Product Name: OPHTHAVET Ophthalmic Ointment

Issue Date: 05/2021 Version No: 2021-1





SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	OPHTHAVET Ophthalmic Ointment
Synonyms:	Not Available
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 use as a lubricant to prevent further irritation, or to relieve
Han advised assistant	dryness of the eye in dogs, cats or horses
Uses advised against:	Not for numan use
1.3 Details of the supplier o	f the substance or mixture
Registered company name (US):	Dechra Veterinary Products
Address:	7015 College Blvd
	Suite 525 Overland Park
	KS 66211
	USA
Telephone:	866-933-2472
Fax:	Not Available
Email:	Not Available
1.4 Emergency telephone n	umbers
Dechra (US):	866-933-2472

Product Name: OPHTHAVET Ophthalmic Ointment

Issue Date: 05/2021 Version No: 2021-1 Page 2 of 11



**SECTION 2: HAZARDS IDENTIFICATION** 

# 2.1 Classification of the substance or mixture

Not considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes (US).

#### 2.2 Label elements

Signal word: Not Applicable

Hazard statement(s):

Not Applicable

Precautionary statement(s) prevention:

Not Applicable

Precautionary statement(s) response:

Not Applicable

Precautionary statement(s) storage:

Not Applicable

Precautionary statement(s) disposal:

Not Applicable

2.3 Other hazard information

May produce skin discomfort

#### **SECTION 3: INFORMATION ON THE INGREDIENTS**

# 3.1 Substances

See section below for composition of mixtures.

# 3.2 Mixtures

CAS No	% w/w	Name
9067-32-7	<1	hyaluronic acid sodium salt
8012-95-1	30-40	paraffin oils
8009-03-8	30-40	petrolatum
61788-49-6	<10	Lanolin alcohol
Not available	balance	ingredients determined not to be hazardous

Safety Data Sheet Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 3 of 11



SECTION 4: FIRST AID N	MEASURES
4.1 Description of first a	aid measures
Eye contact:	Accidental exposure to the eyes should be washed out immediately with plenty of water. Seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental exposure to on the skin should be washed off with plenty of soap and water. Remove contaminated clothes that are in direct contact with skin. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Inhalation:	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.
Ingestion:	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, do not induce vomiting. Seek medical advice immediately and show the package leaflet or the label to themedical practitioner.
4.2 Most important sym	ptoms and effects, both acute and delayed
May cause slight irritation	to the skin and eyes.
	iate medical attention and special treatment needed ial immediate treatment required.

SECTION 5: FIRE FIGHT	ING MEASURES		
5.1 Extinguishing media			
Suitable:	Select extinguishing media suitable for surrounding area.		
Unsuitable:	There is no restriction on the type of extinguisher which may be used.		
5.2 Special hazards aris	ing from the substance or mixture		
Fire incompatibility:	Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result		
5.3 Special protective a	5.3 Special protective actions for fire-fighters:		
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. DO NOT approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use.		
Fire / explosion hazard:	Combustible and low fire hazard when exposed to heat or flame, on combustion, may emit toxic fumes of carbon monoxide.		

Safety Data Sheet Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 4 of 11



SECTION 6: ACCIDENTAL RELEASE MEASURES		
6.1 Personal preca	nutions, protective equipment and emergency procedures	
See Section 8.		
6.2 Environmental	precautions	
See Section 12.		
6.3 Methods and m	aterial for containment and cleaning up	
Minor spills:	Clean up all spills immediately. Avoid breathing vapors 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. Place in a suitable, labelled container for waste disposal. Flush spill area with water.	
Major spills:	Clear area of personnel and move upwind. Alert the fire department and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent spillage from entering drains or watercourse.	

SECTION 7: HANDI	SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for	r safe handling	
Safe handling:	Wear suitable protective gloves and clothing when handling the product. DO NOT eat, drink or smoke when handling the product. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.	
Other information:	Keep out of the reach and sight of children.	
7.2 Conditions for	safe storage, including any incompatibilities	
Suitable container:	5 g tube	
Storage incompatibility:		
7.3 Specific end us	es	
Not Available		

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION		
8.1 Control parameters		
Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
paraffin oils	Inhalation 5 mg/m³ (Systemic, Chronic)	Not Available

Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 5 of 11



	Inhalation 5 mg/m³ (Local, Chronic)	
	Inhalation 5 mg/m³ (Systemic, Acute)	
	Inhalation 5 mg/m³ (Local, Acute)	
	Dermal 5.81 mg/kg bw/day (Systemic, Chronic)	
petrolatum	Inhalation 2.73 mg/m³ (Systemic, Chronic)	9.33 mg/kg food (Oral)
	Oral 0.74 mg/kg bw/day (Systemic, Chronic)*	
* Value for Ge	eneral Population	

# OCCUPATIONAL EXPOSURE LIMITS (OEL)

Not Available

EMERGENCY LIMITS:				
Ingredient	TEEL-1		TEEL-2	TEEL-3
paraffin oils	140 mg/m <sup>3</sup>		1,500 mg/m <sup>3</sup>	8,900 mg/m <sup>3</sup>
petrolatum	140 mg/m <sup>3</sup>		1,500 mg/m <sup>3</sup>	8,900 mg/m <sup>3</sup>
Ingredient		Origin	al IDLH	Revised IDLH
paraffin oil		2,500	mg/m³	Not Available
petrolatum		2,500	mg/m³	Not Available
lanolin alcohol acetate		Not Av	/ailable	Not Available
hyaluronic acid sodium salt		Not Av	/ailable	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:	Not Required
Eye and face protection:	Not Required
Skin protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves.
Hands / feet protection:	See skin protection above.
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 exposu	ire controls
See Section 12.	

Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 6 of 11



# **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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

Appearance: White ointment

Container: 5 g tube

Physical state: Non Slump Paste

Odor: None

Odor threshold: Not Available

pH (as supplied): 7.0

Melting point / freezing point (degrees C): Not Available Initial boiling point and boiling range: Not Available

Flash point: Not Available Evaporation rate: 0

Flammability: Not Available

Upper / lower flammability or explosive limits: Not Available

Vapor pressure: Not Available

Relative density (at degrees C): Not Available

Solubility in water and solvents (mg/l): Partial in water, soluble in hydrophobic solvents

Vapor density: Not Available

Auto ignition temperature (degrees C): None

Decomposition temperature (degrees C): Not Available

Viscosity (degrees C): Not Available

**Explosive properties:** None **Oxidizing properties:** None

Partition coefficient: Not Available Molecular weight: Not Applicable

Taste: Not Available

Surface tension: Not Available Volatile component: Not Available

Gas group: Not Available pH as a solution: Not Available

VOC g/L: Not Available

Specific gravity @ 20 degrees C (water = 1): Not Available

# 9.2 Other information

Not Available

10: REACTIVITY AND STABILITITY	
10.1 Reactivity:	See Section 7.
10.2 Chemical stability:	Product is considered stable. Hazardous polymerization will not occur.
10.3 Possibility of hazardous reactions:	See Section 7.
10.4 Conditions to avoid:	See Section 7.
10.5 Incompatible materials:	See Section 7.
10.6 Hazardous composition:	See Section 5.

Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 7 of 11



SECTION 11: TOXICO	LOGICAL INFORMATION		
Inhalation:	The material is not thought to produirritation of the respiratory tract. Inhirritate the nose, throat and lungs.		
Ingestion:	In the case of accidental oral intake, seek medical advice immediately and show the package leaflet. Ingestion may cause nausea, vomiting and diarrhea.		
Skin contact:	May cause skin irritation.		
Eye contact:	May cause eye irritation.		
Chronic:	Long-term exposure to the product is not thought to produce chronic adverse health effects.		
OPHTHAVET	Acute toxicity Irritation		
Ophthalmic Ointment	Not Available	Not Available	
	Acute toxicity	Irritation	
paraffin oils:	Inhalation (Rat) LC <sub>50</sub> ; 2,062 ppm 4h <sup>[2]</sup>	Eye (rabbit): 500 mg moderate	
	Oral (Mouse) LD <sub>50</sub> ; 22,000 mg/kg <sup>[2]</sup>	Skin (rabbit): 100 mg/24h mild	
		Skin (rabbit): 100 mg/24h mild Irritation	
Petrolatum:	Oral (Mouse) LD <sub>50</sub> ; 22,000 mg/kg <sup>[2]</sup> Acute toxicity  Dermal (rabbit) LD <sub>50</sub> ; >2000 mg/kg <sup>[1]</sup>		
	Oral (Mouse) LD <sub>50</sub> ; 22,000 mg/kg <sup>[2]</sup> <b>Acute toxicity</b> Dermal (rabbit) LD <sub>50</sub> : >2000 mg/kg <sup>[1]</sup> Oral (Rat) LD <sub>50</sub> ; >5000 mg/kg <sup>[1]</sup>	Irritation  Eye: no adverse effect observed (not irritating) <sup>[1]</sup> Skin: no adverse effect	
Petrolatum: lanolin alcohol acetate:	Oral (Mouse) LD <sub>50</sub> ; 22,000 mg/kg <sup>[2]</sup> Acute toxicity  Dermal (rabbit) LD <sub>50</sub> : >2000 mg/kg <sup>[1]</sup> Oral (Rat) LD <sub>50</sub> ; >5000 mg/kg <sup>[1]</sup> Acute toxicity	Irritation  Eye: no adverse effect observed (not irritating) <sup>[1]</sup> Skin: no adverse effect observed ((not irritating) <sup>[1]</sup>	
lanolin alcohol acetate: hyaluronic acid	Oral (Mouse) LD <sub>50</sub> ; 22,000 mg/kg <sup>[2]</sup> Acute toxicity  Dermal (rabbit) LD <sub>50</sub> : >2000 mg/kg <sup>[1]</sup> Oral (Rat) LD <sub>50</sub> ; >5000 mg/kg <sup>[1]</sup> Acute toxicity  Not Available  Acute toxicity	Irritation  Eye: no adverse effect observed (not irritating) <sup>[1]</sup> Skin: no adverse effect observed ((not irritating) <sup>[1]</sup> Irritation	
lanolin alcohol acetate: hyaluronic acid	Oral (Mouse) LD <sub>50</sub> ; 22,000 mg/kg <sup>[2]</sup> Acute toxicity  Dermal (rabbit) LD <sub>50</sub> : >2000 mg/kg <sup>[1]</sup> Oral (Rat) LD <sub>50</sub> ; >5000 mg/kg <sup>[1]</sup> Acute toxicity  Not Available	Irritation  Eye: no adverse effect observed (not irritating) <sup>[1]</sup> Skin: no adverse effect observed ((not irritating) <sup>[1]</sup> Irritation  Not Available	

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

#### Skin corrosion / irritation:

Data either not available or does not fill the criteria for classification

# Serious eye damage / irritation:

Data either not available or does not fill the criteria for classification

# Respiratory or skin sensitization:

Data either not available or does not fill the criteria for classification

#### Germ cell mutagenicity:

Data either not available or does not fill the criteria for classification

# Carcinogenicity:

Data either not available or does not fill the criteria for classification

# Reproductive toxicity:

Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 8 of 11



Data either not available or does not fill the criteria for classification
STOT – single exposure:
Data either not available or does not fill the criteria for classification
STOT – repeated exposure:
Data either not available or does not fill the criteria for classification
Aspiration hazard:
Data either not available or does not fill the criteria for classification

SECTION 12: ECOLOGICAL INFORMATION							
12.1 Toxicity	/						
Ingredient	Endpoint	Test duration (hr)	Species	Value	Source		
No data availa	able for all ingre	edients					

# DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability						
Ingredient		Persistence: Water / Soil	Persistence: Air			
No data availab	le for all ingred	ients				
12.3 Bioaccun	nulative poten	tial				
Ingredient	Bioaccumulative potential					
No data availab	le for all ingred	ients				
12.4 Mobility i	n soil					
Ingredient	Mobility					
No data availab	le for all ingred	ients				
12.5 Results of	of PBT and vPv	B assessment				
Not Applicable						
12.6 Other adv	erse effects					
Not Available						

SECTION 13: DISPOSAL CONSIDERATIONS						
13.1 Waste treatment methods						
	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.					
Waste treatment options:	Contact the local authorities. Avoid discharge to drain or surface water.					
Sewage disposal options:	Not Available					

Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 9 of 11



**SECTION 14: TRANSPORT INFORMATION** 

Labels required:

Marine pollutant: No

Land transport (US: DOT):

Not regulated for transport of dangerous goods

Air transport (ICAO-IATA / DGR):

Not regulated for transport of dangerous goods

Sea transport (IMDG-Code / GGVSee):

Not regulated for transport of dangerous goods

Inland waterways transport (ADN):

Not regulated for transport of dangerous goods

### **SECTION 15: REGULATORY INFORMATION**

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

Product regulated by FDA as an OTC drug

#### 15.2 Chemical Safety Assessment

Chemical safety assessment has not been performed.

# **SECTION 16: OTHER INFORMATION**

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

#### **Definitions and abbreviations**

PBT: Persistent, Bioaccumulative and Toxic vPvB: Very Persistent and Very Bioaccumulative TEEL: Temporary Emergency Exposure Limit

IDLH: Immediately Dangerous to Life or Health Concentrations

STOT: Specific target organ toxicity

The information provided in this Safety Data Sheet has been compiled by Dechra Veterinary Products LLC using a number of different sources, and is correct to the best of its knowledge, information and belief as of the date of its publication. However, Dechra Veterinary Products LLCmakes 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. Theuser 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, 2021 Dechra Veterinary Products LLC. All rights reserved.

Product Name: Lubrithal - Eye Gel for Dogs and Cats Issue

Date: 05/2021 Version No: 2021-1 Page 10 of 11



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