SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	**Semintra 4 mg/mL Oral Solution for Cats**
Product code:	A011021
Recommended use:	For the reduction of proteinuria in cats with chronic kidney disease.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 263 1400
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	18 September 2018
Date of review:	7 February 2020

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Liquid

Active constituent:

4 mg/mL Telmisartan

Product components:

Name	CAS	Proportion
Telmisartan	144701-48-4	0.4%
Other ingredients	N/A	Balance

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications: Not classified as Hazardous according to the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, New Zealand. Not classified as Dangerous Goods for transport according to the New Zealand Standard NZS 5433:2012 Transport of Dangerous Goods on Land.

Priority and secondary identifiers: N/A

Risk and safety phrases: N/A

SECTION 4: FIRST AID MEASURES

Necessary first aid measures: For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately.
Ingestion: Unlikely to cause adverse effects as this is an oral medicine. If ingested in large amounts, seek medical attention.
Eyes: If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing for several minutes until all contaminants are washed out completely. If symptoms develop, seek medical attention.
Skin: Wash affected area thoroughly with soap and water. If symptoms develop, seek medical attention.
Inhalation: If inhaled, remove affected person from contaminated area to fresh air. Keep at rest until recovered. If symptoms persist, seek medical attention.

Workplace facilities: No special facilities required.

Required instructions:	Observe good work practices and avoid skin contact. **Pregnant women should use gloves when handling and administering the product**. Wash hands and exposed skin before meals and after use. Do not eat or drink while using.
Notes for medical personnel:	Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	This product will burn if exposed to fire.
Fire hazard properties:	Under fire conditions this product may emit toxic and/or irritating fumes, smoke and gases including carbon monoxide and carbon dioxide.
Extinguishing media and methods:	Use appropriate fire extinguisher for surrounding environment.
Hazchem code:	N/A
Recommended protective clothing:	Fire fighters should wear Self-Contained Breathing Apparatus operated in positive pressure mode and full protective clothing to prevent exposure to vapours or fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	Wear appropriate personal protective equipment and clothing to prevent exposure. Increase ventilation. If possible, contain the spill. Place inert absorbent material onto spillage. Collect the material and place into a suitable labelled container. Do not dilute the material but contain. Dispose of waste according to the applicable local and national regulations. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations. As a water based product, if spilt on electrical equipment the product will cause short-circuits.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Used as directed on label or package insert. Avoid inhalation of vapours and mists, and skin or eye contact. Use only in a well ventilated area. Keep containers sealed when not in use. Prevent the buildup of mists or vapours in the work atmosphere. Maintain high standards of personal hygiene, i.e. Washing hands prior to eating, drinking, smoking or using toilet facilities. Avoid exposure. Do not handle until all safety precautions have been read and understood. It is recommended that pregnant or breastfeeding women should not handle this product unless adequate exposure protection (e.g. gloves) can be assured at all times. Female personnel planning pregnancy should be made aware of the potential risks.
Approved handlers:	Not required
Conditions for safe storage:	Store in a cool, dry, well-ventilated area, out of direct sunlight. Store in suitable, labelled containers. Keep containers tightly closed. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations. Protect from freezing.
Store site requirements:	Store below 30 °C.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	No exposure standards have been established for the mixture. However, over- exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels.

Application in the workplace:	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.
Engineering controls:	Use with good ventilation. If mists/vapours are produced, local exhaust ventilation should be used.
Personal protection:	**Respiratory Protection** Industrial application: If engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable dust/particulate filter should be used.[1] **Eye Protection** Industrial application: Safety glasses with side shields or chemical goggles or full-face shield as appropriate should be used. Final choice of appropriate eye/face protection will vary according to individual circumstances.[2] **Hand Protection** Wear gloves of impervious material. Final choice of appropriate gloves will vary according to individual circumstances i.e. methods of handling or according to risk assessments undertaken.[3] **Body Protection** Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended. Chemical resistant apron is recommended where large quantities are handled.
References:	1. Reference should be made to Australian/New Zealand Standards AS/NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices, in order to make any necessary changes for individual circumstances. 2. Eye protection devices should conform with Australian/New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications. 3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	Formulation type: Liquid Appearance: packaged in a 45 mL HDPE bottle (fill volume 30 mL). The bottle is fitted with a LDPE plug-in adapter. A specially designed 2 mL oral syringe, which fits exactly into the plug-in adapter, is used to measure and deliver the dose. The bottle is closed with a tamper evident, child-resistant polypropylene (PP) closure and a polyethylene (PE) sealing disk. Specific gravity: Not available Boiling Point: Not available Vapour Pressure: Not available Solubility in Water: Soluble Flammability: Non-combustible

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions of use and storage.
Conditions to avoid:	Extremes of temperature and direct sunlight.
Material to avoid:	Not available.
Hazardous decomposition products:	Thermal decomposition may result in the release of toxic and/or irritating fumes.
Hazardous polymerization:	Not available.
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:

Toxicology Information
No toxicity data available for this material. The available acute toxicity data for the ingredients are given below.
Acute toxicity – Oral
Telmisartan
LD50 (rat): >2,000 mg/kg
LD50 (dog): >2,000 mg/kg
Ingestion
Ingestion of this product in large quantities may irritate the gastric tract causing nausea and vomiting.
Inhalation
Inhalation of product vapours may cause irritation of the nose, throat and respiratory system.
Skin
May be irritating to skin. The symptoms may include redness, itching and swelling.
Eye
May be irritating to eyes. The symptoms may include redness, itching and tearing.
Respiratory sensitisation
Not expected to be a respiratory sensitiser.
Skin Sensitisation
Not expected to be a skin sensitiser.
Germ cell mutagenicity
Not considered to be a mutagenic hazard.
Telmisartan:
Genetic toxicity in vitro:
Ames-test (*Salmonella typhimurium*): negative (OECD Guideline 471)
HGPRT assay V79 cells (Chinese hamster): negative
Chromosomal aberration test (human lymphocytes): negative
Genetic toxicity in vivo
Micronucleus assay (Mouse): negative
Carcinogenicity
Not considered to be a carcinogenic hazard.
Telmisartan did not show carcinogenic effects in animal experiments
Reproductive Toxicity
Not considered to be toxic to reproduction.
STOT-single exposure
Not expected to cause toxicity to a specific target organ.
STOT-repeated exposure
Not expected to cause toxicity to a specific target organ.
Aspiration Hazard
Not expected to be an aspiration hazard.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

No ecological data available for this product. The data available for the ingredients are given below.

Data organisation :

Persistence and degradability
Telmisartan not readily biodegradable (7% exposure: 28d)
Mobility
Telmisartan KOC: 895
Bioaccumulative Potential
Not available
Other Adverse Effects
Not available
Environmental Protection

	Prevent this material entering waterways, drains and sewers. **Acute toxicity – Fish** Telmisartan LC50 (Onchorhynchus mykiss): 3.74 mg/l/96h (OECD 203) **Acute toxicity – Daphnia** Telmisartan EC50 (Daphnia): 18.0 mg/l/48h **Acute toxicity – Algae** Telmisartan EC50 (Desmodesmus subspicatus): 9.87 mg/l/72h (OECD 201) (Growth rate) EC50 (Desmodesmus subspicatus): 1.75 mg/l/72h (OECD 201) (Biomass) **Other information** Telmisartan NOEC (Activated sludge): 1,000 mg/l/3h (OECD 209)
Environmental risk and safety phrases:	

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	The disposal of the spilled or waste material and container must be done in accordance with applicable local and national regulations.

SECTION 14: TRANSPORT INFORMATION

Relevant information:	Not classified as dangerous for rail, road, air or sea transport.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A011021 See www.foodsafety.govt.nz for registration conditions Restricted Veterinary Medicine For use only under the authority or prescription of a veterinarian. Approved pursuant to the HSNO Act, Approval Code HSR100757 See www.epa.govt.nz for approval conditions
HSNO and ACVM controls:	Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Boehringer Ingelheim website www.boehringer-ingelheim.co.nz While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.