



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Isaderm® 5 mg/g + 1 mg/g gel
Synonyms:	Previously known as Fuciderm
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:	For the topical treatment of surface pyoderma in the dog such as acute moist dermatitis ('hot spots') and intertrigo (skin fold dermatitis).
Uses advised against:	<ul style="list-style-type: none"> • Do not use for the treatment of deep pyoderma. • Do not use in pyotraumatic furunculosis and pyotraumatic folliculitis with 'satellite' lesions of papules or pustules. • Do not use where fungal or viral infection is present. • Do not apply to the eye. • Do not use over large surface areas or for prolonged treatment. • Do not use in cases of known hypersensitivity to the active substances or to any of the excipients. • Pregnant women should take special care to avoid accidental exposure.
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:	
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	5%	Fusidic acid	Acute toxicity (oral) Category 4; H302 ¹
1. 378-44-9 2. Not Available 3. Not Available 4. Not Available	1%	Betamethasone (as valerate)	Reproductive toxicity 2; H361
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 abundantly with fresh water. Seek medical attention if irritation persists.
Skin contact:	In case of accidental contact of the product with the skin rinse abundantly with fresh water. Seek medical attention if irritation persists. Remove contaminated clothes that are in direct contact with the skin. Remove any contaminated clothing.
Inhalation:	Due to physical form of this product, inhalation exposure is unlikely. However, if inhaled seek fresh air, and if irritation occurs seek medical advice.
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

Not available.



SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media	
Suitable:	Powder, foam, carbon dioxide or water mist, as appropriate for the surrounding area.
Unsuitable:	Do not use water stream, as it may spread the fire.
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:	Avoid inhalation of vapour and flue gases

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. 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:	<p>Pregnant women should take special care to avoid accidental exposure.</p> <p>Always wear single-use disposable gloves when applying this product to animals.</p> <p>When handling, DO NOT eat, drink or smoke.</p> <p>Always wash hands with water after handling.</p> <p>Observe manufacturer's storage and handling recommendations.</p>
Other Information:	<p>Do not refrigerate or freeze.</p> <p>Keep out of the reach and sight of children.</p>

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	<p>Do not store above 30°C.</p> <p>Shelf life of the veterinary medicinal product as packaged for sale: 3 years.</p> <p>Shelf life after first opening of the immediate packaging: 6 weeks.</p>
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:

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:	Always wear single-use disposable gloves when applying this product to animals.
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: Isaderm®: White translucent gel
Container: Internally lacquered aluminium tubes of 15g or 30g closed with a white HDPE screw cap
Physical state: Isaderm®: Gel
Odour: Odourless
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
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): Not available
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
Bethasone: 392.461
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:	Corticosteroids may produce irreversible effects in the skin; they can be absorbed and may have harmful effects, especially with frequent and extensive contact or in pregnancy.	
Eye contact:	The product may produce eye irritation in some persons.	
Chronic:	Prolonged and intensive use of topical corticosteroid preparations or treatment of a large cutaneous surface (>10%) is known to trigger local or systemic effects including suppression of adrenal function, thinning of the epidermis and delayed healing.	
Isaderm®:	Acute toxicity	Irritation
	Not Available	Not Available
Fusidic acid:	Acute toxicity	Irritation
	Oral (mouse) LD ₅₀ : 1500mg/kgd ²	Not Available
Betamethasone:	Acute toxicity	Irritation
	Oral (mouse) LD ₅₀ : >4500 mg/kgd ²	Not Available

*1. * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances*

Skin corrosion/ irritation:
Locally applied steroids may cause depigmentation of the skin.
Serious eye damage/ irritation:
Not available
Respiratory or skin sensitization:
Not available
Germ cell mutagenicity:
Not available



SECTION 11: TOXICOLOGICAL INFORMATION

Carcinogenicity:

Not available

Reproductive toxicity:

Corticosteroids may produce irreversible effects in the skin; they can be absorbed and may have harmful effects, especially with frequent and extensive contact or in pregnancy.
 Pregnant women should take special care to avoid accidental exposure.

STOT – single exposure:

Not available

STOT–repeated exposure:

Not available

Aspiration hazard:

Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not Available

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Not Available

12.3 Bioaccumulative potential

Not Available

12.4 Mobility in Soil

Not Available

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 Inventory of Chemical Substances ECICS (English) • European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
BETAMETHASONE (378-44-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:
<ul style="list-style-type: none"> • European Customs Inventory of Chemical Substances 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			

Ingredient	CAS number	Index Number	ECHA Dossier
Betamethasone	378-44-9	Not Available	01-2119901769-29-XXXX
Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Repr. 1B, STOT RE 2	GHS08, Dgr	H360, H373
2	Repr. 1B, STOT RE 2, Acute Tox. 2, STOT RE 1, Aquatic Chronic 1, Repr. 2, Lact., Not Classified, Acute Tox. 4	GHS08, Dgr, GHS09, GHS06	H360D, H330, H372, H410, H362, H319, H302, H312
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, betamethasone)
China - IECSC	N (Fusidic acid, betamethasone)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Fusidic acid)
Korea - KECI	N (Fusidic acid, betamethasone)
New Zealand - NZIoC	Y
Philippines - PICCS	N (Fusidic acid)
USA - TSCA	N (Fusidic acid, betamethasone)
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

The information provided in this Safety Data Sheet has been compiled by Dechra Ltd using a number of different sources, and is correct to the best of its knowledge, information and belief as at the date of its publication. However, Dechra Ltd makes no warranties, express or implied, in relation to the information set out in this Safety Data Sheet, including, without limitation, as to its accuracy or completeness.

The information provided is not a quality specification, and is prepared by way of guidance as to the safe handling, use, processing, storage, transportation, disposal and release of the relevant products referred to. The user is responsible for determining whether or not the product is fit for any particular purpose and/or suitable for the user's proposed method of use and application.

Copyright, 2017, Dechra Ltd. All rights reserved.

Copying and/or downloading of this information for the purpose of properly utilizing Dechra Ltd products is permitted provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Dechra Ltd, and (2) neither the copy nor the original is resold or otherwise distributed for the purposes of making a profit thereon.