

SECTION 1: IDENTIFICATION

1.1 Product identifier		
Product name	Apex Meloxicam (1 mg, 2.5 mg) Tablets	
Chemical name	Not Applicable	
Synonyms	Meloxicam 1 mg tablets; Meloxicam 2.5 mg tablets	
Chemical formula	Not Applicable	
Other means of identification	Not Available	
1.2 Recommended use of the cher	mical and restrictions on use	
Relevant identified uses	For the alleviation of inflammation and pain in both acute and chronic musculo-skeletal	
	disorders in dogs.	
Uses advised against	Not for human use.	
1.3 Details of the supplier of the substance or mixture		
Registered company name (US)	Dechra Veterinary Products (Australia) Pty Ltd	
Address	2 Cal Close Somersby NSW 2250 Australia	
Telephone	(02) 4372 1661 1300 015 825	
Fax	(02) 4372 1668	
Website	http://www.dechra.com.au/	
1.4 Emergency telephone numbers		
Dechra	(02) 4372 1661 1300 015 825	

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of the substance or mixture				
Poisons Schedule	S4			
Classification ^[1]	Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3			
1. Classified by Chemwatch; 2.	assification drawn from Regulation (EU) No 1272/2008 - Annex VI			
2.2 Label elements				
Hazard pictogram(s)				
Signal word	Warning			
Hazard statement(s)				
H335	May cause respiratory irritation.			
Precautionary statement(s)	Prevention			
P271	Use only outdoors or in a well-ventilated area.			
P261	Avoid breathing dust/fumes.			
Precautionary statement(s) Response				
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.			
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.			
Precautionary statement(s) s	storage			
P405	Store locked up.			
P403+P233	Store in a well-ventilated place. Keep container tightly closed.			
Precautionary statement(s)	lisposal			
P501	P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.			

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

J.I Substances			
See section below for	composition of Mixtures		
3.2 Mixtures			
CAS No	%[weight]	Name	
9004-34-6	10-30	<u>cellulose</u>	
14807-96-6	1-10	talc	
557-04-0	1-5	magnesium stearate	
71125-38-7	<1	<u>meloxicam</u>	
Not Available	balance	Ingredients determined not to be hazardous	
1. Classified by Chemwatch: 2. Classification drawn from HCIS: 3. Classification drawn from Regulation (FLI) No. 1272/2008 - Anney VI: 4			

 Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOEL Vs available

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contactIf this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete
irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting
the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention.
Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.



Skin contact	If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.			
Inhalation	If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.			
Ingestion	Ingestion If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.			
4.3 Indication of	4.3 Indication of immediate medical attention and special treatment needed			
Treat sym	Treat symptomatically.			

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

2. Charaid because anising from the authorem on minture	L
area.	
There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding	

5.2 Special hazards arising from the substance or mixture				
Fire incompatibility Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlor				
	etc. as ignition may result.			
5.3 Special protective	e actions for fire-fighters:			
Firefighting	Firefighting Alert Fire Brigade and tell them location/nature of hazard. Wear breathing apparatus plus protective			
	gloves. Prevent, by any means available, spillage from entering drains or water courses. Use firefighting			
	procedures suitable for surrounding area. DO NOT 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.			
Fire / explosion	Solid which exhibits difficult combustion or is difficult to ignite. Avoid generating dust, particularly clouds			
hazard	of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any			
	source of ignition, i.e. flame or spark, will cause fire or explosion Decomposes on heating and produces			
	carbon monoxide, carbon dioxide, and other pyrolysis products typical of burning organic material			
HAZCHEM	Not Applicable			

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	1 Personal precautions, protective equipment and emergency procedures				
	See section 8.				
6.2	Environmental pre	cautions			
	See Section 12				
6.3	Methods and mater	ial for containment and cleaning up			
	Minor spills				
		and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures			
		and avoid generating dust. Place in a suitable, labelled container for waste disposal.			
	Major spills	Moderate hazard: CAUTION: Advise personnel in area. Alert Emergency Services and tell them			
		location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any			
	means available, spillage from entering drains or water courses. Recover product wherever possible.				
	IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed				
		plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled			
		containers for disposal. ALWAYS: Wash area down with large amounts of water and prevent runoff			
		into drains. If contamination of drains or waterways occurs, advise Emergency Services.			
Pe	Personal Protective Equipment advice is contained in Section 8 of the SDS.				

SECTION 7: HANDLING AND STORAGE



	Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source. Do NOT cut, drill, grind or weld such containers.
Other information	Store in original containers/ Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and foodstuff containers. Observe manufacturer's storage and handling recommendations contained within this SDS. For major quantities: Consider storage in bunded areas. Ensure storage areas are isolated from sources of community water (includingstormwater, ground water, lakes and streams). Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.
7.2 Conditions for safe s	storage, including any incompatibilities
Suitable container	Packaging as recommended by manufacturer. Glass container is suitable for laboratory quantities
	Polyethylene or polypropylene container. Check all containers are clearly labelled and free from
	leaks. it is recommended to store securely, under 30°C, dry, & well ventilated area.
Storage incompatibility	Avoid reaction with oxidising agents.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION						
8.1 Control paramet	ters					
Occupational exposure limits (OEL) INGREDIENT DATA						
Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	cellulose	Cellulose (paper fiber)	10 mg/m ³	Not Available	Not Available	This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Australia Exposure Standards	talc	Talc, (containing no asbestos fibers)	2.5 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	magnesium stearate	Stearates	10 mg/m ³	Not Available	Not Available	This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Emergency limits						
Ingredient			TEEL-1		TEEL-2	TEEL-3
Apex Meloxicam (1 m	g, 2.5 mg) T	ablets	Not Available	•	Not Available	Not Available
Ingredient			Original IDL	.H	Revised IDLH	1
cellulose			Not Available		Not Available	
talc			1,000 mg/m ³		Not Available	
magnesium stearate			Not Available		Not Available	
meloxicam			Not Available	•	Not Available	
Occupational Expos	ure Banding	9				
Ingredient			nal Exposur	e Band Rating		nal Exposure Band Limit
meloxicam		E			≤ 0.01 mg/n	n ³ sed on a chemical's potency and
		associated with exposi sure concentrations th				nal exposure band (OEB), which
8.2 Exposure control	ols					
8.2.1. Appropriate		te engineering contr	ols should be	in place where	individuals are	exposed to dust, vapors; mist;
engineering						mended limits. Local exhaust
controls	essential	to obtain adequat	e protection.	Supplied-air t	ype respirator	wed respirator. Correct fit is may be required in special
		nces. Correct fit is e	ssential to er	nsure adequate	protection.	
8.2.2. Personal protection	1115					
Eye and face protection	larger sca glasses w	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs, use safety glasses with side shields or chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.				
Skin protection						
Hands/feet		Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national				
protection		equivalent).				
Body protection		protection below	1-1			
Other protection	laboratory and cuffs. permeabil be require	For quantities up to 500 g a laboratory coat may be suitable. For quantities up to 1 kg a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. Eye wash unit. Ensure there is ready access to an emergency shower. For Emergencies: Vinyl suit.				
Respiratory Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.			ols do not adequately prevent			



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	5
Appearance: Off white to pale yellow solid	Vapor density: Not Available
Physical state: Solid	Auto ignition temperature (°C): Not Available
Odor: Mild characteristic odor	Decomposition temperature (°C): Not Available
Odor threshold: Not Available	Viscosity (°C): Not Available
pH (as supplied): Not Available	Explosive properties: Not Available
Melting point / freezing point (°C): Not Available	Oxidizing properties: Not Available
Initial boiling point and boiling range: Not Available	Partition coefficient: Not Available
Flash point (°C): Not Available	Molecular weight: Not Available
Evaporation rate: Not Available	Taste: Not Available
Flammability: Not Available	Surface tension: Not Available
Upper/lower flammability or explosive limits: Not Available	Volatile component (%vol): Not Available
Vapor pressure: Not Available	Gas group: Not Available
Relative density (Water = 1): Not Available	pH as a solution: Not Available
Solubility in water (mg/l): Soluble	VOC g/L: Not Available
	Specific gravity @ 20 °C (water = 1): Not Available

SECTION 10: STABILITY AND REACTIVITY			
Reactivity See Section 7			
Chemical stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.		
Possibility of hazardous reactions	See Section 7		
Conditions to avoid	See Section 7		
Incompatible materials	See Section 7		
Hazardous composition	See Section 5		

SECTION 11: TOXICOLOGICAL INFORMATION						
11.1 Informat	ion on toxicologic	al effects				
Inhalation	Evidence shows, Persons with imp	Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.				
Ingestion	Accidental ingesti	on of the mater	ial may be d	amaging to the	e health of the individual.	
Skin contact	skin in a substan when applied to the	Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals.				
Eye contact	eye may cause tr	ansient discom	fort.		assified by EC Directives), direct conta	
Chronic					ase of the airways involving difficult bro concentrations may cause changes in lu	
Apex Melo	xicam (1 mg, 2.5	Acute toxicity	1		Irritation	
•	mg) Tablets	Not Available			Not Available	
		Acute toxicity	1		Irritation	
cellulose		Dermal (rabbit) LD ₅₀ : >2000 mg/kg ^[2] Inhalation (rat\) LC ₅₀ : >5.8 mg/L4h ^[2] Oral (rat) LD ₅₀ : >5000 mg/kg ^[2]			Not Available	
		Acute toxicity		0	Irritation	
talc Dermal (rat Inhalation (Dermal (rat) LI	rmal (rat) $\dot{L}D_{50}$: >2000 mg/kg ^[1] alation (rat\) LC ₅₀ : >2.1 mg/L4h ^[1] al (rat) LD ₅₀ : >5000 mg/kg ^[1]		Eye: no adverse effect observed (not irritating) ^[1] Skin (human): 0.3 mg/3d-I mild Skin: no adverse effect observed (not irritating) ^[1]	
magnesium stearate		Acute toxicity			Irritation	
		Oral (rat) LD ₅₀ : >10000 mg/kg ^[2]			Not Available	
		Acute toxicity			Irritation	
meloxicam Oral (rabbit) L		-	Skin (rabbit): Not irritating*			
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances					s otherwise	
Acute Toxicity		×		Carcinogenicity	35	
Skin Irritation/Corrosion		×		Reproductivity	×	
Serios Eye Damage/Irritation		×	STOT – Single Exposure 🗸		✓	
Respiratory or Skin Sensitization		×	STOT – Repeated Exposure 😕		×	
Mutagenicity		×		Aspiration Hazard	×	
× - Data eithe	er not available or doe	s not fill the criteri	a for classifica	tion, 🗹 - Data ava	ailable to make classification.	

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity					
Apex Meloxicam (1 mg,	Endpoint	Test Duration	Species	Value	Source
2.5 mg) Tablets	Not Available				



cellulose	Endpoint	Test Duration	Species	Value	Source
cellulose	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration	Species	Value	Source
talc	LC50	96h	Fish	89581.016mg/	2
taic	EC50	96h	Algae or other aquatic plants	7202.7mg/l	2
	NOEC(ECx)	720h	Algae or other aquatic plants	918.089mg/l	2
magnasium staateta	Endpoint	Test duration	Species	Value	Source
magnesium stearate	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test duration	Species	Value	Source
meloxicam	NOEC(ECx)	144h	Fish	0.1mg/l	4
EPIWIN Suite V3.12 (QSAR)	- Aquatic Toxicity	y Data (Estimated)	red Substances - Ecotoxicologica) 4. US EPA, Ecotox database - A on Data 7. METI (Japan) - Bioconce	Aquatic Toxicity D	ata 5. ECETOC
DO NOT discharge into se	wer or waterways	S.			

12.2 Persistence and degradabilit	y	
Ingredient	Persistence: Water/Soil	Persistence: Air
cellulose	LOW	LOW
12.3 Bioaccumulative potential		
Ingredient	Bioaccumulation	
cellulose	LOW (LogKOW = -5.1249)	
12.4 Mobility in soil	· · · · ·	
Ingredient	Mobility	
cellulose	LOW (KOC = 10)	

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods				
Product/	DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to			
packaging	collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local			
disposal	laws and regulations and these should be considered first. Where in doubt contact the responsible authority.			

SECTION 14: TRANSPORT INFORMATION					
Labels required					
Marine pollutant: NO	NO				
HAZCHEM Not Ap	Not Applicable				
Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS					
Air transport (ICAO-IATA / DGR):	NOT R	REGULATED FOR TRANSPORT OF DANGEROUS GOODS			
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS					
Transport in bulk according to Annex II of MARPOL and the IBC code					
Not Applicable					
		ARPOL Annex V and the IMSBC Code			
Product n		Group			
cellulose		Not Available			
talc		Not Available			
magnesium stearate					
		Not Available			
Transport in bulk in accordance with ICG Code					
Product name		Group			
cellulose		Not Available			
talc		Not Available			
magnesium stearate					
melox	icam I	Not Available			

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for thesubstance or mixture

cellulose is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC), International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

talc is found on the following regulatory lists

AllC, Chemical Footprint Project - Chemicals of High Concern List, International Agency for Research on Cancer (IARC) -Agents Classified by the IARC Monographs, IARC - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans, IARC - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic International WHO List of Proposed OEL Values for MNMS

magnesium stearate is found on the following regulatory lists

AIIC, International WHO List of Proposed OEL Values for MNMS

meloxicam is found on the following regulatory lists Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4, FEI Equine Prohibited



Substances List - Controlled Medication, FEI Equine Prohibited Substances List (EPSL)

National Inventory Status		
Australia - AIIC / Australia Non-Industrial Use	No (meloxicam)	
Canada - DSL	No (meloxicam)	
Canada - NDSL	No (talc; magnesium stearate; meloxicam)	
China - IECSC	No (meloxicam)	
Europe - EINEC / ELINCS /NLP	No (meloxicam)	
Japan - ENCS	No (meloxicam)	
Korea - KECI	No (meloxicam)	
New Zealand - NZIoC	Yes	
Philippines - PICCS	No (meloxicam)	
USA - TSCA	No (meloxicam)	
Taiwan - TCSI	Yes	
Mexico - INSQ	Yes	
Vietnam - NCI	Yes	
Russia - FBEPH	No (meloxicam)	
Yes = All CAS declared ingredients are on the inventory		

Yes = All CAS declared ingredients are on the inventory

No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will requireregistration

SECTION 16: OTHER INFORMATION

Initial date: March 2023

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. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

NZIoC: New Zealand Inventory of Chemicals PC-TWA: Permissible Concentration-Time Weighted Average STEL: Short Term Exposure Limit PC-STEL: Permissible Concentration-Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit IARC: International Agency for Research on Cancer ES: Exposure Standard ACGIH: American Conference of Governmental Industrial OSF: Odor Safety Factor Hygienists NOAEL :No Observed Adverse Effect Level IDLH: Immediately Dangerous to Life or Health Concentrations LOAEL: Lowest Observed Adverse Effect Level AIIC: Australian Inventory of Industrial Chemicals TLV: Threshold Limit Value IECSC: Inventory of Existing Chemical Substance in China LOD: Limit Of Detection EINECS: European INventory of Existing Commercial chemical OTV: Odor Threshold Value Substances BCF: BioConcentration Factors ELINCS: European List of Notified Chemical Substances BEI: Biological Exposure Index ENCS: Existing and New Chemical Substances Inventory PICCS: Philippine Inventory of Chemicals and Chemical DSL: Domestic Substances List Substances NDSL: Non-Domestic Substances List NLP: No-Longer Polymers INSQ: Inventario Nacional de Sustancias Químicas KECI: Korea Existing Chemicals Inventory NCI: National Chemical Inventory TSCA: Toxic Substances Control Act FBEPH: Russian Register of Potentially Hazardous Chemical and TCSI: Taiwan Chemical Substance Inventory **Biological Substances** The information provided in this Safety Data Sheet has been compiled by Dechra Veterinary Products LLC and is correct to

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