ISSUED: **20 February 2018**

SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name: **Broncopulmin Plus TMPS Powder**

Product Identifier: Clenbuterol hydrochloride, trimethoprim, sufadiazine powder.

Product Code: 501805 (500 g)

Recommended Use: Oral bronchodilator and antibacterial for use in the treatment of respiratory disease in horses.

Restrictions on Use: For animal treatment only.

Company Identification: Jurox Pty Limited

Address: 85 Gardiner Street,
Rutherford, NSW 2320,
Australia

Customer Centre: 1800 023 312

Email: customerservice@jurox.com.au

National Poisons Information Centre: 13 1126 (24 hours)

Emergency Telephone Number: 1800 023 312 (9am – 5pm, Monday to Friday)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as follows:

GHS Category	Hazard code	Hazard Statement
Acute Toxicity (Oral) Category 4	H302	Harmful if swallowed
Skin Corrosion/Irritation Category 2	H315	Causes skin irritation
Eye Irritation Category 2A	H319	Causes serious eye irritation
Respiratory Sensitizer Category 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin Sensitizer Category 1	H317	May cause an allergic skin reaction
Germ cell mutagenicity Category 2	H341	Suspected of causing genetic defects
Reproductive Toxicity Category 1B	H360	May damage fertility or the unborn child
Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation)	H335	May cause respiratory irritation

GHS Label Elements:

Signal Word: **DANGER**

Pictograms:

Exclamation mark | Health hazard

Precautionary Statements:

Prevention
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dusts.
P264 Wash hands thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves and eye protection.
P281 Use personal protective equipment as required.
P285 In case of inadequate ventilation wear respiratory protection.

Response
P301 + P312 IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
P330 Rinse mouth.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.
P362 Take off contaminated clothing and wash before reuse.
P363 Wash contaminated clothing before reuse.

Storage
P405 Store locked up.

Disposal
P501 Dispose of container and any unused product by wrapping with paper and putting in garbage.

N.B.: The above statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Other hazards: None known.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Sulfadiazine	68-35-9	33.5%
Trimethoprim	738-70-5	6.7%
Clenbuterol hydrochloride	21898-19-1	< 0.01%
Ingredients not contributing to the hazards	-	~ 60%

Section 4: FIRST AID MEASURES

General Information: Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

Symptoms and Effects of Exposure: Clenbuterol causes a stimulatory effect on the heart and central nervous system. Symptoms of exposure include increased heart rate and irregularity of heartbeat, tightness and a constricting pain in the chest, palpitations and heart stoppage; low blood pressure with dizziness, fainting and flushing may also occur.

Inhalation: If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.

Ingestion: If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact a doctor or the National Poisons Centre on 13 1126.

Skin: If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.

Eye: If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. If eye irritation persists, get medical advice/attention.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Contains clenbuterol which is a bronchodilator and tocolytic agent, and the antimicrobials sulfadiazine and trimethoprim. Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point: No data available on the mixture. None of the ingredients are flammable.

Hazardous Combustion Products: If involved in a fire may emit toxic and corrosive fumes.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Protective gloves and boots and breathing apparatus.

Hazchem Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear appropriate protective clothing. For small spills, wash area well with excess water. For large spills, exclude non-essential people from the area. Use dry clean up procedures, avoiding the generation of dust and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Handling: The product should be handled with care to avoid exposure. Avoid contact with skin, eyes and inhalation of dusts. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children. Store below 30ºC (room temperature) in a dry place. Protect from light. Store away from foodstuffs.

Other Information: Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: No exposure limits have been assigned for this product nor for any ingredients.

Engineering Controls: Use only in a well ventilated area. Ensure that the work environment remains clean.

Personal Protective Equipment (PPE):

Eye Protection: Protective glasses or goggles are recommended when handling bulk quantities of this product.

Skin Protection: When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory Protection: Not required for the normal use of this product. When handling bulk quantities of this product a respirator (particulate) may be necessary when engineering and administrative controls do not adequately prevent exposure.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Fine, white powder.	**Upper / Lower Flammability Limits:**	Not available.
Odour:	Not available.	**Vapour Pressure:**	Not available.
Odour Threshold:	Not available.	**Vapour Density:**	Not available.
pH:	Not applicable	**Relative Density / Specific Gravity:**	Not applicable.
Melting Point / Freezing Point:	Not available.	**Solubility:**	Partly miscible.
Boiling Point and Boiling Range:	Not available.	**Partition Coefficient (n-octanol/water):**	Not available.
Flash Point:	Not available.	**Auto-Ignition Temperature:**	Not available.
Evaporation Rate:	Not applicable.	**Decomposition Temperature:**	Not available.
Flammability:	Not available.	**Viscosity:**	Not applicable.

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Chemical Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: No data available.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:
Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Acute Toxicity (Oral) Category 4**.

Sulfadiazine: LD_{50} (oral): 1500mg/kg (mouse), TDLo (oral): 1800mg/kg/5D (child), LDLo (oral): 500 mg/kg (dog).
Trimethoprim: LD50 (oral): 1500 – 1850 (rat); 2764 mg/kg (mouse).
Clenbuterol: LD_{50} (oral): 147 mg/kg (mouse), TDLo (oral) = 0.0046 mg/kg (woman).

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Aspiration Hazard: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Corrosion/Irritation Category 2**. Sulfadiazine is irritating to the skin.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Eye Irritation Category 2A**. Sulfadiazine is irritating to the eye.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as a **Respiratory Sensitizer Category 1** and **Skin Sensitizer Category 1**. Sulfadiazine is classified as a respiratory sensitiser and skin sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Germ cell mutagenicity Category 2**.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Reproductive Toxicity Category 1B**.

Clenbuterol is a tocolytic agent and may arrest uterine contractions in labour.
Exposure to trimethoprim for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Specific Target Organ Toxicity (STOT): Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation)**.

Specific Target Organ Toxicity (STOT): Repeated exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeat exposure.

However, repeated dose toxicity studies were carried out in which Beagle dogs were administered either trimethoprim alone or mixtures of trimethoprim and sulphadiazine for up to 90 days. Following oral (gavage) dosing with 135 mg/kg bw trimethoprim alone, the effects included reduced white blood cell counts, increased serum cholesterol concentrations and changes in thyroid weights. Minor changes in haematology parameters were observed following oral dosing with 45 mg/kg bw trimethoprim for 3 months. The NOEL was 2.5 mg/kg bw per day of trimethoprim.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have any narcotic effects.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be toxic to the environment.

Fish
Sulfadiazine: No data.
Trimethoprim: No data.
Clenbuterol hydrochloride: No data.

Crustacea
Sulfadiazine: EC_{50} (48 hour): 88 mg/L (*Daphnia magna*).
Trimethoprim: No data.
Clenbuterol hydrochloride: No data.

Algae and other aquatic plants
Sulfadiazine: EC_{50} (7 day): 0.135 mg/L (algae).
Trimethoprim: NOEC (72 hour): 16 mg/L (algae).
Clenbuterol hydrochloride: No data.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Sulfadiazine	HIGH	HIGH	LOW (LogKOW = -0.09)	LOW (KOC = 188.9)
Trimethoprim	HIGH	HIGH	LOW (LogKOW = 0.91)	LOW (KOC = 905)
Clenbuterol	HIGH	HIGH	LOW (LogKOW = 2.2222)	LOW (KOC = 149.7)

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not considered a Dangerous Good for land, sea and air transport.

Hazchem Code: None specified.

Section 15: REGULATORY INFORMATION

Poisons Schedule: S4

APVMA Registration No: 50718

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

SUSMP: Clenbuterol is mentioned in the SUSMP.

Section 16: OTHER INFORMATION

Legend:

AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
bw	Bodyweight.
CAS No.	Chemical Abstracts Service Registry Number.
EC_{50}	The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms or a 50% reduction in growth or in the growth rate of organisms.
EPA	Environmental Protection Authority of New Zealand.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
KOC	Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution.
KOW	Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.
LD_{50}	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
LDLo	Lethal Dose Low. The lowest published lethal dose.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
NOEC	No-observable-effect-concentration.
NOEL	No-observable-effect-level.
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
TDLo	Lowest published toxic dose.

References:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 20 February 2018 and is valid for 5 years from this date.

Supercedes: This SDS supercedes the version issued on 12 February 2013.

Revision History:

Date of Revision	Reason
20 February 2018	Additional data for ingredients included in Sections 11 and 12.

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein do so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

END OF SDS