

# SAFETY DATA SHEET

#### Profender

# **Section 1. Identification**

**Product identifier** 

**Product code** 

Other means of identification

- : Profender
- : 122000001666

87147371; 87147363; 87147355; Drontal S. O. Cats; Drontal Spot On Cats; DrontSpot; DrontSpot Vet; Felpreva Small Cats; Felpreva Medium Cats; Felpreva Large Cats; Profender; Profender Cat; Profender S.O. Cat; Profender S.O. Sol. Cat; Profender® Spot On; Profender Small Cats & Kittens; Profender For Medium Cats; Profender For Large Cats; Profender Topical Solution; Bay 60-7500 / Profender® Spot On Katze; Profender® Spot On Chat; Profender® Spot On Gato; Profender® Spot On Gatto; Profender® Spot On Kat; Profender® Spot On Kedi; Profender® Spot On 고양이; 3615026; 3615034; 3615042; 3627105; 3627253; 3627261; 3636856; 3636872; 3636880; 3636899; 3636910; 3636929; 3636953; 3636961; 3640527; 3640691; 3640764; 3873157; 3873165; 3873173; 3873440; 3873459; 3873467; 3920899; 3920902; 3920929; 3930592; 3930606; 3930614; 3930622; 3930630; 3966902; 3966937; 3967194; 4468949; 4468957; 80057505; 80057548; 80057580; 80632674; 80654643; 80654678; 80804393; 81047839; 81055662; 81055697; 81055727; 81069361; 81069388; 81074217; 81149098; 81150869; 81150877; 81150893; 81283703; 81309680; 81309699; 81309702; 81465010; 81465134; 81465142; 81508194; 81508410; 81508429; 81630623; 81630658; 81663475; 81663483; 81846162; 81846170; 82084631; 82084690; 82214569; 82214607; 82214615; 82232699; 82237097; 82237100; 82237119; 82285016; 82285024; 82285032; 82482521; 82482572; 82482580; 82482602; 83872358; 83872536; 83872579; 83968664; 84026507; 84026523; 84026876; 84026884; 84185915; 84185923; 84329630; 84355127; 84370290; 84370312; 84370320; 84509493; 84509507; 84509523; 84607606; 84607614; 84607622; 84627186; 84696706; 84696870; 84696889; 84848581; 84848700; 84871141; 85008994; 85027565; 85027573; 85135139; 85209841; 85209868; 85209876; 85216872; 85216929; 85216945; 85217445; 85217453; 85217461; 85238159; 85238213; 85238248; 85446959; 85455109; 85456334; 85456342; 85469576; 85469630; 85469711; 85487574; 85530909; 85530917; 85530925; 85530933; 85530941; 85530976; 85622331; 85622374; 85655760; 85655779; 85655787; 85688383; 85713655; 85713663; 85713671; 85713698; 85713701; 85713752; 85713760; 85713833; 85713868; 85730649; 85976699; 86115867; 86115883; 86115891; 86303205; 86303248; 86307340; 86362317; 86362325; 86377527; 86377578; 86377713; 86468522; 86468530; 86468573; 86514257; 86514265; 86514281; 86514303; 86544644; 86546981; 86547007; 86547015; 86547023; 86547031; 86548062; 86548070; 86597195; 86597209; 86597217; 86597233; 86597446; 86597454; 86597462; 86598116; 86598140; 86811499; 86811545; 86811561; 86876558; 86876582; 86905280; 86905299; 86905302; 86905426; 86905442; 86905450; 86920611; 86920638; 86920719; 86984113; 86984148; 86984156; 86984172; 86984210; 86984229; 86984296; 86984326; 86984342; 87014665; 87032981; 87036014; 87036030; 87036049; 87036057; 87036065; 87036073; 87038696; 87038718; 87038769; 87038777; 87038785; 87038793; 87038823; 87038831; 87038882; 87053695; 87053709; 87053717; 87087034; 87097439; 87147320; 87147339; 87147347; 87177106; 87177149; 87441539; 87441547; 87441563; 87444260; 87444295; 87444309; 87444317; 87444325; 87444333; 87444341; 87444376; 87444384; 87444392; 87444406; 87444414; 87444422; 87444449; 87444457; 87444465; 87444473; 87446158; 87446174; 87446212; 87446239; 87446255; 87446263; 87446298; 87446328; 87446336; 87446425; 87446433; 87446441; 87448355; 87448371; 87448401; 87448428; 87448436; 87448444; 87448452; 87448460; 87448479; 87448533; 87448541; 87448568; 87450422; 87452433; 87452441; 87452468; 90197924; 90197927; 90197930; 90200109; 90200110; 90200280; 90200301; 90200303; 90200306; 90200307; 90200308; 90200649; 90200650; 90201670; 90201711; 90201712; 90201888; 90201889; 90201890; 90202125; 90202126; 90202127; 90202289; 90202290; 90202301; 90203432; 90203433; 90203434; 90204410; 90204461; 90204474; 90204476; 90204477; 90204478; 90204479; 90204480; 90204484; 90204485; 90204486; 90204487; 90204488; 90204489; 90204490; 90204501; 90204502; 90204512; 90204513; 90204514; 90204515; 90204516; 90204539; 90204544; 90204545; 90205234; 90205235; 90205710; 90205741; 90205742;

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90206299; 90206311; 90206312; 90206678; 90206679; 90206680; 90206739; 90206783; 90207647; 90207649; 90207650; 90207658; 90207659; 90207697; 90207698; 90207758; 90207759; 90207760; 90207783; 90207784; 90207785; 90207786; 90207787; 90207788; 90207845; 90207846; 90207847; 90207848; 90207849; 90207850; 90208288; 90208290; 90208301; 90208302; 90208303; 90208304; 90209126; 90209127; 90209191; 90209192; 90209219; 90209220; 90209231; 90209232; 90209233; 90209234; 90209235; 90210068; 90210069; 90210070; 90210081; 90210082; 90210086; 90209575; 90209587; 90209604; 90209606; 90209602; 90209588; Profender S.O. Cat; Profender®

Spot On; CA8406; CA7949; CA8407

#### Relevant identified uses of the substance or mixture and uses advised against

Identified uses: Veterinary product.Uses advised against: None known.

Company Name : Elanco New Zealand

106 Wiri Station Road, Manukau, Auckland 2140

**Telephone number** : +64 0800 352 626

0800 446 121 (Adverse Events Local Number)

**Emergency telephone** 

number

: CHEMTREC International: 00 1 703-527-3887 (24 hours)

CHEMTREC: +64 9-801 0034 (Local) CHEMTREC: 0800 425 459 (Freephone)

Email : elanco sds@elancoah.com

### Section 2. Hazards identification

HSNO Approval Number : HSR100757

**HSNO Group Standard** 

: Veterinary Medicines (Limited Pack Size, Finished Dose)

**HSNO Classification** : FLAMMABLE LIQUIDS - Category 4 SKIN IRRITATION - Category 2

EYE IRRITATION - Category 2 SKIN SENSITISATION - Category 1

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE - Category 2

SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1

This material is classified as hazardous according to criteria in the Hazardous Substances (Hazard Classification) Notice 2020.

This material is classified as DANGEROUS GOODS according to criteria in New Zealand Standard 5433:2020 Transport of Dangerous Goods on Land.

#### **GHS label elements**

Signal word : Warning

Hazard statements : H227 - Combustible liquid. H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H373 - May cause damage to organs through prolonged or repeated exposure. (central nervous system (CNS), Glucose Metabolism, kidneys, liver, pancreas)

H410 - Very toxic to aquatic life with long lasting effects.

#### **Precautionary statements**

**Prevention**: P280 - Wear protective gloves, protective clothing, eye protection, face protection,

or hearing protection.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking.

P273 - Avoid release to the environment.

P260 - Do not breathe vapour.

P264 - Wash thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.

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### Section 2. Hazards identification

Response : P391 - Collect spillage.

P314 - Get medical advice/attention if you feel unwell.

P362 + P364 - Take off contaminated clothing and wash it before reuse.

P302 + P352 - IF ON SKIN: Wash with plenty of water.

P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.

: Not applicable. **Storage** 

: P501 - Dispose of contents and container in accordance with all local, regional, **Disposal** 

national and international regulations.

**Symbol** 







Other hazards which do not : None known. result in classification

# Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	% (w/w)	CAS number
Praziquantel	≤10	55268-74-1
Lactic acid	<3	50-21-5
Cyclo[(αR)-α-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl-(αR)-α-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl]	≤3	155030-63-0
Butylated hydroxyanisole	<1	25013-16-5

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

### Section 4. First aid measures

#### Description of necessary first aid measures

Inhalation

: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention following exposure or if feeling unwell. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Ingestion

: Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention following exposure or if feeling unwell. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

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#### Section 4. First aid measures

**Skin contact**: Wash with plenty of soap and water. Remove contaminated clothing and shoes.

Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before

reuse. Clean shoes thoroughly before reuse.

**Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower

eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10

minutes. Get medical attention.

#### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

Inhalation : No known significant effects or critical hazards.Ingestion : No known significant effects or critical hazards.

**Skin contact**: Causes skin irritation. May cause an allergic skin reaction.

**Eye contact** : Causes serious eye irritation.

#### Over-exposure signs/symptoms

Inhalation: No specific data.Ingestion: No specific data.

**Skin** : Adverse symptoms may include the following:

irritation redness

**Eyes**: Adverse symptoms may include the following:

pain or irritation watering redness

#### Indication of immediate medical attention and special treatment needed, if necessary

**Specific treatments**: No specific treatment.

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed.

The exposed person may need to be kept under medical surveillance for 48 hours.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It

may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear

gloves.

See toxicological information (Section 11)

# Section 5. Firefighting measures

#### **Extinguishing media**

**Suitable** : Use dry chemical, CO<sub>2</sub>, water spray (fog) or foam.

Not suitable : Do not use water jet.

Specific hazards arising from the chemical

: Combustible liquid. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. This material is very toxic to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Hazardous thermal decomposition products

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides

Hazchem code : 3Z

Special precautions for firefighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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#### Section 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

#### For emergency responders:

If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

#### **Environmental precautions**

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

#### Methods and material for containment and cleaning up

#### Small spill

: Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

#### Large spill

: Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with noncombustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

# Section 7. Handling and storage

#### **Protective measures**

**Protective measures** 

: Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not breathe vapour or mist. Do not ingest. Avoid release to the environment. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Empty containers retain product residue and can be hazardous. Do not reuse container.

#### **Advice on general** occupational hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

# including any incompatibilities

Conditions for safe storage, : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and wellventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidising materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

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## Section 8. Exposure controls/personal protection

#### **Control parameters**

#### Occupational exposure limits

Ingredient name	Exposure limits
praziquantel	Elanco OEL (ELANCO).
	TWA: 3 mg/m³ 8 hours.
Cyclo[( $\alpha$ R)- $\alpha$ -hydroxy-4-(4-morpholinyl)	Elanco OEL (ELANCO).
benzenepropanoyl-N-methyl-L-leucyl-(2R)	TWA: 28 μg/m³ 8 hours.
-2-hydroxypropanoyl-N-methyl-L-leucyl-(αR)-α-hydroxy-4-	
(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)	
-2-hydroxypropanoyl-N-methyl-L-leucyl]	

#### **Biological exposure indices**

No exposure indices known.

# Appropriate engineering controls

: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapour or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

# **Environmental exposure** controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

#### **Individual protection measures**

#### **Hygiene measures**

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

#### Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

#### **Skin protection**

**Hand protection** 

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

#### **Body protection**

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

#### Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

#### **Respiratory protection**

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

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# Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

#### **Appearance**

Physical state : Liquid.
Colour : Colourless.
Odour : weak

Odour threshold : Not available.

PH : Not available.

Melting point/freezing point : Not available.

Boiling point, initial boiling : 190°C (374°F)

point, and boiling range

Flash point : Closed cup: 80°C (176°F)

Evaporation rate
Flammability
Lower and upper explosion
limit/flammability limit

Not available.Not available.

: Not available.

Vapour pressure :

	Vapour Pressure at 20°C			Vapour pressure at 50°C		
Ingredient name	mm Hg	kPa	Method	mm Hg	kPa	Method
2,2-dimethyl- 1,3-dioxolan- 4-ylmethanol	-	0.032 to 0.036				

Relative vapour density : Not available.
Relative density : Not available.

**Density** : 1.081 g/cm³ [20°C (68°F)] [DIN 51757]

1:001 g/siii [20 0 (00 1 )] [Dii 1011 01

Solubility(ies) : Media Result

cold water Easily soluble Easily soluble

Solubility in water : Not available.

Miscible with water : Yes.

Partition coefficient: n-

octanol/water

: Not applicable.

**Auto-ignition temperature** 

Ingredient name	°C	°F	Method
Cyclo[(αR)-α-hydroxy-4- (4-morpholinyl)benzenepropanoyl-N- methyl-L-leucyl-(2R) -2-hydroxypropanoyl-N-methyl-L- leucyl-(αR)-α-hydroxy-4- (4-morpholinyl)benzenepropanoyl-N- methyl-L-leucyl-(2R) -2-hydroxypropanoyl-N-methyl-L- leucyl]	>230	>446	BAM method
lactic acid	400	752	EU A.15

Decomposition temperature : Not available.Viscosity : Not available.Flow time (ISO 2431) : Not available.

**Particle characteristics** 

Median particle size : Not applicable.

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## Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

**Chemical stability** : The product is stable.

Possibility of hazardous

reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

**Conditions to avoid** : Avoid all possible sources of ignition (spark or flame). Do not pressurise, cut, weld,

braze, solder, drill, grind or expose containers to heat or sources of ignition.

: Reactive or incompatible with the following materials: Incompatible materials

oxidising materials

**Hazardous decomposition** 

products

: Under normal conditions of storage and use, hazardous decomposition products

should not be produced.

# **Section 11. Toxicological information**

#### Information on likely routes of exposure

Inhalation : No known significant effects or critical hazards. Ingestion : No known significant effects or critical hazards.

**Skin contact** : Causes skin irritation. May cause an allergic skin reaction.

Eye contact : Causes serious eye irritation.

#### Symptoms related to the physical, chemical and toxicological characteristics

Inhalation : No specific data. : No specific data. Ingestion

Skin contact : Adverse symptoms may include the following:

> irritation redness

**Eye contact** Adverse symptoms may include the following:

pain or irritation

watering redness

## Delayed and immediate effects as well as chronic effects from short and long-term exposure

#### **Acute toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
Praziquantel	LD50 Dermal	Rat	>2000 mg/kg	-
	LD50 Oral	Rat	2249 mg/kg	-
Lactic acid	LC50 Inhalation Dusts and mists	Rat	>7.94 mg/l	4 hours
	LD50 Dermal	Rabbit	>2000 mg/kg	-
			(no mortality)	
	LD50 Oral	Rat	3543 mg/kg	-
Cyclo[(αR)-α-hydroxy-4-	LD50 Dermal	Rat	>2000 mg/kg	-
(4-morpholinyl)				
benzenepropanoyl-N-methyl-				
L-leucyl-(2R)				
-2-hydroxypropanoyl-N-				
methyl-L-leucyl-(αR)-α-				
hydroxy-4-(4-morpholinyl)				
benzenepropanoyl-N-methyl-				
L-leucyl-(2R)				
-2-hydroxypropanoyl-N-				
methyl-L-leucyl]	L D50 01	D-4	500 to 4000	
	LD50 Oral	Rat	500 to 1000 mg/	-
			kg	

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Butylated hydroxyanisole	LD50 Dermal	Rabbit	>2000 mg/kg	-	
	LD50 Oral	Rat	2 g/kg	-	

#### **Irritation/Corrosion**

Product/ingredient name	Result	Species	Score	Exposure	Observation
Lactic acid	Eyes - Severe irritant Skin - Moderate irritant	Rabbit Rabbit	-	750 ug 24 hours 100	-
	Skin - Severe irritant	Rabbit	-	mg 24 hours 5	-
	Skin - Severe irritant	Rabbit	-	mg 88 %	-

#### **Sensitisation**

Product/ingredient name	Route of exposure	Species	Result
Cyclo[(αR)-α-hydroxy-4- (4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl-(αR)-α- hydroxy-4-(4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl]		Guinea pig	Not sensitizing

#### Potential chronic health effects

General : May cause damage to organs through prolonged or repeated exposure. Once

sensitized, a severe allergic reaction may occur when subsequently exposed to very

low levels.

**Inhalation** : No known significant effects or critical hazards.

**Ingestion** : No known significant effects or critical hazards.

**Skin contact**: Once sensitized, a severe allergic reaction may occur when subsequently exposed

to very low levels.

Eye contact
 : No known significant effects or critical hazards.
 Carcinogenicity
 : No known significant effects or critical hazards.
 Mutagenicity
 : No known significant effects or critical hazards.
 Teratogenicity
 : No known significant effects or critical hazards.

**Developmental effects** : No known significant effects or critical hazards.

**Fertility effects**: No known significant effects or critical hazards.

#### **Chronic toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
Cyclo[(αR)-α-hydroxy-4- (4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl-(αR)-α- hydroxy-4-(4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl]		Mouse - Female	79.1 mg/kg	13 weeks
	Chronic LOAEL Oral Chronic NOAEL Oral	Rat - Male Mouse - Female	4.2 mg/kg 16.8 mg/kg	4 weeks 13 weeks

#### **Carcinogenicity**

Not available.

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# Section 11. Toxicological information

#### **Mutagenicity**

Product/ingredient name	Test	Experiment	Result
Cyclo[(αR)-α-hydroxy-4- (4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl-(αR)-α- hydroxy-4-(4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl]	OECD 471 Bacterial Reverse Mutation Test	Experiment: In vitro Subject: Bacteria	Negative
, ,,,	OECD 476 In vitro Mammalian Cell Gene Mutation Test	Experiment: In vitro Subject: Mammalian-Animal Cell: Germ	Negative
	OECD 473 In vitro Mammalian Chromosomal Aberration Test	Experiment: In vitro Subject: Mammalian-Animal Cell: Germ	Negative
	OECD 474 Mammalian Erythrocyte Micronucleus Test	Experiment: In vivo Subject: Mammalian-Animal Cell: Germ	Negative

#### **Teratogenicity**

Not available.

#### **Reproductive toxicity**

Not available.

#### Specific target organ toxicity (single exposure)

Not available.

#### Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
$Cyclo[(\alpha R)-\alpha-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl-(\alpha R)-\alpha-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl]$			central nervous system (CNS), Glucose Metabolism, kidneys, liver, pancreas

#### **Aspiration hazard**

Not available.

#### **Numerical measures of toxicity**

### **Acute toxicity estimates**

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Profender® Spot On Cat Praziquantel Lactic acid Cyclo[(αR)-α-hydroxy-4-(4-morpholinyl) benzenepropanoyl-N-methyl-L-leucyl-(2R) -2-hydroxypropanoyl-N-methyl-L-leucyl-(αR)-α- hydroxy-4-(4-morpholinyl)benzenepropanoyl-N- methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl- L-leucyl]	4193.2	N/A	N/A	N/A	N/A
	500	N/A	N/A	N/A	N/A
	500	N/A	N/A	N/A	N/A
	500	N/A	N/A	N/A	N/A

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# Section 11. Toxicological information

Butylated hydroxyanisole N/A N/A N/A N/A

# Section 12. Ecological information

#### **Ecotoxicity**

: This material is very toxic to aquatic life with long lasting effects.

#### **Aquatic and terrestrial toxicity**

Product/ingredient name	Result	Species	Exposure
praziquantel	Acute EC50 77 mg/l	Algae	72 hours
	Acute EC50 35 mg/l	Crustaceans	48 hours
	Acute LC50 29.22 mg/l Fresh water	Fish - Carassius auratus	96 hours
lactic acid	Acute EC50 3500 mg/l	Algae	72 hours
	Acute LC50 130 mg/l	Fish	96 hours
	Chronic NOEC 1900 mg/l	Algae	72 hours
Cyclo[(αR)-α-hydroxy-4- (4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl-(αR)-α-	Acute EC50 0.0021 mg/l	Daphnia - Daphnia magna	48 hours
hydroxy-4-(4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl]			
tert-butyl-4-methoxyphenol	EC50 3.4 mg/l	Crustaceans - Dreissena polymorpha	48 hours

#### Persistence/degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Cyclo[(αR)-α-hydroxy-4- (4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl-(αR)-α- hydroxy-4-(4-morpholinyl) benzenepropanoyl-N-methyl- L-leucyl-(2R) -2-hydroxypropanoyl-N- methyl-L-leucyl]	-	-	Not readily

#### **Bioaccumulative potential**

Product/ingredient name	LogPow	BCF	Potential
lactic acid	-0.72	-	Low
Cyclo[(αR)-α-hydroxy-4-	4.9	-	High
(4-morpholinyl)			
benzenepropanoyl-N-methyl-			
L-leucyl-(2R)			
-2-hydroxypropanoyl-N-			
methyl-L-leucyl-(αR)-α-			
hydroxy-4-(4-morpholinyl)			
benzenepropanoyl-N-methyl-			
L-leucyl-(2R)			
-2-hydroxypropanoyl-N-			
methyl-L-leucyl]			
tert-butyl-4-methoxyphenol	1	-	Low

#### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Not available.

: No known significant effects or critical hazards. Other adverse effects

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# Section 13. Disposal considerations

#### **Disposal methods**

The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapour from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

# **Section 14. Transport information**

	New Zealand - Land - road/ railway	IMDG	IATA
UN number	UN3082	UN3082	UN3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (EMODEPSIDE)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Emodepside)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Emodepside)
Transport hazard class(es)	9	9	9
Packing group	III	III	III
Environmental hazards	Yes.	Yes.	Yes.

#### **Additional information**

**New Zealand** 

: Hazchem code 3Z

**Remarks** Land - road/railway: This product is not regulated as a dangerous good when transported in sizes of  $\leq 5$  L or  $\leq 5$  kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

**IMDG** 

: This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

**IATA** 

: This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

Special precautions for user :

**Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments

: Not available.

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## **Section 15. Regulatory information**

**HSNO Approval Number** 

: HSR100757

**HSNO Group Standard** 

: Veterinary Medicines (Limited Pack Size, Finished Dose)

**HSNO Classification** 

FLAMMABLE LIQUIDS - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2 SKIN SENSITISATION - Category 1

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE - Category 2

SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1

**ACVM No.** : A009546

**Inventory list** 

New Zealand : All components are listed or exempted.

### Section 16. Other information

#### **History**

Date of issue/Date of

revision

: 11/23/2023

Date of previous issue

6/28/2023

Version

: 0.02

Key to abbreviations

: ADG = Australian Dangerous Goods

ADR = The European Agreement concerning the International Carriage of

Dangerous Goods by Road ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships,

1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

RID = The Regulations concerning the International Carriage of Dangerous Goods

by Rail

SGG = Segregation Group UN = United Nations

References : Not available.

Indicates information that has changed from previously issued version.

#### **Notice to reader**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact: Elanco Animal Health

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Product name : Profender NZ : ENGLISH

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