

### Safety data sheet according to 29 CFR 1910.1200

## Norbrook Laboratories Ltd - Selamectin Spot for Cats (including puppies & kittens) - ANDA 200-663 Res: 69025

#### **SECTION 1: IDENTIFICATION**

**1.1 Product identifier:** Norbrook Laboratories Ltd - Selamectin Spot for Cats (including puppies & kittens) - ANDA

200-663 Res: 69025

Other means of identification:

Non-applicable

#### 1.2 Recommended use of the chemical and restrictions on use:

Relevant uses (Professional users): Veterinary Pharmaceutical Product Relevant uses (Industrial user): Veterinary Pharmaceutical Product Uses advised against: All uses not specified in this section or in section 7.3

#### 1.3 Name, U.S. address, and U.S. telephone number of the chemical manufacturer, importer, or other responsible party:

Norbrook Laboratories Ltd Carnbane Industrial Estate BT35 6QQ Newry - Northern Ireland

Phone: +44 (0)28 3026 4435 - Fax: +44 (0)28 3026 5060

http://www.norbrook.com

Norbrook, Inc. 9733 Loiret Blvd Lenexa, KS 66219

1.4 Emergency phone number: +44 (0)28 3026 4435 USA Emergency phone number: 913-599-5777

#### SECTION 2: HAZARD(S) IDENTIFICATION

#### 2.1 Classification of the substance or mixture:

#### 29 CFR 1910.1200:

Classification of the chemical in accordance with paragraph (d)(1)(i) of 29 CFR 1910.1200

Eye Irrit. 2A: Eye irritation, Category 2A, H319 Flam. Liq. 2: Flammable liquids, Category 2, H225 Repr. 2: Reproductive toxicity, Category 2, H361

STOT SE 3: Specific toxicity causing drowsiness and dizziness, single exposure, Category 3, H336

#### 2.2 Label elements:

#### 29 CFR 1910.1200:

#### Danger







#### **Hazard statements:**

Eye Irrit. 2A: H319 - Causes serious eye irritation.

Flam. Liq. 2: H225 - Highly flammable liquid and vapour.

Repr. 2: H361 - Suspected of damaging fertility or the unborn child.

STOT SE 3: H336 - May cause drowsiness or dizziness.

#### **Precautionary statements:**

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P280: Wear protective gloves/face protection/protective clothing/respiratory protection/protective footwear.

P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

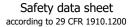
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308+P313: IF exposed or concerned: Get medical advice/attention.

P370+P378: In case of fire: Use Foam extinguisher (AB), Dry Chemical Powder (ABC) Fire Extinguisher, Carbon dioxide extinguisher (BC) to extinguish.

P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

Substances that contribute to the classification





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#### SECTION 2: HAZARD(S) IDENTIFICATION (continued)

propan-2-ol (CAS: 67-63-0); Selamectin (CAS: 165108-07-6)

#### 2.3 Hazards not otherwise classified (HNOC):

Non-applicable

#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances:

Non-applicable

#### 3.2 Mixtures:

Chemical description: Aqueous emulsion

#### Components:

Remaining components are non-hazardous and/or present at amounts below reportable limits. The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of 29 CFR 1910.1200.Therefore, in accordance with Appendix D to 29 CFR 1910.1200, the product contains:

Ide	ntification	Chemical name/Classification	
CAS:	67-63-0	propan-2-ol	Proprietary
		Eye Irrit. 2A: H319; Flam. Liq. 2: H225; STOT SE 3: H336 - Danger	
CAS:	165108-	Selamectin	Proprietary
	07-6	Repr. 2: H361 - Warning	

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

#### Other information:

Identification		M-factor
Selamectin	Acute	10000
CAS: 165108-07-6	Chronic	10000

#### SECTION 4: FIRST-AID MEASURES

#### 4.1 Description of necessary measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

#### By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

#### By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

#### By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

#### By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS of this product.

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

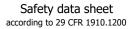
Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

#### **SECTION 5: FIRE-FIGHTING MEASURES**

- CONTINUED ON NEXT PAGE -





#### SECTION 5: FIRE-FIGHTING MEASURES (continued)

#### 5.1 Suitable (and unsuitable) extinguishing media:

#### Suitable extinguishing media:

Foam extinguisher (AB), Dry Chemical Powder (ABC) Fire Extinguisher, Carbon dioxide extinguisher (BC)

#### Unsuitable extinguishing media:

Water jet

#### 5.2 Specific hazards arising from the chemical:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

#### 5.3 Special protective equipment and precautions for fire-fighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

#### **Additional provisions:**

As in any fire, prevent human exposure to fire, smoke, fumes or products of combustion. Only properly trained personnel should be involved in firefighting. Evacuate nonessential personnel from the fire area. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inert medium. Remove any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

#### For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

#### 6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

#### 6.3 Methods and materials for containment and cleaning up:

For accidental releases in excess of reportables quantities (RQ) (Table 302.4), refer to 40 CFR 302 for detailed instructions concerning reporting requirements and notify the National Response Center (800) 424-8802.

Prevent the entrance of product in drains, sewers or watercourses. Absorb the spill using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. Collect the product in appropriate containers and manage it according to current legislation.

Spillages in water or sea:

Small spillages:

Contain spillage using barriers or similar equipment. Use suitable absorbents for collection and treat the waste in accordance with current regulations.

Large spillages:

If possible, contain spillage in open water using barriers or similar equipment. If this is not possible, try to control its spread and collect the product with suitable mechanical means. Always consult experts before using dispersants and make sure you have the necessary approvals if they are to be used. Treat the waste according to current regulations.

#### 6.4 Reference to other sections:

See sections 8 and 13.

#### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling:

A.- General precautions for safe use

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#### SECTION 7: HANDLING AND STORAGE (continued)

Comply with the current standards 29 CFR 1910 Occupational Safety and Health Standards. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Because the product is a flammable liquid, storage should meet the requirement of 29 CFR 1910.106, Flammable and Combustible Liquids Code. Transfer in well ventilated areas, preferably through localized extraction. Fully control sources of ignition (mobile phones, sparks,...) and ventilate during cleaning operations. Avoid the existence of dangerous atmospheres inside containers, applying inertization systems where possible. Transfer at a slow speed to avoid the creation of electrostatic charges. Against the possibility of electrostatic charges: ensure a perfect equipotential connection, always use groundings, do not wear work clothes made of acrylic fibres, preferably wearing cotton clothing and conductive footwear. Comply with the essential security requirements for equipment and systems and with the minimum requirements for protecting the security and health of workers. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

PREGNANT WOMEN SHOULD NOT BE EXPOSED TO THIS PRODUCT. Transfer in fixed places that comply with the necessary security conditions (emergency showers and eyewash stations in close proximity), using personal protection equipment, especially on the hands and face (See section 8). Limit manual transfers to containers of small amounts. Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

#### 7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Maximum Temp.: 86 of

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

#### 7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters:

Substances whose occupational exposure limits have to be assessed in the workplace:

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000):

Identification	Occupa	itional exposure lim	nits
propan-2-ol	8-hour TWA PEL	400 ppm	980 mg/m <sup>3</sup>
CAS: 67-63-0	Ceiling Values - TWA PEL		
Dipropylene Glycol Methyl Ether (1)	8-hour TWA PEL	100 ppm	600 mg/m <sup>3</sup>
CAS: 34590-94-8	Ceiling Values - TWA PEL		

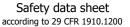
#### US. ACGIH Threshold Limit Values (2022):

Identification	Occupational exposure limits		nits
propan-2-ol	TLV-TWA	200 ppm	
CAS: 67-63-0	TLV-STEL	400 ppm	
Dipropylene Glycol Methyl Ether (1)	TLV-TWA	100 ppm	
CAS: 34590-94-8	TLV-STEL	150 ppm	
2,6-di-tert-butyl-p-cresol	TLV-TWA		2 mg/m <sup>3</sup>
CAS: 128-37-0	TLV-STEL		

#### CALIFORNIA- TABLE AC-1 PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS:

Identification	Occupational exposure limits		
propan-2-ol	PEL	400 ppm	980 mg/m <sup>3</sup>
CAS: 67-63-0	STEL	500 ppm	1225 mg/m <sup>3</sup>
Dipropylene Glycol Methyl Ether (1)	PEL	100 ppm	600 mg/m <sup>3</sup>
CAS: 34590-94-8	STEL	150 ppm	900 mg/m <sup>3</sup>
2,6-di-tert-butyl-p-cresol	PEL		10 mg/m <sup>3</sup>

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#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

CALIFORNIA- TABLE AC-1 PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS:

Identification	Occupa	tional exposure lim	its
CAS: 128-37-0	STEL		

#### NIOSH: Immediately Dangerous To Life or Health (IDLH) Values:

Identification	Occupational exposure limits		
propan-2-ol	TWA		
CAS: 67-63-0	IDLH Value	2000 ppm	
Dipropylene Glycol Methyl Ether (1)	TWA		
CAS: 34590-94-8	IDLH Value	600 ppm	

<sup>(1)</sup> Skin

#### **Biological limit values:**

Biological Exposure Indices (BEIs®) - ACGIH

Identification	BEIs®	Determinant	Sampling Time
propan-2-ol CAS: 67-63-0	40 mg/L	Acetone in urine	End of shift at end of workweek

#### 8.2 Appropriate engineering controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protection Equipment. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation, the information on clothing performance must be combined with professional judgment, and a clear understanding of the clothing application, to provide the best protection to the worker. All chemical protective clothing use must be based on a hazard assessment to determine the risks for exposure to chemicals and other hazards. Conduct hazard assessments in accordance with 29 CFR 1910.132.

#### B.- Respiratory protection

Pictogram	PPE	Remarks
Mandatory respiratory tract protection	Filter mask for gases and vapours (Filter type: A)	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment. Use respirator in accordance with manufacturer's use limitations and OSHA standard 1910.134 (29CFR)

#### C.- Specific protection for the hands

Pictogram	PPE	Remarks
Mandatory hand protection	Chemical protective gloves (Material: Linear low- density polyethylene (LLDPE), Breakthrough time: > 480 min, Thickness: 0.062 mm)	The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. Do not use protective creams after the product has come into contact with skin. Use gloves in accordance with manufacturer 's use limitations and OSHA standard 1910.138 (29CFR)

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

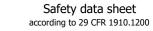
#### D.- Eye and face protection

Pictogram	PPE	Remarks
Mandatory face protection	Face shield	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. Use this PPE in accordance with manufacturer's use limitations and OSHA standard 1910.133 (29CFR)

#### E.- Bodily protection

Pictogram	PPE	Remarks
Mandatory complete	Disposable clothing for protection against chemical risks, with antistatic and fireproof properties	For professional use only. Clean periodically according to the manufacturer 's instructions.

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#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Remarks
Mandatory foot protection	Safety footwear for protection against chemical risk, with antistatic and heat resistant properties	Replace boots at any sign of deterioration.

#### F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

Emerge	ency measure	Standards	Emergency measure	Standards
	ency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

#### **Environmental exposure controls:**

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

#### 40 CFR Part 59 (VOC):

V.O.C.(weight-percent): 93.92 % weight

V.O.C. at 68 °F: 747.73 kg/m³ (747.73 g/L)

#### California Air Resources Board (CARB) - VOC Regulatory:

V.O.C.(weight-percent): 93.92 % weight

V.O.C. at 68 °F: 747.73 kg/m³ (747.73 g/L)

#### South Coast Air Quality Management District (AQMD) - VOC Regulatory:

V.O.C.(weight-percent): 93.92 % weight

V.O.C. at 68 °F: 747.73 kg/m³ (747.73 g/L)

Ozone Transport Commission (OTC) Rules - VOC Regulatory:

V.O.C.(weight-percent): 93.92 % weight

V.O.C. at 68 °F: 747.73 kg/m³ (747.73 g/L)

#### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

For complete information see the product datasheet.

#### Appearance:

Physical state at 68 °F: Liquid

Appearance: Non-applicable \*
Color: Non-applicable \*
Odor: Non-applicable \*
Odour threshold: Non-applicable \*

Volatility:

Boiling point at atmospheric pressure: 186 °F Vapour pressure at 68 °F: 4968 Pa

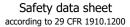
Vapour pressure at 122 °F: 24953.82 Pa (24.95 kPa)

Evaporation rate at 68 °F: Non-applicable \*

**Product description:** 

Density at 68 °F: 796.1 kg/m<sup>3</sup>

\*Non-applicable due to the nature of the product, not providing information property of its hazards.





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Non-applicable \*

#### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Relative density at 68 °F: 0.796 Dynamic viscosity at 68 °F: 2.41 mPa·s Kinematic viscosity at 68 °F: 3.02 mm<sup>2</sup>/s Kinematic viscosity at 104 °F: Non-applicable \* Concentration: Non-applicable \* pH: Non-applicable \* Vapour density at 68 °F: Non-applicable \* Partition coefficient n-octanol/water 68 °F: Non-applicable \* Solubility in water at 68 °F: Non-applicable \* Solubility properties: Non-applicable \* Decomposition temperature: Non-applicable \*

Flammability:

Flash Point: 70 °F

Flammability (solid, gas): Non-applicable \*

Autoignition temperature: 518 °F

Lower flammability limit: Non-applicable \*
Upper flammability limit: Non-applicable \*

**Particle characteristics:** 

Melting point/freezing point:

Median equivalent diameter:

Non-applicable \*

#### 9.2 Other information:

#### Information with regard to physical hazard classes:

Explosive properties:

Oxidising properties:

Non-applicable \*

Corrosive to metals:

Heat of combustion:

Aerosols-total percentage (by mass) of flammable components:

Non-applicable \*

Non-applicable \*

Other safety characteristics:

Surface tension at 68 °F:

Refraction index:

\*Non-applicable \*

\*Non-applicable due to the nature of the product, not providing information property of its hazards.

#### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

#### 10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

#### 10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

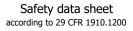
#### 10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	1	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable		Not applicable	Risk of combustion	Avoid direct impact	Not applicable

#### 10.5 Incompatible materials:

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#### SECTION 10: STABILITY AND REACTIVITY (continued)

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

#### 10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO<sub>2</sub>), carbon monoxide and other organic compounds.

#### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

#### **Dangerous health implications:**

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

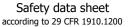
- A- Ingestion (acute effect):
  - Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
  - Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- B- Inhalation (acute effect):
  - Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
  - Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- C- Contact with the skin and the eyes (acute effect):
  - Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
  - Contact with the eyes: Produces eye damage after contact.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
  - Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
    - IARC: propan-2-ol (3); 2,6-di-tert-butyl-p-cresol (3)
  - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
  - Reproductive toxicity: Suspected of damaging fertility or the unborn child
- E- Sensitizing effects:
  - Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
  - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- F- Specific target organ toxicity (STOT) single exposure:

Exposure in high concentration can cause a breakdown in the central nervous system causing headache, dizziness, vertigo, nausea, vomiting, confusion, and in serious cases, loss of consciousness.

- G- Specific target organ toxicity (STOT)-repeated exposure:
  - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
  - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

#### Other information:





#### SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Non-applicable

#### Specific toxicology information on the substances:

Identification	Acute	Acute toxicity	
propan-2-ol	LD50 oral	>5840 mg/kg	Rat
CAS: 67-63-0	LD50 dermal	>13900 mg/kg	Rabbit
	LC50 inhalation vapour	>25 mg/L (6 h)	Rat
Selamectin	LD50 oral	>5000 mg/kg	
CAS: 165108-07-6	LD50 dermal	>5000 mg/kg	
	LC50 inhalation vapour	>20 mg/L	

#### **Acute Toxicity Estimate (ATE mix):**

ATE mix		Ingredient(s) of unknown toxicity	
Oral	>5000 mg/kg (Calculation method)	0 %	
Dermal	>5000 mg/kg (Calculation method)	0 %	
LC50 inhalation vapour	>20 mg/L (4 h) (Calculation method)	0 %	

#### SECTION 12: ECOLOGICAL INFORMATION

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

#### 12.1 Ecotoxicity (aquatic and terrestrial, where available):

#### **Product-specific aquatic toxicity:**

Acute toxicity		Species	Genus	
LC50	4.4 mg/L (96 h)	Non-applicable	Fish	
EC50	0 mg/L (48 h)	Non-applicable	Crustacean	

#### Substance-specific aquatic toxicity:

#### Acute toxicity:

Identification	Concentration		Species	Genus
propan-2-ol	LC50	9640 mg/L (96 h)	Pimephales promelas	Fish
CAS: 67-63-0	EC50	10000 mg/L (24 h)	Daphnia magna	Crustacean
	EC50	Non-applicable		
Selamectin	LC50	0.266 mg/L (96 h)	N/A	Fish
CAS: 165108-07-6	EC50	0.000026 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	Non-applicable		

#### **Chronic toxicity:**

Identification		Concentration	Species	Genus
Selamectin	NOEC	>0.00001 - 0 mg/L		Fish
CAS: 165108-07-6	NOEC	>0.00001 - 0 mg/L		Crustacean

#### 12.2 Persistence and degradability:

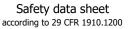
#### **Substance-specific information:**

Identification	Degradability		Biodegradability	
propan-2-ol	BOD5	1.19 g O2/g	Concentration	100 mg/L
CAS: 67-63-0	COD	2.23 g O2/g	Period	14 days
	BOD5/COD	0.53	% Biodegradable	86 %

#### 12.3 Bioaccumulative potential:

#### **Substance-specific information:**

Identification	Bioaccumulation potential		
propan-2-ol	BCF	3	
CAS: 67-63-0	Pow Log	0.05	
	Potential	Low	





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#### SECTION 12: ECOLOGICAL INFORMATION (continued)

#### 12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
propan-2-ol	Koc	1.5	Henry	8.207E-1 Pa·m³/mol
CAS: 67-63-0	Conclusion	Very High	Dry soil	Yes
	Surface tension	2.24E-2 N/m (77 °F)	Moist soil	Yes

#### 12.5 Results of PBT and vPvB assessment:

Non-applicable

#### 12.6 Other adverse effects:

Not described

#### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Disposal methods:

The next characteristic per RCRA could apply to the unused product if it becomes a waste material: Ignitability. The next EPA hazardous waste number could apply: D001.

IT IS THE RESPONSIBILITY OF THE WASTE GENERATOR TO EVALUATE WHETHER HIS WASTES ARE HAZARDOUS BY CHARACTERISTICS OR LISTING.

#### Waste management (disposal and evaluation):

Follow RCRA framework and EPA regulation for to ensure that hazardous waste is managed safely and properly. Waste should not be disposed of to drains. Remind, It is the responsibility of the waste generator to evaluate whether his wastes are hazardous by characteristics or listing. See section 6 for further information about Accidental release measures.

#### Regulations related to waste management:

Legislation related to waste management:

40 CFR Solid Wastes - Part 239 through 282.

State regulatory requirements for generators may be more stringent than those in the federal program. Be sure to check the state's policies.

#### SECTION 14: TRANSPORT INFORMATION

#### Transport of dangerous goods by land:

With regard to 49 CFR on the Transport of Dangerous Goods:



**14.1 UN number:** UN1993

**14.2 UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (propan-2-ol; Selamectin)

14.3 Transport hazard class(es): 3
 Labels: 3

 14.4 Packing group, if applicable: II
 14.5 Marine pollutant: Yes

14.6 Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises

Physico-Chemical properties: see section 9

Limited quantities: 1 L

Under 49 CFR 171.4, Except when transporting aboard a vessel, the requirements of this subchapter specific to marine pollutants do not apply to non-bulk packagings transported by motor vehicles, rail cars,

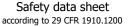
and aircraft

14.7 Transport in bulk (according Non-applicable

to Annex II of MARPOL 73/78 and the IBC Code):

#### Transport of dangerous goods by sea:

With regard to IMDG 41-22:





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#### SECTION 14: TRANSPORT INFORMATION (continued)

**14.1 UN number:** UN1993

**14.2 UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (propan-2-ol; Selamectin)

> 14.3 Transport hazard class(es): 3
Labels: 3
14.4 Packing group, if applicable: II

14.5 Marine pollutant:

14.6 Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises

Special regulations: 274

EmS Codes: F-E, S-E

Physico-Chemical properties: see section 9

Limited quantities: 1 L

Segregation group: Non-applicable **Transport in bulk (according** Non-applicable

14.7 Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):

#### Transport of dangerous goods by air:

With regard to IATA/ICAO 2025:



**14.1 UN number:** UN1993

**14.2 UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (propan-2-ol; Selamectin)

14.3 Transport hazard class(es): 3
 Labels: 3

 14.4 Packing group, if applicable: II
 14.5 Marine pollutant: Yes

14.6 Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises

Physico-Chemical properties: see section 9

to Annex II of MARPOL 73/78 and the IBC Code):

14.7 Transport in bulk (according

Non-applicable

#### SECTION 15: REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations specific for the product in question:

- CALIFORNIA LABOR CODE The Hazardous Substances List: propan-2-ol (67-63-0)
- California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) Birth defects or other reproductive harm: Non-applicable
- California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) Cancer: Non-applicable
- CANADA-Domestic Substances List (DSL): propan-2-ol (67-63-0)
- CANADA-Non-Domestic Substances List (NDSL): Non-applicable
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Reportable Quantities: Non-applicable
- Hazardous Air Pollutants (Clean Air Act): Non-applicable
- Massachusetts RTK Substance List: propan-2-ol (67-63-0)
- Minnesota Hazardous substances ERTK: propan-2-ol (67-63-0)
- New Jersey Worker and Community Right-to-Know Act: propan-2-ol (67-63-0)
- New York RTK Substance list: propan-2-ol (67-63-0)
- NTP (National Toxicology Program): Non-applicable
- OSHA Specifically Regulated Substances (29 CFR 1910.1001-1096): Non-applicable
- Pennsylvania Worker and Community Right-to-Know Law: Non-applicable
- Protective Action Criteria (PAC) with AEGLs, ERPGs, & TEELs: propan-2-ol (67-63-0)
- Rhode Island Hazardous substances RTK: Non-applicable
- SB-258 Cleaning Product Right to Know Act: propan-2-ol (67-63-0)
- The Toxic Substances Control Act (TSCA): propan-2-ol (67-63-0)
- Toxic chemical release reporting under EPCRA section 313 (40 CFR Part 372): propan-2-ol (67-63-0)

Specific provisions in terms of protecting people or the environment:

# No.

### Safety data sheet according to 29 CFR 1910.1200

## Norbrook Laboratories Ltd - Selamectin Spot for Cats (including puppies & kittens) - ANDA 200-663

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#### SECTION 15: REGULATORY INFORMATION (continued)

It is recommended to use the information provided in this safety data sheet as a foundation for conducting workplace-specific risk assessments. These assessments will help establish the appropriate risk prevention measures for handling, using, storing, and disposing of this product.

#### Other legislation:

Take into consideration other applicable federal, state, and local laws and local regulations.

#### **SECTION 16: OTHER INFORMATION**

#### Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with Appendix d to 29 CFR 1910.1200 - Safety data sheets

#### Texts of the legislative phrases mentioned in section 2:

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

H361: Suspected of damaging fertility or the unborn child.

H225: Highly flammable liquid and vapour.

#### Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

#### 29 CFR 1910.1200:

Eye Irrit. 2A: H319 - Causes serious eye irritation.

Flam. Liq. 2: H225 - Highly flammable liquid and vapour.

Repr. 2: H361 - Suspected of damaging fertility or the unborn child.

STOT SE 3: H336 - May cause drowsiness or dizziness.

#### Advice related to training:

According to 29 CFR 1910. 1200, training on chemical hazards is necessary for employees using this product. This training will facilitate their understanding and interpretation of the safety data sheet, as well as the product label.

#### Principal bibliographical sources:

Occupational Safety & Health Administration (OSHA).

#### **Abbreviations and acronyms:**

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor LD50: Lethal Dose 50 CL50: Lethal Concentration 50 EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient Koc: Partition coefficient of organic carbon IARC: International Agency for Research on Cancer

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END OF SAFETY DATA SHEET

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