SAFETY DATA SHEETS

This SDS packet was issued with item:

078343405

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).

078343348 078343371 078823859 078823883 078823917

Material Safety Data Sheet
ISO/DIS 11014 / 29 CFR 1910.1200 / ANSI Z400.1

Printing date 05/25/2000 Reviewed on 05/25/2000

1 Identification of substance

· **Product details**

· **Trade name:** **Ivermectin**
HEARTGARD-30 PLUS

· **Product number:** 37811-37819, 19076I, 19086I, 19066I

· **Manufacturer/Supplier:**
Merial Limited
2100 Ronson Road
Iselin, NJ 08830-3077
· **Emergency information:**
Spill Information: CHEMTREC® 1-800-424-9300
CHEMTREC® International 1+703-527-3887
Reverse charges.
Health Information: 1-888-637-4251, Option 5

2 Composition/Data on components

· **Chemical characterization**
· **Description:** Mixture of the substances listed below.

Components:

Non hazardous inert ingredients		~88.0 %
15686-83-6	pyrantel T; R 25	3.0-7.94 %
57-55-6	Propylene Glycol	4.0 %
70288-86-7	Ivermectin Comp. Bla (C48H74O1) Comp. Blb (C47H72O14) T, N; R 20/21-25-50	0.0034 %

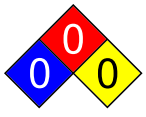
3 Hazards identification

· **Hazard description:**



Xn Harmful

· **Information pertaining to particular dangers for man and environment:**
R 22 Harmful if swallowed.
· **Classification system:**
The classification was made according to the latest editions of international substances lists, and from company and regulatory data.
· **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 0
Reactivity = 0

Obtained by Global Safety Management, Inc. (www.globalsafetynet.com)

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· **HMIS-ratings (scale 0 - 4)**

HEALTH	0
FIRE	0
REACTIVITY	0

4 First aid measures

· **After inhalation:** Not an expected route of entry.
· **After skin contact:**
No skin irritation is expected with this formulation.
· **After eye contact:**
Rinse opened eye for a minimum of 15 minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** Immediately call a doctor.
· **Information for doctor:**
· **The following symptoms may occur:**
Overexposure to ivermectin may cause drowsiness, depressed motor activity, slowed breathing, dilation of the pupils, tremors, vomiting, anorexia and incoordination.

5 Fire fighting measures

· **Suitable extinguishing agents:**
Use water spray or all purpose dry chemical.
· **Protective equipment:**
Fire fighters should wear self-contained breathing apparatus and full protective equipment.

6 Accidental release measures

· **Person-related safety precautions:** Not required.
· **Measures for environmental protection:**
Prevent seepage into sewage system, workpits and cellars.
· **Measures for cleaning/collecting:**
Vacuum, shovel, sweep-up all spilled materials and place in sealed container for proper disposal IAW Section XIII.

7 Handling and storage

· **Handling:**
· **Information for safe handling:**
Store in cool, dry place in tightly closed containers.
Handle with care. Avoid jolting and impact.
· **Information about protection against explosions and fires:**
No special measures required.

· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Store only in the original container.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Store in a cool, dry, well ventilated place.
· **Recommended storage temperature:** 15°C-30°C

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8 Exposure controls and personal protection

Components with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:**
The lists that were valid during the creation were used as basis.

· **Personal protective equipment:**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Do not eat, drink, smoke or inhale.
Do not store food in the working area.
· **Breathing equipment:**
Not required for this formulation when used in accordance with directions.
· **Protection of hands:** Rubber gloves in case of overexposure.
· **Eye protection:** Not required under normal conditions of use.

9 Physical and chemical properties

· **Form:** Solid
· **Color:** Brown
· **Odor:** Meaty aroma

	Value/Range	Unit	Method
· **Change in condition**			
· **Melting point/Melting range:**	Undetermined.		
· **Boiling point/Boiling range:**	Undetermined.		
· **Flash point:**	Not applicable.		
· **Auto igniting:**	Product is not self-igniting.		
· **Danger of explosion:** Product does not present an explosion hazard.			
· **Specific gravity:**	Not determined.		
· **Solubility in / Miscibility with**			
· **Water:**	Insoluble in water.		
· **pH-value:** at 20 ° C	4.0-6.0		

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Dangerous reactions** No dangerous reactions known.
· **Dangerous products of decomposition:**
Carbon monoxide and carbon dioxide
Nitrogen oxides
Sulfur oxides (SOx)

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HEARTGARD-30 PLUS

11 Toxicological information

· **Acute toxicity:**
LD/LC50 values that are relevant for classification:
70288-86-7 Ivermectin Comp. Bla (C48H74O1)
Comp. Blb (C47H72O14)
Oral: LD50: ~80 mg/kg (dog)
LD50: 25 mg/kg (mouse)
LD50: 50 mg/kg (rat)
Dermal: LD50: 406 mg/kg (rabbit)
LD50: >660 mg/kg (rat)
Inhalative: LC50/4 h: 5.11 mg/l (rat)
· **Primary irritant effect:**
· **on the skin:** No irritating effect known.
· **on the eye:** No irritating effect known.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful.

12 Ecological information

· **Ecotoxological effects:**
Acquatic toxicity:
70288-86-7 Ivermectin Comp. Bla (C48H74O1)
Comp. Blb (C47H72O14)
LC50 / 48 hrs: 0.025 ppt (daphnia magna)
LC50/96 hours: .3 ug/l (Rainbow Trout)
· **General notes:** Not known to be hazardous to water.

13 Disposal considerations

· **Product:**
· **Recommendation:** Incinerate at an EPA approved incinerator facility.

· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to official regulations.

14 Transport information

· **DOT regulations:**
· **Hazard class:** Non regulated

· **Land transport ADR/RID (cross-border):**
· **ADR/RID class:** Non regulated

· **Maritime transport IMDG:**
· **IMDG Class:** Non regulated
· **Marine pollutant:** No

· **Air transport ICAO-TI and IATA-DGR:**
· **ICAO/IATA Class:** Non regulated

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HEARTGARD-30 PLUS

15 Regulations

· **Sara**
Section 355 (extremely hazardous substances):
None of the ingredients are listed.
Section 313 (Specific toxic chemical listings):
None of the ingredients are listed.
TSCA (Toxic Substances Control Act):
57-55-6 Propylene Glycol
· **CA Proposition 65**
Chemicals known to cause cancer:
None of the ingredients are listed.
Chemicals known to cause reproductive toxicity:
None of the ingredients are listed.

· **Product related hazard informations:**
The product has been classified and marked in accordance with directives on hazardous materials.

· **Hazard symbols:** Xn Harmful

· **Hazard-determining components of labelling:** pyrantel

· **Risk phrases:** 22 Harmful if swallowed.

· **Safety phrases:**
2 Keep out of the reach of children.
13 Keep away from food, drink and animal feedingstuffs.
29 Do not empty into drains.
36 Wear suitable protective clothing.
46 If swallowed, seek medical advice immediately and show this container or label.
52 Not recommended for interior use on large surface areas.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
· **Contact:** MSDS Coordinator, 706-552-2739, msds@merial.com

USA

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MATERIAL SAFETY DATA SHEET

HEARTGARD 30 Plus Chewables for Dogs

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product description:	Blue pack:	beef chewables for dogs up to 11kg: 68µg ivermectin/57 mg pyrantel embonate per chewable
	Green pack:	beef chewables for dogs 12 to 22kg: 136µg ivermectin/114 mg pyrantel embonate per chewable
	Brown pack:	beef chewables for dogs 23 to 45kg: 272µg ivermectin/227 mg pyrantel embonate per chewable
Recommended use:		For use in dogs for heartworm prevention and monthly treatment and control of roundworms and hookworms. Prevents heartworm disease by eliminating heartworm larvae that infected the dog in the month before treatment and controls heartworm infections acquired in the previous 4 months if monthly treatment is continued for at least 12 months.
Supplier name:		Merial Australia Pty Ltd
Address:		Building D, 12-24 Talavera Road Macquarie Park NSW 2113
Telephone number (toll-free):		1800 808 691 All hours emergency phone number - Poisons Information Centre 131126 anywhere in Australia

SECTION 2 HAZARDS IDENTIFICATION

Classified as hazardous according to the National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].
APPROVED CRITERIA:CLASSIFICATION: HARMFUL Xn
Not classified as Dangerous Goods according to the ADG Code.

Risk phrase(s) (Hazard):	HARMFUL IF SWALLOWED (R22)
Safety phrase(s)):	KEEP OUT OF THE REACH OF CHILDREN (S2)
(Precautionary statements)	KEEP AWAY FROM FOOD AND DRINK (S13) DO NOT EMPTY INTO DRAINS (S29) IF SWALLOWED, SEEK MEDICAL ADVICE IMMEDIATELY AND SHOW THE CONTAINER OR LABEL (S46)

SUSDP CLASSIFICATION -	POISONS SCHEDULE: 5
ADG CODE CLASSIFICATION:	Not classified
UN No.	None

<u>LOCAL EFFECTS OF PRODUCT:</u>
<u>Acute:</u>

SWALLOWED:	Poisonous if swallowed. Symptoms following over-exposure to the ivermectin ingredient may include: drowsiness, nausea, vomiting, tachycardia, somnolence, blood pressure variations, slow breathing, dilation of pupils, tremors, and incoordination. In humans, no toxic effects of ivermectin have been reported for oral doses up to 2000 µg/kg bodyweight. Ivermectin can be excreted in milk.
INHALATION:	Not a likely route of exposure for this formulation.
SKIN CONTACT:	Not expected to cause irritation.
EYE CONTACT:	Will irritate eyes. Avoid contact with eyes. Under normal conditions of use, no eye contact is expected

CHRONIC EFFECTS: Unknown for product mixture. Pure ivermectin is a reproductive toxin in mice and rats only at doses that cause toxicity to the mother; however, in rabbits foetotoxicity and teratogenicity were noted at doses not toxic to the mother. Rats exposed *in utero* through lactation, and for an additional three months, showed signs indicative of intravascular haemolysis.

CARCINOGEN STATUS: Not classified by NOHSC, NTP or IARC

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS No.	Content	Classification	Cut-off conc. %	Risk phrase
Pyrantel	15686-83-6	3 to 8%	Toxic T	-	R 25
Solvent	Confidential	4%	-	-	-
Ivermectin	70288-86-7	<1%	Toxic T	0.1	R20/21/25/50
Not contributing to hazardous characteristics	various	to 100 %	Not classified		-

SECTION 4 FIRST AID MEASURES

ADVICE: For advice, contact a Poisons Information Centre (Phone 131126 anywhere in Australia), or call a doctor at once.

INGESTION: If swallowed urgent hospital treatment is likely to be needed. Follow instruction of Poisons Information Centre. Medical observation for delayed symptoms needs to be carried out for up to 48 hours.
Medical conditions aggravated by exposure - none known.
Treatment is symptomatic.

INHALATION: Not an expected route of exposure given the physical form.

SKIN CONTACT: No effects on skin expected. Wash hands after use

EYE CONTACT: If in eyes, hold eyelids apart and flush the eye continuously with running water until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.

PHARMACOLOGY: Ivermectin is believed to bind to glutamate-gated chloride ion channels in patients with potentially toxic ivermectin exposure avoid drugs that also interact with other ligand-gated chloride channels, including those that enhance GABA activity (barbiturates, benzodiazepines, valproic acid).

SECTION 5 FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARDS: Not flammable or combustible.

EXTINGUISHING MEDIA: Water spray/fog, dry chemical, CO2 or foam.

FIRE FIGHTING:

Special advice in case of fire: Emergency workers should wear full protective equipment and supplied-air breathing apparatus. Toxic or irritant gases, vapours or particulates may be generated in a fire. Spray water on containers to cool. Contain contaminated fire-fighting water.

Hazardous products of combustion: Oxides of carbon and nitrogen, various organic substances.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Initial Emergency response Guide: None

If spill is of significant quantity, move non-essential persons away. Seal leak. Remove leaking packages and place in over-bin. Do not allow to enter drains or sewer. Sweep up and pack in properly labelled container for disposal. Consult waste authority regarding disposal.

OCCUPATIONAL RELEASE: As for accidental release. Wear impervious gloves and eye protection to deal with a large spill.

SECTION 7 HANDLING AND STORAGE

Poisonous if swallowed. Will irritate the eyes. Avoid contact with eyes.
Wash hands after use. Keep away from foodstuffs and beverages. Do not eat, drink or smoke when using the product.
Not classified as Dangerous Goods. Do not store with food. Store in original container below 30ºC (Room Temperature). Do not freeze. Protect from light.

Ventilation:	No special requirements
Sources of ignition:	No special requirements.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

No ingredients that require workplace atmosphere monitoring have been identified by the manufacturer
NOHSC TWA = not established
NOHSC STEL= not established
No exposure limits have been established for more toxic ingredients such as the active ingredients.

Exposure Controls / Industrial hygiene: Not required.
Avoid contact with eyes. Wear eye protection if there is likelihood of particles entering the eye.

Personal Protective Equipment for cleaning up a significant spill.

EYE PROTECTION:	Goggles complying with AS 1336/1337.
SKIN PROTECTION:	If required, wear impervious gloves such as PVC coated cotton gloves complying with AS/NZS 2161.2.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Brown solid cube.
Odour.	Meaty
pH.	Not applicable
Boiling point/range.	Not applicable
Freezing Point	Not applicable
Melting point	Not applicable
Solubility in water	Insoluble
Specific gravity or density.	Not applicable
Flash point	Not applicable
Reactivity	Not an oxidising agent.
Incompatible materials.	None identified.

SECTION 10 STABILITY & REACTIVITY

Thermal decomposition:	None at normal temperatures.
Dangerous reactions:	None known.
REACTIVITY:	Stable.
CONDITIONS TO AVOID:	Exposure to elevated temperatures and light.
HAZARDOUS DECOMPOSITION:	No significant decomposition expected at normal temperatures.
POLYMERISATION:	No hazardous polymerisation will occur.

SECTION 11 TOXICOLOGICAL INFORMATION

Does not contain heavy metals or halogenated compounds. Health effects from the likely routes of exposure:
For ingredient **ivermectin**

Oral:	LD50:	37 mg/kg (mouse)
	LD50:	50 mg/kg (rat)
Dermal:	LD50:	406 mg/kg (rabbit)
	LD50:	>660 mg/kg (rat)
Inhalation:	LC50/4h:	5.11 mg/L (rat)

LOCAL EFFECTS OF PRODUCT:

Skin:	No irritating effect known.
Eye:	Slightly irritating.
Sensitization:	No sensitizing effects known.
TARGET ORGANS:	Eyes.
HAZARDOUS INGREDIENTS:	**Ivermectin and pyrantel** R-Phrase 25 TOXIC IF SWALLOWED
MUTAGENICITY DATA:	Not available

SECTION 12 ECOLOGICAL INFORMATION

Information applies to **Ivermectin** active ingredient.

Biological elimination:	Not available	
Bioaccumulation potential:	Not available	
TOXICITY TO FISH:	LC50 Rainbow Trout 96 hr	0.3 µg/L - poisonous.
TOXICITY TO DAPHNIA:	EC50 48 hr (*D. magna)*	0.025 µg/L
TOXICITY TO ALGA:	Not available	
TOXICITY TO BACTERIA:	Not available	
READY BIODEGRADABILITY:	Not available	
For the product itself:	Not known to be hazardous to water.	

SECTION 13 DISPOSAL CONSIDERATIONS

As the active ingredient is toxic to aquatic organisms, care is required to ensure that the product does not reach drains or waterways.
Empty packaging may be disposed of by wrapping in paper and placing in garbage. For the disposal of the clean-up materials from a **significant spill**, consult waste authority.

SECTION 14 TRANSPORT INFORMATION

UN Number	None
UN Proper Shipping Name	None
Class and subsidiary risk	None
Packing Group	None
Special precautions for user Labelling:	None

SECTION 15 REGULATORY INFORMATION

HEARTGARD[30] Plus Chewables are registered with the Australian Pesticides and Veterinary Medicines Authority.

APVMA Approval Numbers: 39541
39540
39539

SECTION 16 OTHER INFORMATION

ACRONYMS USED IN THIS MSDS

SUSDP	Standard for the Uniform scheduling of Drugs and Poisons
ADG Code	Australian Dangerous Goods (DG) Code
CAS No.	Chemical Abstracts number
UN No.	United Nations identifying number for DG
R-phrases	Risk phrases identifying main hazard of ingredient or product
S-phrases	Safety phrases identifying main safety measures to be used
NOHSC	National Occupational Health and Safety Commission
NTP	National Toxicology Programme (USA)
IARC	International Agency for Research on Cancer

Heartgard[30] is a registered trademark of Merial.

SUPPLIER STATEMENT: *The product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations.. The information in this MSDS is based on the level of knowledge at the time of preparation and relates to the product in the state in which it is supplied. The information describes the product from the safety point of view and is not intended to guarantee any particular properties .and shall not establish a legally valid contractual relationship*