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Safety data sheet
According to 1907/2006/EC (REACH), 453/2010/EU, 2015/830/EU

**Norbrook® Norbrook Laboratories Ltd - Noromectin 0.5% w/v Pour-On Solution
- Vm 02000/4172
Res : 94602**

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** Norbrook Laboratories Ltd - Noromectin 0.5% w/v Pour-On Solution - Vm 02000/4172
Res : 94602
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Veterinary Pharmaceutical Product
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:** Norbrook Laboratories Ltd
Cambane Industrial Estate
BT35 6QQ Newry - Northern Ireland
Phone.: +44 (0)28 3026 4435 -
Fax: +44 (0)28 3026 5060
<http://www.norbrook.com>
- 1.4 Emergency telephone number:** +44 (0)28 3026 4435

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

CLP Regulation (EC) n° 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) n° 1272/2008.

Acute Tox. 4: Acute toxicity if swallowed, Category 4, H302

Aquatic Chronic 3: Hazardous to the aquatic environment, long-term hazard, Category 3, H412

Eye Irrit. 2: Eye irritation, Category 2, H319

Flam. Liq. 2: Flammable liquids, Category 2, H225

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

2.2 Label elements:

CLP Regulation (EC) n° 1272/2008:

Danger



Hazard statements:

Acute Tox. 4: H302 - Harmful if swallowed

Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects

Eye Irrit. 2: H319 - Causes serious eye irritation

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

STOT SE 3: H336 - May cause drowsiness or dizziness

Precautionary statements:

P101: If medical advice is needed, have product container or label at hand

P102: Keep out of reach of children

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

P264: Wash thoroughly after use

P280: Wear protective gloves/protective clothing/eye protection/face protection

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

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

P501: Dispose of contents and / or their container according to the separated collection system used in your municipality

Substances that contribute to the classification

Propan-2-ol; Ivermectin

(N.B. This mixture is regulated under the Veterinary Medicines Directive and will be labelled accordingly).

2.3 Other hazards:

Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continue)

Non-applicable

3.2 Mixture:

Chemical description: Pour On Solution

Components:

In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 67-63-0 EC: 200-661-7 Index: 603-117-00-0 REACH: 01-2119457558-25-XXXX	Propan-2-ol Regulation 1272/2008: Eye Irrit. 2: H319; Flam. Liq. 2: H225; STOT SE 3: H336 - Danger ATP CLP00	75 - <100 %
CAS: 70288-86-7 EC: 274-536-0 Index: Non-applicable REACH: Non-applicable	Ivermectin Regulation 1272/2008: Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410; Repr. 2: H361d - Danger Not classified	<1 %

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid 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 modifications on 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:

Request medical assistance immediately, showing the SDS of this product. Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. In the case of loss of consciousness do not administrate anything orally unless supervised by a doctor. Rinse out the mouth and throat, as they may have been affected during ingestion. Keep the person affected at rest.

4.2 Most important symptoms and effects, both acute and delayed:

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

4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

If possible use polyvalent powder fire extinguishers (ABC powder), alternatively use foam or carbon dioxide extinguishers (CO2). IT IS RECOMMENDED NOT to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

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 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

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SECTION 5: FIREFIGHTING MEASURES (continue)

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. 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:

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 inertization agent. Destroy 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.

6.2 Environmental precautions:

Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed containers. Notify the relevant authority in case of exposure to the general public or the environment.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. 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

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 defined in Directive 94/9/EC (ATEX 100) and with the minimum requirements for protecting the security and health of workers under the selection criteria of Directive 1999/92/EC (ATEX 137). Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

Due to the danger of this product for the environment it is recommended to use it within an area containing contamination control barriers in case of spillage, as well as having absorbent material in close proximity.

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Maximun Temp.: 30 °C

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):

For the treatment and control of gastrointestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice of beef and non-lactating dairy cattle.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

There are no environmental limits for the substances contained in the product

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	888 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	500 mg/m ³	Non-applicable

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	Oral	Non-applicable	Non-applicable	26 mg/kg	Non-applicable
	Dermal	Non-applicable	Non-applicable	319 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	89 mg/m ³	Non-applicable

PNEC:

Identification					
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	STP	2251 mg/L	Fresh water	140.9 mg/L	
	Soil	28 mg/kg	Marine water	140.9 mg/L	
	Intermittent	140.9 mg/L	Sediment (Fresh water)	552 mg/kg	
	Oral	160 g/kg	Sediment (Marine water)	552 mg/kg	



8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. 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 which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.



B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours		EN 405:2001+A1:2009	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.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Chemical protective gloves		EN 420:2003+A1:2009	Replace the gloves at any sign of deterioration.





D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN 172:1994/A1:2000 EN 172:1994/A2:2001 EN ISO 4007:2012	Clean dally and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.



E.- Bodily protection

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory complete body protection	Antistatic and fireproof protective clothing		EN 1149-1:2006 EN 1149-2:1997 EN 1149-3:2004 EN 168:2001 EN ISO 14116:2008/AC:2009 EN 1149-5:2008	Limited protection against flames.
 Mandatory foot protection	Safety footwear with antistatic and heat resistant properties		EN 13287:2008 EN ISO 20345:2011 EN ISO 20344:2011	Replace boots at any sign of deterioration.

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	76.95 % weight
V.O.C. density at 20 °C:	617.47 kg/m ³ (617.47 g/L)
Average carbon number:	3
Average molecular weight:	60.1 g/mol

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 20 °C:	Liquid
Appearance:	Not available
Color:	 Blue
Odor:	Undefined

Volatility:

Boiling point at atmospheric pressure:	82 °C
Vapour pressure at 20 °C:	5100 Pa
Vapour pressure at 50 °C:	25615 Pa (26 kPa)
Evaporation rate at 20 °C:	Non-applicable *

Product description:

Density at 20 °C:	802 kg/m ³
Relative density at 20 °C:	0.802
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continue)

pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	12 °C
Autoignition temperature:	324 °C
Lower flammability limit:	Not available
Upper flammability limit:	Not available

9.2 Other information:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant 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 if the following technical instructions storage of chemicals. See section 7.

10.2 Chemical stability:

Chemically stable under the 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	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Risk of combustion	Avoid direct impact	Not applicable

10.5 Incompatible materials:

Acids	Water	Combustive materials	Combustible materials	Others
Not applicable	Not applicable	Avoid direct impact	Not applicable	Not applicable

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 (CO₂), 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:

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SECTION 11: TOXICOLOGICAL INFORMATION (continue)

- Acute toxicity: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.
 - Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- B- Inhalation:
- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous 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 dangerous for this effect. For more information see section 3.
- C- Contact with the skin and the eyes:
- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous 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 dangerous for the effects mentioned. For more information see section 3.
 - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
 - Reproductive toxicity: Based on available data, the classification criteria are not met, however it does contain substances classified as dangerous for this effect. For more information see section 3.
- E- Sensitizing effects:
- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitizing effects. For more information see section 3.
 - Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- F- Specific target organ toxicity (STOT)-time exposure:
- Exposure in high concentrations can cause a breakdown in the central nervous system causing headache, dizziness, vertigo, nausea, vomiting, confusion, and in serious cases, loss of concentration.
- 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 dangerous 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 dangerous 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 dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	LD50 oral	5280 mg/kg	Rat
	LD50 dermal	12800 mg/kg	Rat
	LC50 inhalation	72.6 mg/L (4 h)	Rat
Ivermectin CAS: 70288-86-7 EC: 274-536-0	LD50 oral	5 mg/kg (ATEI)	
	LD50 dermal	Non-applicable	
	LC50 Inhalation	Non-applicable	

SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Toxicity:

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SECTION 12: ECOLOGICAL INFORMATION (continue)

Identification	Acute toxicity		Specie	Genus
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	LC50	9640 mg/L (96 h)	Pimephales promelas	Fish
	EC50	13299 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	1000 mg/L (72 h)	Scenedesmus subspicatus	Algae
Ivermectin CAS: 70288-86-7 EC: 274-536-0	LC50	0.1 - 1 mg/L (96 h)		Fish
	EC50	0.1 - 1 mg/L		Crustacean
	EC50	0.1 - 1 mg/L		Algae

12.2 Persistence and degradability:

Identification	Degradability		Biodegradability	
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	BOD5	1.19 g O2/g	Concentration	100 mg/L
	COD	2.23 g O2/g	Period	14 days
	BOD5/COD	0.53	% Biodegradable	86 %

12.3 Bioaccumulative potential:

Identification	Bioaccumulation potential	
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	BCF	3
	Pow Log	0.05
	Potential	Low

12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
Propan-2-ol CAS: 67-63-0 EC: 200-661-7	Koc	1.5	Henry	8.207E-1 Pa·m ³ /mol
	Conclusion	Very High	Dry soil	Yes
	Surface tension	22400 N/m (25 °C)	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 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 03 05*	Organic wastes containing dangerous substances	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP14 Ecotoxic, HP3 Flammable, HP4 Irritant — skin irritation and eye damage, HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity, HP6 Acute Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommend disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2015 and RID 2015:

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SECTION 14: TRANSPORT INFORMATION (continue)



- 14.1 UN number:** UN1993
14.2 UN proper shipping name: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
14.3 Transport hazard class(es): 3
 Labels: 3
14.4 Packing group: II
14.5 Dangerous for the environment: No
14.6 Special precautions for user
 Special regulations: 274, 601, 640D
 Tunnel restriction code: D/E
 Physico-Chemical properties: see section 9
 Limited quantities: 1 L
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 37-14:



- 14.1 UN number:** UN1993
14.2 UN proper shipping name: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
14.3 Transport hazard class(es): 3
 Labels: 3
14.4 Packing group: II
14.5 Dangerous for the environment: No
14.6 Special precautions for user
 Special regulations: 274, 944
 EmS Codes: F-E, S-E
 Physico-Chemical properties: see section 9
 Limited quantities: 1 L
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2015:



- 14.1 UN number:** UN1993
14.2 UN proper shipping name: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
14.3 Transport hazard class(es): 3
 Labels: 3
14.4 Packing group: II
14.5 Dangerous for the environment: No
14.6 Special precautions for user
 Physico-Chemical properties: see section 9
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable
 Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable
 Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

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SECTION 15: REGULATORY INFORMATION (continue)

Active substances for which a decision of non-inclusion onto Annex I (Regulation (EU) No 528/2012): Non-applicable
REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):
Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

Texts of the legislative phrases mentioned in section 2:

H319: Causes serious eye irritation
H336: May cause drowsiness or dizziness
H412: Harmful to aquatic life with long lasting effects
H302: Harmful if swallowed
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

CLP Regulation (EC) n° 1272/2008:

Acute Tox. 2: H300 - Fatal if swallowed
Aquatic Acute 1: H400 - Very toxic to aquatic life
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects
Eye Irrit. 2: H319 - Causes serious eye irritation
Flam. Liq. 2: H225 - Highly flammable liquid and vapour
Repr. 2: H361d - Suspected of damaging the unborn child.
STOT SE 3: H336 - May cause drowsiness or dizziness

Classification procedure:

Eye Irrit. 2: Calculation method
STOT SE 3: Calculation method
Aquatic Chronic 3: Calculation method
Acute Tox. 4: Calculation method
Flam. Liq. 2: Calculation method (2.6.4.3)

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>
<http://echa.europa.eu>
<http://eur-lex.europa.eu>

Abbreviations and acronyms:

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SECTION 16: OTHER INFORMATION (continue)

- ADR: European agreement concerning the international carriage of dangerous goods by road
- 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

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -

According to Regulation (EC) No.1907/2006



PRODUCT SAFETY DATA SHEET

NOROMECTIN DRENCH

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

Product Name : Noromectin Drench

Supplier : Norbrook Laboratories (Ireland) Ltd,
Rossmore Industrial Estate,
Clones Road, Monaghan.
Republic of Ireland
Telephone No. +353 (0) 47 81180
Fax No. +353 (0) 47 81187
E-Mail: roienquiries@norbrook.co.uk.
Emergency Telephone +353 (0) 47 81180

2. HAZARDS IDENTIFICATION

Physical and Chemical Hazards : Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC.

Environmental Hazards : Ivermectin is harmful to aquatic life. Surface waters or ditches should not be contaminated with product or used containers.

Adverse Human Health Effects : None known

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation	Active Ingredients	Description	Chemical Family
Preparation	22, 23-Dihydroavermectin B ₁ (Ivermectin)	Anthelmintic Endectocide (Chemical Group 3-AV)	Avermectins

Hazardous Ingredients	% Wt.	CAS No.	EC No.	Symbol	Risk Phrases
Ivermectin	<0.1	69-52-3	200-708-1	Xn	42/43
NN-Dimethylacetamide	<5.0	127-19-5	204-826-4	T	61, 20/21

4. FIRST AID MEASURES

Inhalation : Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.

Skin Contact : Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.

Eyes Contact : Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Ingestion : Do not induce vomiting. Seek medical attention.

5. FIRE FIGHTING MEASURES

- Extinguishing media : Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours.
- Special fire-fighting procedure : Do not use a solid stream of water since the steam will scatter and spread the fire.
- Fire and explosion hazards : Fire-fighters should wear self-contained breathing apparatus and full protective equipment.
Dimethylacetamide is a non-flammable liquid.

6. ACCIDENTAL RELEASE MEASURES

- Personal Precautions : Eliminate all ignition sources. Prevent skin and eye contact.
- Environmental Precautions : Keep away from drains, surface-water, ground-water and soil.
- Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material.

7. HANDLING AND STORAGE

- Handling : Avoid contact with eyes, skin and clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use.
- Storage : Store in closed containers in a cool, dry, well-ventilated area away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light.
Keep container closed when not in use. Before opening large containers, release any pressure build-up by loosening closure slowly. Do not transfer contents to unlabelled containers. Do not store in aluminium containers. Use only with adequate ventilation. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Ivermectin		Not Established
NN-Dimethylacetamide	OES (8hr TWA)	10 ppm (36 mg/m ³)
	15 min - STEL	20 ppm (72 mg/m ³)

For pure ivermectin :

LD50 (Oral, mouse)	25 mg/kg
LD50 (Oral, rat)	50 mg/kg
LD50 (Dermal, rat)	> 660 mg/kg

- Protective Equipment : Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Labelling Information	:	None	
Safety Phrases	:	S2	Keep out of reach of children
		S7	Keep container tightly closed

16. OTHER INFORMATION

ML	:	2000/01	For Animal Treatment Only.
VPA	:	10999/78/1	

Revision Date	:	03/08/12
Revision No	:	07
Printing Date	:	02/01/2013

Risk Phrases

R42/43	:	May cause sensitisation by inhalation and skin contact.
R61	:	May cause harm to the unborn child.
R20/21	:	Harmful by inhalation and in contact with skin.

Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

The information contained in this PSDS is believed to be accurate and represents the best information available at the time of preparation. However Norbrook Laboratories (Ireland) Limited makes no warranty, express or implied, with respect to such information and assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes, and Norbrook Laboratories (Ireland) Limited will not be held liable for any damage resulting from the handling of or contact with the above product.



PRODUCT SAFETY DATA SHEET NOROMECTIN MULTI INJECTION FOR CATTLE, SHEEP AND PIGS

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

Product Name : Noromectin Multi Injection for Cattle, Sheep and Pigs
 Supplier : Norbrook Laboratories Ltd,
 Station Works, Newry, Co. Down,
 N. Ireland, BT35 6JP.

Telephone No. +44 (0) 28 3026 4435
 Fax No. +44 (0) 28 3026 1721
 E-Mail: enquiries@norbrook.co.uk
 Emergency Telephone +44 (0) 28 3026 4435

2. HAZARDS IDENTIFICATION

Physical and Chemical Hazards : Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC.
 Environmental Hazards : Ivermectin is harmful to aquatic life. Surface waters or ditches should not be contaminated with product or used containers.
 Adverse Human Health Effects : None known

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation : Preparation
 Active Ingredients : 2,2',23-Dihydroavermectin B₁ (Ivermectin)
 Description : Anthelmintic Endectocide (Chemical Group 3-AV)
 Chemical Family : Avermectins

4. FIRST AID MEASURES

Inhalation : Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.
 Skin Contact : Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.
 Eyes Contact : Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
 Ingestion : Do not induce vomiting. Seek medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing media: Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours.
 Fire and explosion hazards: None

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Provide good ventilation. Prevent skin and eye contact.

Environmental Precautions: Keep away from drains, surface-water, ground-water and soil.

Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material.

7. HANDLING AND STORAGE

Handling : Avoid contact with eyes, skin and clothing. Do not breathe vapours or mist. Do not ingest. Containers should be stored in their original boxes when not in use.

Storage : Store in closed containers in a cool, dry, well-ventilated area away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light.

Keep container closed when not in use. Before opening large containers, release any pressure build-up by loosening closure slowly. Do not transfer contents to unlabelled containers. Do not store in aluminium containers. Use only with adequate ventilation. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Ivermectin

Not Established

For pure ivermectin :

LD50 (Oral, mouse) 25 mg/kg

LD50 (Oral, rat) 50 mg/kg

LD50 (Dermal, rat) > 660 mg/kg

Protective Equipment : Wear vinyl or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Liquid

Colour : Clear, colourless

Odour : None

10. STABILITY AND REACTIVITY

Stability : Stable under normal conditions of storage and use.

Conditions to avoid : None known

Materials to avoid : Polyethylene glycol is incompatible with some colours. Strong acids and strong oxidising agents may evolve formaldehyde from the glycerol formal component.

11. TOXICOLOGICAL INFORMATION

Exposure Effects (Acute)

Eye Contact : Direct contact of the solution with eyes can cause irritation.

Skin Contact : Ivermectin is non-irritating in animal studies. Prolonged or repeated contact with Noromectin Multi Injection for Cattle, Sheep and Pigs may cause irritation and/or drying and cracking of the skin.

Inhalation : None known.

Ingestion : Oral toxicity of the Noromectin Multi Injection for Cattle, Sheep and Pigs solution is low. Pure ivermectin is considered highly toxic in acute animal studies.

If overexposed to ivermectin, symptoms may include decreased activity, slow rate of breathing, dilation of the pupils, muscle tremors and inco-ordination.

Exposure Effects (Chronic)

Unknown for the product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Ivermectin has tested negative in several mutagenicity studies.

12. ECOLOGICAL INFORMATION

Data on the ecological implications for Noromectin Multi Injection for Cattle, Sheep and Pigs is not yet available.

13. DISPOSAL CONSIDERATIONS

Product/Residues : Ivermectin is extremely dangerous to aquatic life. Do not discharge the material into surface or waste water. For disposal, use an incinerator licensed for chemical waste.

Package : Dispose of waste containers using regular disposal methods in accordance with local and national environmental regulations.

14. TRANSPORT INFORMATION

Land, Sea & Air Transport

ADR/RID, IMO/IMDG, IATA/ICAO, UN No. : Not applicable

15. REGULATORY INFORMATION

Labelling Information

Safety Phrases : S2 Keep out of reach of children
S7 Keep container tightly closed

16. OTHER INFORMATION

ML : 2000/01 For Animal Treatment Only.

Vm : 02000/4207

Revision Date : 31/08/12

Revision No : 08

Printing Date : 31/08/2012

Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

The information contained in this PSDS is believed to be accurate and represents the best information available at the time of preparation. However Norbrook Laboratories Limited makes no warranty, express or implied, with respect to such information and assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes, and Norbrook Laboratories Limited will not be held liable for any damage resulting from the handling of or contact with the above product.

According to Regulation (EC) No.1907/2006



PRODUCT SAFETY DATA SHEET

NOROMECTIN PASTE FOR HORSES

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

Product Name	Noromectin Paste for Horses
Supplier	Norbrook Laboratories (Ireland) Ltd, Rossmore Industrial Estate, Clones Road, Monaghan. Republic of Ireland Telephone No. +353 (0) 47 81180 Fax No. +353 (0) 47 81187 E-Mail: roienquiries@norbrook.co.uk. Emergency Telephone +353 (0) 47 81180

2. HAZARDS IDENTIFICATION

Physical and Chemical Hazards	:	Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC
Environmental Hazards	:	Ivermectin is harmful to aquatic life. Surface waters or ditches should not be contaminated with product or used containers.
Adverse Human Health Effects	:	None known

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation	:	Preparation
Active Ingredients	:	22, 23-Dihydroavermectin B ₁ (Ivermectin)
Description	:	Anthelmintic Endectocide (Chemical Group 3-AV)
Chemical Family	:	Avermectins

4. FIRST AID MEASURES

Inhalation	:	Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.
Skin Contact	:	Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.
Eyes Contact	:	Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.
Ingestion	:	Do not induce vomiting. Seek medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing media:	Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours.
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Fire and explosion hazards: None.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Provide good ventilation. Prevent skin and eye contact.
 Environmental Precautions : Keep away from drains, surface-water, ground-water and soil.
 Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material.

7. HANDLING AND STORAGE

Handling : Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use.
 Storage : Store in closed containers in a cool, dry, well-ventilated area, below 25°C and away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light.
 Keep container closed when not in use. Do not transfer contents to unlabelled containers. Use only with adequate ventilation. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Ivermectin

Not Established

For pure ivermectin :

LD50 (Oral, mouse)	25 mg/kg
LD50 (Oral, rat)	50 mg/kg
LD50 (Dermal, rat)	> 660 mg/kg

Protective Equipment : Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Viscous paste
 Colour : White
 Odour : None.

10. STABILITY AND REACTIVITY

Stability : Stable under normal temperatures and pressures.
 Conditions to avoid : None known
 Materials to avoid : None known

11. TOXICOLOGICAL INFORMATION

Exposure Effects (Acute)

Eye Contact	:	Direct contact of the paste suspension with eyes can cause irritation.
Skin Contact	:	Prolonged or repeated contact with Noromectin Equine Paste may cause irritation and/or drying and cracking of the skin.
Inhalation	:	None known.
Ingestion	:	Oral toxicity of the Noromectin Equine Paste is low. Pure ivermectin is considered highly toxic in acute animal studies. If overexposed to ivermectin, symptoms may include decreased activity, slow rate of breathing, dilation of the pupils, muscle tremors and inco-ordination.

Exposure Effects (Chronic)

Unknown for the product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Ivermectin has tested negative in several mutagenicity studies.

12. ECOLOGICAL INFORMATION

Data on the ecological implications for Noromectin Equine Paste is not yet available.

13. DISPOSAL CONSIDERATIONS

Product/Residues	:	Do not discharge the product material into surface or waste water. For disposal, use an incinerator licensed for chemical waste.
Package	:	Dispose of waste containers using regular disposal methods in accordance with local and national environmental regulations.

14. TRANSPORT INFORMATION

Land, Sea & Air Transport

ADR/RID, IMO/IMDG, IATA/ICAO, UN No. : Not applicable

15. REGULATORY INFORMATION

Labelling Information	:	None
Safety phrases	:	S2 Keep out of reach of children S7 Keep container tightly closed

16. OTHER INFORMATION

ML : 2000/01	For Animal Treatment Only	
VPA : 10999/91/1		
Revision Date	:	03/08/12
Revision No	:	07
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Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

