SAFETY DATA SHEETS

This SDS packet was issued with item:

078784792

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

078784776 078784784 078784800 078784818 078917087 078917088 078917089 078917090

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078914073 078917092 078917093 078917094

PRODUCT SAFETY DATA SHEET
NOROMECTIN PLUS INJECTION

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

Product Name	Noromectin Plus Injection (USA)
Supplier	Norbrook Laboratories Ltd,
	Station Works, Newry, Co.Down,
	N.Ireland, BT35 6JP.
Supplier	Norbrook, Inc.
	9733 Loiret Blvd
	Lenexa, KS 66219
	Phone: 913 599 5777
	Fax: 913 599 5766

2. COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Preparation	:	Preparation
Active Ingredients	:	22, 23-Dihydroavermectin B_1 (Ivermectin)
		Clorsulon
Description	:	Anthelmintic Endectocide (Chemical Group 3-AV)
Chemical Family	:	Avermectins / Benzenesulfonamides

3. 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

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. 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
Clorsulon	Not Established

For pure ivermectin :

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

For pure clorsulon :

LD50 (Oral, mouse)	>10000 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 : Liquid

Colour : Clear, pale yellow to yellow

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 Plus may cause irritation and/or drying and cracking of the skin.
Inhalation	:	None known.
Ingestion	:	Oral toxicity of the Noromectin Plus 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 Plus Injection 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 No., IMO/IMDG code, IATA/ICAO Class 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.

ANADA 200-436, approved by FDA

Revision Date	:	20/03/07
Revision No	:	01
Printing Date	:	23/03/2007

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.

Section 1 - Identification of Chemical Product and Company

Norbrook NZ Ltd **Freecall: 0800 224 022**
KPMG Centre, 18 Viaduct Harbour Ave
Auckland, New Zealand

Chemical nature: Ivermectin is a macrocyclic lactone; Clorsulon is a benzenesulphonamide derivative.

Trade Name: **Noromectin Plus**

Product Use: Broad-spectrum antiparasitic injection.

Creation Date: **August, 2016**

This version issued: **August, 2016** and is valid for 5 years from this date.

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: T, Toxic. N, Dangerous to the environment. Hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA and IMDG/IMSBC criteria.

SUSMP Classification: S5
ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.
UN Number: None allocated

ERMA Number: HSR001840
Haz Classes: 6.1D, 6.6B, 6.8B, 6.8C, 6.9B, 9.1A, 9.2C, 9.3C, 9.4A
Group Standard: None established.

GHS Signal word: DANGER

HAZARD STATEMENT:

H301: Toxic if swallowed.
H360: May damage fertility or the unborn child.
H362: May cause harm to breast-fed children.
H401: Toxic to aquatic life.

PREVENTION

P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe fumes, mists, vapours or spray.
P262: Do not get in eyes, on skin, or on clothing.
P263: Avoid contact during pregnancy or while nursing.
P264: Wash contacted areas thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P281: Use personal protective equipment as required.

RESPONSE

P301+P310: IF SWALLOWED: Immediately call a POISON CENTRE or doctor.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P308+P313: If exposed or concerned: Get medical advice.
P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P410: Protect from sunlight.
P411+P235: Store at temperatures not exceeding 25°C. Keep cool.

DISPOSAL

P501: Dispose of contents and containers as specified on the registered label.

Emergency Overview

Physical Description & Colour: Clear, pale yellow liquid.
Odour: Mild odour.
Major Health Hazards: may cause harm to unborn children, may cause harm to breastfed babies.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m^3)	STEL (mg/m^3)
Ivermectin	70288-86-7	10g/L	not set	not set
Clorsulon	60200-06-8	100g/L	not set	not set
Other non hazardous ingredients	secret	to 100	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak "is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Self Injection: Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.
Skin Contact: Wash gently and thoroughly with water (use non-abrasive soap if necessary) for 5 minutes or until chemical is removed.
Eye Contact: No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.
Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: There is no risk of an explosion from this product under normal circumstances if it is involved in a fire. Violent steam generation or eruption may occur upon application of direct water stream on hot liquids.
Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.
Extinguishing Media: Suitable extinguishing media are carbon dioxide, dry chemical, foam, water fog.
Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: Combustible liquid not meeting the AS 1940 definition of a Flammable Liquid.
Upper Flammability Limit: No data.
Lower Flammability Limit: No data.
Autoignition temperature: No data.
Flammability Class: Flammable Category 4 (GHS), C1 combustible (AS 1940)

Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern, except if spilled into waterways such as streams, lakes or dams. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product.

However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits **TWA (mg/m^3)** **STEL (mg/m^3)**

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

The ADI for Ivermectin is set at 0.001mg/kg/day. The corresponding NOEL is set at 0.1mg/kg/day.

The ADI for Clorsulon is set at 0.02mg/kg/day. The corresponding NOEL is set at 2mg/kg/day. ADI means Acceptable Daily Intake and NOEL means No-observable-effect-level. Values taken from Australian ADI List, June 2014.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

Eye Protection: Eye protection such as protective glasses or goggles is recommended when this product is being used.

Skin Protection: You should avoid contact even with mild skin irritants. Therefore you should wear suitable impervious elbow-length gloves and facial protection when handling this product. See below for suitable material types.

Protective Material Types: We suggest that protective clothing be made from the following materials: latex (gloves).

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Section 9 - Physical and Chemical Properties:

Physical Description & colour:	Clear, pale yellow liquid.
Odour:	Mild odour.
Boiling Point:	Not available.
Freezing/Melting Point:	No specific data. Liquid at normal temperatures.
Volatiles:	No specific data. Expected to be low at 100°C.
Vapour Pressure:	No data.
Vapour Density:	No data.
Specific Gravity:	1.15
Water Solubility:	No data. Based in ingredients, this is likely to be soluble.
pH:	5.5-6.3
Volatility:	No data.
Odour Threshold:	No data.
Evaporation Rate:	No data.
Coeff Oil/water Distribution:	No data
Autoignition temp:	No data.

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.
Conditions to Avoid: Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.
Incompatibilities: strong acids, strong bases, strong oxidising agents.
Fire Decomposition: Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Small quantities of nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Small quantities of oxides of sulfur (sulfur dioxide is a respiratory hazard) and other sulfur compounds. Most will have a foul odour. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.
Polymerisation: Polymerisation reactions are unlikely; they are not expected to occur.

Section 11 - Toxicological Information

Local Effects:
Target Organs: There is no data to hand indicating any particular target organs.

Ivermectin is a SWA Class 2 Reproductive risk, may cause harm to the unborn child.

Classification of Hazardous Ingredients

Ingredient	Risk Phrases
Ivermectin	>=1%Conc<3%: T; R61; R64; R25

Ivermectin: LD_{50} Oral, Mouse = 11.6mg/kg LD_{50} Dermal, Rat = >660mg/kg
LD_{50} Dermal, Rabbit = 406mg/kg

From plasma analyses in humans and in laboratory animals, after oral and/or parenteral administration of Ivermectin, the following half-lives have been calculated.

SPECIES	ROUTE	$T_{1/2}$
Human	Oral	10 - 12 hours
Rat	I.V.	1 day
Cattle	Oral	2.7 days
	S.C.	2.9 days
	Topical	15.9 days

Metabolism Ivermectin undergoes metabolism and is excreted mainly in the faeces. Ivermectin is little metabolised by mammals; 90% of the administered dose is excreted in the faeces and tissue residues are of the parent.
Elimination by route of exposure Ivermectin is excreted mainly in the faeces (unchanged), less than 1% appearing in the urine and less than 2% in breast milk. In animal studies, regardless of whether Ivermectin is administered parenterally or orally, only 0.5 to 2% of the dose is excreted in urine; the remainder (about 90%) appears in the faeces.
Clorsulon: LD_{50} Oral, Rat >10,000mg/kg LD_{50} Oral, Mouse = >10,000 mg/kg
There is no evidence of carcinogenicity for Clorsulon

Potential Health Effects

Inhalation:
Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.
Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:
Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. However product may be irritating, but is unlikely to cause anything more than mild transient discomfort.
Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:
Short Term Exposure: This product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.
Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. However, this product may be irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.
Long Term Exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA.
NTP: No significant ingredient is classified as carcinogenic by NTP.
IARC: No significant ingredient is classified as carcinogenic by IARC.

Section 12 - Ecological Information

Toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment. Do not contaminate dams, rivers or streams with product or empty containers.

IVERMECTIN: Very toxic to certain aquatic species.
LC_{50} - Daphnia magna, 48 hours = 0.025 ppb; NOEL Daphnia magna = 0.01 ppb;
LC_{50} - Rainbow trout, 96 hours = 3.0 ppb;
LC_{50} - Bluegill sunfish, 96 hours = 4.8 ppb.

ENVIRONMENTAL FATE (persistence, degradation, hydrolytic/photolytic stability, etc.): Ivermectin photodegrades rapidly in the environment and is metabolized in the soil. Water solubility is limited and it binds to soil very tightly. It does not bioconcentrate in fish and is not taken up from soil to plants. Both aquatic and terrestrial studies confirm rapid degradation of Ivermectin in the environment and lack of accumulation and persistence.

Section 13 - Disposal Considerations

Disposal: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

Section 14 - Transport Information

ADG Code: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.
ERMA Number: HSR001840
Group Standard: None established.

- 6.1D: Substances that are acutely toxic – Harmful.
- 6.6B: Substances that are suspected human mutagens.
- 6.8B: Substances that are suspected human reproductive or developmental toxicants.
- 6.8C: Substances that produce toxic human reproductive or developmental effects on or via lactation.
- 6.9B: Substances that are harmful to human target organs or systems.
- 9.1A: Substances that are very ecotoxic in the aquatic environment.
- 9.2C: Substances that are harmful in the soil environment.
- 9.3C: Substances that are harmful to terrestrial vertebrates.
- 9.4A: Substances that are very ecotoxic to terrestrial invertebrates.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)

R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS

OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

Date of preparation: August, 2016.