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3

Not Available	
8.2 Exposure controls	
Appropriate engineering controls:	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.
Personal protection:	
Eye and face protection:	Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	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: Isathal®: Sterile, white to off-white, viscous formulation.
Container: 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.
Physical state: Isathal®: eye drops, suspension.
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): 192°C -193°C
Initial boiling point and boiling range: Not available
Flash Point: Not available
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): 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: Fusidic acid: 516.709
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

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
10.4 Conditions to avoid:	See Section 7.
10.5 Incompatible	See section 7.

materials:	
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	The product does not release hazardous vapours. Due to physical form of this product, inhalation exposure is unlikely.	
Ingestion:	Ingestion may cause discomfort.	
Skin contact:	The product may very rarely produce slight skin irritation in some persons.	
Eye contact:	The product may very rarely produce eye irritation in some persons.	
Chronic:	Allergic reactions or hypersensitivity to the active substance or the excipients might occur. Discontinue use if hypersensitivity to the product develops.	
Atipam®:	Acute toxicity	Irritation
	Not Available	Not Available
Atipamezole hydrochloride:	Acute toxicity	Irritation
	Oral (mouse) LD ₅₀ : 1500 mg/kgd ²	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>		
Skin corrosion/ irritation:		
Not Available		
Serious eye damage/ irritation:		
Not available		
Respiratory or skin sensitization:		
Not available		
Germ cell mutagenicity:		
Not available		
Carcinogenicity:		
Not available		
Reproductive toxicity:		

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 ₅₀	96	Fish	2.249mg/L	3
	EC ₅₀	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

13.1 Waste treatment methods	
Product / packaging disposal:	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.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION

Labels required:	None	
Marine pollutant:	NO	
Hazchem:	Not Applicable	
Land transport (ADR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA / DGR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	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
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	

14.3 Transport hazard class(es)	IMDG Class	N/a	
	IMDG Sub risk	N/a	
14.4 Packing group	N/a		
14.5 Environmental hazards	N/a		
14.6 Special precautions for user	EMS Number	N/a	
	Special provisions	N/a	
	Limited quantities	N/a	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a		
Inland waterways transport (ADN):			
14.1 UN Number	N/a		
14.2 UN Proper Shipping Name	N/a		
14.3 Transport hazard class(es)	N/a		N/a
14.4 Packing group	N/a		
14.5 Environmental hazard	N/a		
14.6 Special precautions for user	Classification Code	N/a	
	Special provisions	N/a	
	Limited quantity	N/a	
	Equipment required	N/a	
	Fire cones number	N/a	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a		

SECTION 15: REGULATORY INFORMATION			
15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture			
FUSIDIC ACID (6990-06-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS:			
<ul style="list-style-type: none"> • European Customs of Chemicals ECICS (English) • European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English) 			
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			
15.2 Chemical Safety Assessment			
ECHA SUMMARY			
Ingredient	CAS number	Index Number	ECHA Dossier
Fusidic acid	6990-06-3	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
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)
Legend:	<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 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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