SAFETY DATA SHEETS

This SDS packet was issued with item:

078950736

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078950731 078950732 078950733 078950734 078950735 078950771



SAFETY DATA SHEET

Profender® Spot On Cat

Section 1. Identification

GHS product identifier

Product code

Other means of identification

- : Profender® Spot On Cat
- : 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;

Product name :Profender® Spot On CatUS : ENGLISHVersion : 0.02Date of revision : 19 July 2023Date of previous issue : 27 March 20231/14

Section 1. Identification

90204513; 90204514; 90204515; 90204516; 90204539; 90204544; 90204545; 90205234; 90205235; 90205710; 90205741; 90205742; 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; 90209515; 90209575; 90209587; 90209604; 90209606; 90209602; 90209588; Profender S.O. Cat; Profender® Spot On

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

Identified uses : Veterinary pharmaceutical.; Unfinished drug mixture

Uses advised against : None known.

Company Name : Elanco US Inc.

2500 Innovation Way Greenfield IN, US 46140

Telephone number : 1-877 Elanco1 (1-877-352-6261)

Emergency telephone

number

: Elanco Product Technical Support / Human or Animal Exposure Reporting:

1-888-545-5973

Email Transportation Emergency

telephone number

: CHEMTREC: 1-800-424-9300

: elanco sds@elancoah.com

(Outside U.S. CHEMTREC International: 00 1-703-527-3887)

Section 2. Hazards identification

OSHA/HCS status

: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture

: FLAMMABLE LIQUIDS - Category 4 EYE IRRITATION - Category 2A CARCINOGENICITY - Category 2

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (central nervous

system (CNS), Glucose Metabolism, kidneys, liver, pancreas) - Category 1

GHS label elements

Hazard pictograms





Signal word : Danger

Hazard statements : H227 - Combustible liquid.

H319 - Causes serious eye irritation. H351 - Suspected of causing cancer.

H372 - Causes damage to organs through prolonged or repeated exposure. (central

nervous system (CNS), Glucose Metabolism, kidneys, liver, pancreas)

Precautionary statements

Prevention: P280 - Wear protective gloves, protective clothing and eye or face protection.

P210 - Keep away from flames and hot surfaces. No smoking.

P260 - Do not breathe vapor.

P270 - Do not eat, drink or smoke when using this product.

P264 - Wash thoroughly after handling.

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Section 2. Hazards identification

Response : P314 - Get medical advice or attention if you feel unwell.

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.

Storage : P403 + P235 - Store in a well-ventilated place. Keep cool.

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

and international regulations.

Supplemental label

elements

: None known.

Hazards not otherwise

classified

: None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
lactic acid	<3	50-21-5
$Cyclo[(\alpha R)-\alpha-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl-(\alpha R)-\alpha-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl]$	≤3	155030-63-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified 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

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.

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.

Skin contact

: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention following exposure or if feeling unwell. Wash clothing before reuse. Clean shoes thoroughly before reuse.

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.

Most important symptoms/effects, acute and delayed Potential acute health effects

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Section 4. First aid measures

Eye contact Causes serious eye irritation.

Inhalation : No known significant effects or critical hazards. **Skin contact** : No known significant effects or critical hazards. : No known significant effects or critical hazards. Ingestion

Over-exposure signs/symptoms

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

pain or irritation watering redness

Inhalation : No specific data. Skin contact : No specific data. Ingestion : No specific data.

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

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.

Specific treatments : No specific treatment.

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.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

Unsuitable extinguishing

media

: Use dry chemical, CO₂, water spray (fog) or foam.

: 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.

Hazardous thermal decomposition products : Decomposition products may include the following materials: carbon dioxide

carbon monoxide nitrogen oxides

Special protective actions for fire-fighters

: 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.

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 spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

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Section 6. Accidental release measures

For emergency responders: If specialized 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 nonemergency personnel".

Environmental precautions

: Avoid dispersal of spilled 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).

Methods and materials 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 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 non-combustible, 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 spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

: Put on appropriate personal protective equipment (see Section 8). Do not breathe vapor or mist. Do not ingest. Avoid contact with eyes, skin and clothing. 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.

Conditions for safe storage, including any incompatibilities

: 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 well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
lactic acid	None.
emodepside	Elanco OEL (ELANCO).
	TWA: 28 μg/m³ 8 hours.
tert-butyl-4-methoxyphenol	None.

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Section 8. Exposure controls/personal protection

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, vapor 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. 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.

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.
Color : Colorless.
Odor : weak

Odor threshold : Not available.

pH : Not available.

Melting point/freezing point : Not available.

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

point, and boiling range

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Section 9. Physical and chemical properties and safety characteristics

Flash point Closed cup: 80°C (176°F)

: Not available. **Evaporation rate** : Not available. **Flammability** Lower and upper explosion : Not available. limit/flammability limit

Vapor pressure

	Vapor Pressure at 20°C			Vapor 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 vapor density

Relative density

Density Solubility(ies) : Not available. Not available.

1.081 g/cm³ [20°C (68°F)] [DIN 51757]

Media Result cold water Easily soluble Easily soluble hot water

Solubility in water

Miscible with water

Partition coefficient: n-

octanol/water

: Not available.

Yes.

: 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

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

: Not available.

Particle characteristics

Median particle size : Not applicable.

Section 10. Stability and reactivity

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

Chemical stability : The product is stable.

Possibility of hazardous reactions

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

: Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, **Conditions to avoid** braze, solder, drill, grind or expose containers to heat or sources of ignition.

: Reactive or incompatible with the following materials: Incompatible materials oxidizing materials

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Section 10. Stability and reactivity

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
lactic acid	LC50 Inhalation Vapor LD50 Dermal	Rat Rabbit	>7.94 mg/l >2000 mg/kg (no mortality)	4 hours -
	LD50 Oral	Rat	3543 mg/kg	-
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]	LD50 Dermal	Rat	>2000 mg/kg	-
, ,,	LD50 Oral	Rat	500 to 1000 mg/ kg	-

Irritation/Corrosion

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

Skin

: 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]: Non-irritating to the skin.

Eyes

: 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]: Non-irritating to the eyes.

Sensitization

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]	skin	Guinea pig	Not sensitizing	

Mutagenicity

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Section 11. Toxicological information

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 <i>In vitro</i> Mammalian Cell Gene Mutation Test	Experiment: In vitro Subject: Mammalian-Animal Cell: Germ	Negative
	OECD 473 <i>In vitro</i> 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

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
$Cyclo[(\alpha R)-\alpha-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl-(\alpha R)-\alpha-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl]$	Category 1	oral	central nervous system (CNS), Glucose Metabolism, kidneys, liver, pancreas

Aspiration hazard

Not available.

Information on the likely routes of exposure

: Not available.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

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Section 11. Toxicological information

Eye contact: Adverse symptoms may include the following:

pain or irritation watering redness

Inhalation: No specific data.Skin contact: No specific data.Ingestion: No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Long term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Potential chronic health effects

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]	Chronic LOAEL Oral	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

General : Causes damage to organs through prolonged or repeated exposure.

Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/ I)
Profender® Spot On Cat 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]	12402.4	16176.9	N/A	N/A	N/A
	3543	2500	N/A	N/A	N/A
	500	2500	N/A	N/A	N/A

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Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Iactic 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]	Acute EC50 3500 mg/l	Algae	72 hours
	Acute LC50 130 mg/l	Fish	96 hours
	Chronic NOEC 1900 mg/l	Algae	72 hours
	Acute EC50 0.0021 mg/l	Daphnia - Daphnia magna	48 hours

Persistence and 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-(α R)- α -			
hydroxy-4-(4-morpholinyl)			
benzenepropanoyl-N-methyl-			
L-leucyl-(2R)			
-2-hydroxypropanoyl-N-			
methyl-L-leucyl]			

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects

: No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: The generation of waste should be avoided or minimized 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

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Section 13. Disposal considerations

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. Vapor 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 spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	TDG Classification	Mexico Classification	IMDG	IATA
UN number	Not regulated.	UN3082	UN3082	UN3082	UN3082
UN proper shipping name	-	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (EMODEPSIDE)			
Transport hazard class(es)	-	9	9	9	0
Packing group	-	III	III	III	III
Environmental hazards	No.	Yes.	Yes.	Yes.	Yes.

Additional information

TDG Classification

: Product classified as per the following sections of the Transportation of Dangerous Goods Regulations: 2.43-2.45 (Class 9), 2.7 (Marine pollutant mark). Non-bulk packages of this product are not regulated as dangerous goods when transported by road or rail.

Mexico Classification

IMDG

IATA

: The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg.

: 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.

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: Not available. to IMO instruments

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

Clean Air Act Section 112 (b) Hazardous Air

Pollutants (HAPs)

: Not listed

Clean Air Act Section 602 Class I Substances

: Not listed

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Section 15. Regulatory information

Clean Air Act Section 602

Class II Substances

: Not listed

DEA List I Chemicals

(Precursor Chemicals)

: Not listed

DEA List II Chemicals

(Essential Chemicals)

: Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : FLAMMABLE LIQUIDS - Category 4

EYE IRRITATION - Category 2A

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (central nervous

system (CNS), Glucose Metabolism, kidneys, liver, pancreas) - Category 1

Composition/information on ingredients

Name	%	Classification
2,2-dimethyl-1,3-dioxolan- 4-ylmethanol	≥75 - ≤90	FLAMMABLE LIQUIDS - Category 4
lactic acid	<3	SERIOUS EYE DAMAGE - Category 1
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	ACUTE TOXICITY (oral) - Category 4 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (central nervous system (CNS), Glucose Metabolism, kidneys, liver, pancreas) (oral) - Category 1

State regulations

Massachusetts : None of the components are listed. **New York** : None of the components are listed. **New Jersey** : None of the components are listed. **Pennsylvania** : None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

Inventory list

United States : Not determined.

Section 16. Other information

History

Date of issue/Date of

revision

: 7/19/2023

Date of previous issue Version

: 3/27/2023

: 0.02

Key to abbreviations

: 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

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Section 16. Other information

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973

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

N/A = Not available 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.

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