

Bromotrimidine Paste

International Animal Health Products Pty Ltd

Chemwatch: 4856-96 Version No: 9.1

Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

Chemwatch Hazard Alert Code: 3

Issue Date: 10/03/2023 Print Date: 15/04/2024 S.GHS.AUS.EN.E

SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	Bromotrimidine Paste
Chemical Name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

For the treatment of respiratory infections in horses due to organisms susceptable to the combination of Sulphadimidine and Trimethoprim. Prescription animal remedy only. Keep out of reach of children. Animal treatment only. For oral administration only. Administer 20 mL/450kg bodyweight twice daily. Administer using syringe into animal's mouth.

Details of the manufacturer or supplier of the safety data sheet

Registered company name	International Animal Health Products Pty Ltd
Address	18 Healey Circuit Huntingwood NSW 2148 Australia
Telephone	+61 2 9672 7944
Fax	+61 2 9672 7988
Website	www.iahp.com.au
Email	info@iahp.com.au

Emergency telephone number

Association / Organisation	Australian Poison Information Centre
Emergency telephone numbers	13 11 26 (24 Hours)
Other emergency telephone numbers	New Zealand: National Poisons Centre 0800 764 766 (24 hours)

SECTION 2 Hazards identification

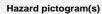
Classification of the substance or mixture

HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

Poisons Schedule	S4
Classification [1]	Serious Eye Damage/Eye Irritation Category 2B, Germ Cell Mutagenicity Category 2, Reproductive Toxicity Category 1B
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

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Signal word

Danger

Hazard statement(s)

H320	Causes eye irritation.
H341	Suspected of causing genetic defects.
H360Df	May damage the unborn child. Suspected of damaging fertility.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P280	Wear protective gloves and protective clothing.
P264	Wash all exposed external body areas thoroughly after handling.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: 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.

Precautionary statement(s) Storage

P405	Store locked up.
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Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
57-68-1	30-60	sulfamethazine
738-70-5	<10	<u>trimethoprim</u>
611-75-6	<1	bromhexine hydrochloride
Not Available	balance	Ingredients determined not to be hazardous
Legend:	-	2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - awn from C&L * EU IOELVs available

SECTION 4 First aid measures

Description of first aid mea	If this product comes in contact with the eyes: Wash out immediately with fresh running water. 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. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.	
Skin Contact	If skin contact occurs: ► Immediately remove all contaminated clothing, including footwear. ► Flush skin and hair with running water (and soap if available). ► Seek medical attention in event of irritation.	
Inhalation	▶ If fumes or combustion products are inhaled remove from contaminated area.	

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	 Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
Ingestion	 If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice. If spontaneous vomiting appears imminent or occurs, hold patient's head down, lower than their hips to help avoid possible aspiration of vomitus.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically

To treat poisoning by the higher aliphatic alcohols (up to C7):

- Gastric lavage with copious amounts of water.
- It may be beneficial to instill 60 ml of mineral oil into the stomach.
- Oxygen and artificial respiration as needed.
- Electrolyte balance: it may be useful to start 500 ml. M/6 sodium bicarbonate intravenously but maintain a cautious and conservative attitude toward electrolyte replacement unless shock or severe acidosis threatens.
- ▶ To protect the liver, maintain carbohydrate intake by intravenous infusions of glucose.
- Haemodialysis if coma is deep and persistent. [GOSSELIN, SMITH HODGE: Clinical Toxicology of Commercial Products, Ed 5)

BASIC TREATMENT

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- ▶ Administer oxygen by non-rebreather mask at 10 to 15 l/min.
- Monitor and treat, where necessary, for shock.
- Monitor and treat, where necessary, for pulmonary oedema.
- Anticipate and treat, where necessary, for seizures.
- DO NOT use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.
- Give activated charcoal.

ADVANCED TREATMENT

▶ Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.

- ▶ Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- If the patient is hypoglycaemic (decreased or loss of consciousness, tachycardia, pallor, dilated pupils, diaphoresis and/or dextrose strip or glucometer readings below 50 mg), give 50% dextrose.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

EMERGENCY DEPARTMENT

Laboratory analysis of complete blood count, serum electrolytes, BUN, creatinine, glucose, urinalysis, baseline for serum aminotransferases (ALT and AST), calcium, phosphorus and magnesium, may assist in establishing a treatment regime. Other useful analyses include anion and osmolar gaps, arterial blood gases (ABGs), chest radiographs and electrocardiograph.

- Positive end-expiratory pressure (PEEP)-assisted ventilation may be required for acute parenchymal injury or adult respiratory distress syndrome.
- Acidosis may respond to hyperventilation and bicarbonate therapy.
- Haemodialvsis might be considered in patients with severe intoxication.
- Consult a toxicologist as necessary. BRONSTEIN, A.C. and CURRANCE, P.L. EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

For C8 alcohols and above.

Symptomatic and supportive therapy is advised in managing patients.

SECTION 5 Firefighting measures

Extinguishing media

- Alcohol stable foam.
- Dry chemical powder.

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- ► BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog Large fires only.

Special hazards arising from the substrate or mixture

Fire Incompatibility

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

Advice for firefighters

Advisoro: in originaro	
Fire Fighting	 Alert Fire Brigade and tell them location and nature of hazard. Wear full body protective clothing with breathing apparatus. Prevent, by any means available, spillage from entering drains or water course. Use water delivered as a fine spray to control fire and cool adjacent area. Avoid spraying water onto liquid pools. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire.
Fire/Explosion Hazard	 Combustible. Slight fire hazard when exposed to heat or flame. Heating may cause expansion or decomposition leading to violent rupture of containers. On combustion, may emit toxic fumes of carbon monoxide (CO). May emit acrid smoke. Mists containing combustible materials may be explosive. Combustion products include: carbon dioxide (CO2) acrolein nitrogen oxides (NOx) sulfur oxides (SOx) other pyrolysis products typical of burning organic material. May emit corrosive fumes. May emit corrosive fumes.
HAZCHEM	Not Applicable

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	 Environmental hazard - contain spillage. Remove all ignition sources. Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
Major Spills	Environmental hazard - contain spillage. Moderate hazard. Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. No smoking, naked lights or ignition sources. Increase ventilation. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite. Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. If contamination of drains or waterways occurs, advise emergency services.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

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Precautions for safe handling

▶ DO NOT allow clothing wet with material to stay in contact with skin Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. • DO NOT enter confined spaces until atmosphere has been checked. Avoid smoking, naked lights or ignition sources. Avoid contact with incompatible materials. Safe handling ▶ When handling, **DO NOT** eat, drink or smoke. ▶ Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. • Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions. Store in original containers. ▶ Keep containers securely sealed. ▶ No smoking, naked lights or ignition sources. Other information Store in a cool, dry, well-ventilated area

Store away from incompatible materials and foodstuff containers.
 Protect containers against physical damage and check regularly for leaks.

Suitable container	Check that containers are clearly labelled Packaging as recommended by manufacturer.
Storage incompatibility	Glycerol: • reacts violently with strong oxidisers, acetic anhydride, alkali metal hydrides, calcium hypochlorite, calcium oxychloride, chlorine, chromic anhydride, chromium oxides, ethylene oxide, hydrogen peroxide, phosphorous triiodide, potassium chlorate, potassium permanganate, potassium peroxide, silver perchlorate, sodium hydride, sodium peroxide, sodium triiodide, sodium tetrahydroborate,is incompatible with strong acids, caustics, aliphatic amines, isocyanates, uranium fluoride • is able to polymerise above 145 C • Avoid reaction with oxidising agents

Observe manufacturer's storage and handling recommendations contained within this SDS.

SECTION 8 Exposure controls / personal protection

Conditions for safe storage, including any incompatibilities

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Department of the Department o	Ingredient	TEEL-1	TEEL-2	TEEL-3
Bromotrimidine Paste Not Available Not Available Not Available		Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
sulfamethazine	Not Available	Not Available
trimethoprim	Not Available	Not Available
bromhexine hydrochloride	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating Occupational Exposure Band Limit			
trimethoprim	E ≤ 0.01 mg/m³			
bromhexine hydrochloride	E ≤ 0.01 mg/m³			
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.			

Exposure controls

Appropriate engineering controls

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.

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When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.

Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.

Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50- 100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

10; high efficiency particulate (HEPA) filters or cartridges

10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.

25-50; a full face-piece negative pressure respirator with HEPA filters

50-100; tight-fitting, full face-piece HEPA PAPR

100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

Individual protection measures, such as personal protective equipment











When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- ► Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]
- ▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.

Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

Eye and face protection

Skin protection

See Hand protection below

Hands/feet protection

NOTE:

- The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
- ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

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Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- · frequency and duration of contact,
- · chemical resistance of glove material,
- · glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374. AS/NZS 2161.10.1 or national equivalent) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- \cdot Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
- · Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- · Excellent when breakthrough time > 480 min
- · Good when breakthrough time > 20 min
- · Fair when breakthrough time < 20 min
- · Poor when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task. Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.
- ▶ Double gloving should be considered.
- PVC gloves.
- ▶ Change gloves frequently and when contaminated, punctured or torn.
- Wash hands immediately after removing gloves.
- ▶ Protective shoe covers. [AS/NZS 2210]
- Head covering.

Body protection

See Other protection below

Other protection

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- ▶ Eye wash unit.
- ▶ Ensure there is ready access to an emergency shower.
- ▶ For Emergencies: Vinyl suit

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the *computer-generated* selection:

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Material	СРІ
NATURAL RUBBER	С
NATURAL+NEOPRENE	С
NITRILE	С
PE/EVAL/PE	С

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	A-AUS / Class1 P2	-
up to 50	1000	-	A-AUS / Class 1 P2
up to 50	5000	Airline *	-
up to 100	5000	-	A-2 P2
up to 100	10000	-	A-3 P2

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* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

100+	Airline**
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- * Continuous Flow ** Continuous-flow or positive pressure demand A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)
 - Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
 - The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
 - Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Aqua coloured paste with a slight vanilla odour; does not mix with water. Bulk density:1.19-1.31 g/mL		
Physical state	Liquid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n- octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	6.6	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

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TOXICITY

Oral (Mouse) LD50; 2764 mg/kg^[2]

trimethoprim

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Inhaled	There is some evidence to suggest that the material can cause resuch irritation can cause further lung damage. Inhalation of vapours may cause drowsiness and dizziness. This reflexes, lack of co-ordination, and vertigo. Inhalation of vapours or aerosols (mists, fumes), generated by the damaging to the health of the individual. Aliphatic alcohols with more than 3-carbons cause headache, diz depression, coma, seizures and behavioural changes. Secondar pressure and irregular heart rhythms, may follow.	may be accompanied by sleepiness, reduced alertness, loss of the material during the course of normal handling, may be azziness, drowsiness, muscle weakness and delirium, central
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. Overexposure to non-ring alcohols causes nervous system symptoms. These include headache, muscle weakness and incoordination, giddiness, confusion, delirium and coma. Sulfonamides and their derivatives can cause extensive kidney damage, and destroy red blood cells. Overdose may cause an accumulation of acid in the blood or a diminished blood sugar level with confusion and coma resulting.	
Skin Contact	The material may accentuate any pre-existing dermatitis condition A single prolonged exposure is not likely to result in the material damaged skin as a topical preparation or by contact with clothing potential to absorb the material in harmful amounts. Most liquid alcohols appear to act as primary skin irritants in humont apparently in man. Open cuts, abraded or irritated skin should not be exposed to this the material may cause mild but significant inflammation of the same Repeated exposure can cause contact dermatitis which is characteristical evidence suggests that repeated exposure may cause sale	causing harm. However, when applied in large quantities to gracidentally contaminated by the material, there may be the nans. Significant percutaneous absorption occurs in rabbits but as material skin either following direct contact or after a delay of some time. cterised by redness, swelling and blistering.
Еуе	Eye drops with sulfonamides can cause local irritation, sensations of burning and stinging, blurred vision and loss of depth perception. The conjunctiva and cornea may become inflamed, and the cornea and lens may become clouded. Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individual Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn).	
Chronic	Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn). Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Prolonged oral treatment with sulfonamides has caused nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, inflammation of the mouth cavity, impaired folic acid absorption, exacerbation of porphyria, acidosis, liver damage with impaired blood clotting, jaundice and inflammation of the pancreas. Effects on the kidney include blood and crystals in the urine, painful and frequent urination or lack of urine with nitrogen retention. There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Chronic poisoning from ionic bromides has historically resulted from medical use of bromides but not from exposure in the environment or workplace. In the absence of other signs of poisoning, there may be depression, hallucinations and schizophrenia-like psychosis. Bromides may also cause sedation, irritability, agitation, delirium, memory loss, confusion, disorientation, forgetfulness, inability to speak, difficulty speaking, weakness, fatigue, a spinning sensation, stupor, coma, decreased appetite, nausea, womiting, an acne-like rash on the face (bronchoderma), legs and trunk, swelling of the bronchi and a profuse discharge from the nostrils. There may also be inco-ordina	
	TOXICITY	IRRITATION
Bromotrimidine Paste	Not Available	Not Available
	тохісіту	IRRITATION
sulfamethazine	Inhalation(Guinea) LC50; 8.764 mg/L4h ^[2]	Not Available
	Oral (Mouse) LD50; 50000 mg/kg ^[2]	

IRRITATION

Eye (rabbit): slight * Skin (rabbit): slight * Chemwatch: **4856-96**Page **10** of **15**Issue Date: **10/03/2023**Version No: **9.1**Print Date: **15/04/2024**

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bromhexine hydrochloride	TOXICITY	IRRITATION
	Oral (Mouse) LD50; 3000 mg/kg ^[2]	Not Available
Legend:	Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

SULFAMETHAZINE

Somnolence, dyspnea recorded.

The substance is classified by IARC as Group 3:

NOT classifiable as to its carcinogenicity to humans.

Evidence of carcinogenicity may be inadequate or limited in animal testing.

ADI: 0.02 mg/kg/day NOEL: 33 mg/kg/day Not photoallergenic *Roche MSDS

Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation.

The antifolate action specifically targets the fast-dividing cells, and tend to have adverse effects on the bone marrow, skin, and hair. As folate is vital in the first trimester of pregnancy for healthy fetal development, the use of antifolates is strongly contraindicated in pregnancy and carries significant teratogenic risk.

Sometimes it is necessary to halt the administration of the antifolate because of the severe side effects. These can include mucositis, a serious symptom of gastrointestinal toxicity and renal toxicity. Occasionally, the chronic use of antifolates causes hepatoxicity, neuro, pulmonary, and skin toxicity.

The body s resistance to antifolates is often natural, but can also be acquired. Known causes of resistance include: reduced influx of the drug into the cell by the reduced folate carrier or because of the decrease of polyglutamation; an increase in DHFR because of gene enhancement; or a mutation in the DHFR enzyme which leads to decreased binding to the antifolate. Newer antifolates will have greater solubility in lipids, improved cellular uptake, and/or enhanced polyglutamation ability. The newer antifolates have potential for improved therapeutic efficacy along with decreased toxicity.

TRIMETHOPRIM

When using antifolate drugs, the cell-cycle must be taken into consideration to ensure its maximum efficacy. Many of the same enzymes and proteins that are involved with folate metabolism fluctuate in accordance with the cell cycle. In fact, the folate-dependant enzymes, such as dihydrofolate reductase (DHFR), increase during the S-phase of mitosis. Cells in the resting (G0) phase are less affected by the same amount of antifolate drug than are cells in other stages. Therefore, antifolates are most effective when there are relatively few cells, as in the G0 phase. Another important factor is that when using a folate antagonist, the synthesis of DNA in both normal and cancerous cells will be hindered. However, RNA and protein synthesis will still take place within the cell. If folates are not replenished, megaloblasts (giant cells), will form and cell death will then increase. No significant acute toxicological data identified in literature search.

Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.

Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure. The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

BROMHEXINE HYDROCHLORIDE

Lachrymation, tremor, ataxia recorded.

Most undiluted cationic surfactants satisfy the criteria for classification as Harmful (Xn) with R22 and as Irritant (Xi) for skin and eyes with R38 and R41.

For quaternary ammonium compounds (QACs):

Quaternary ammonium compounds are synthetically made surfactants. Studies show that its solubility, toxicity and irritation depend on chain length and bond type while effect on histamine depends on concentration. QACs may cause muscle paralysis with no brain involvement. There is a significant association between the development of asthma symptoms and the use of QACs as disinfectant.

Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	×	Reproductivity	✓
Serious Eye Damage/Irritation	~	STOT - Single Exposure	×
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	✓	Aspiration Hazard	×

Legend: X − Data either not available or does not fill the criteria for classification

🛹 – Data available to make classification

SECTION 12 Ecological information

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Bromotrimidine Paste	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	EC10(ECx)	168h	Algae or other aquatic plants	0.039- 0.723mg/L	4
sulfamethazine	EC50	48h	Crustacea	26.5- 37.3mg/l	4
	LC50	96h	Fish	>100mg/l	4
trimethoprim	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	74.4- 86.7mg/l	4
	EC50	96h	Algae or other aquatic plants	59.81- 117.4mg/l	4
	EC50	48h	Crustacea	52.15- 57.5mg/l	4
	LC50	96h	Fish	>100mg/l	4
	EC10(ECx)	72h	Algae or other aquatic plants	0.01- 103mg/l	4
bromhexine hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	4. US EPA, Ed	-	ECHA Registered Substances - Ecotoxicologica ta 5. ECETOC Aquatic Hazard Assessment Da entration Data 8. Vendor Data	•	

Toxic to soil organisms.

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
sulfamethazine	HIGH	HIGH
trimethoprim	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
sulfamethazine	LOW (LogKOW = 0.89)
trimethoprim	LOW (LogKOW = 0.91)

Mobility in soil

Ingredient	Mobility
sulfamethazine	LOW (Log KOC = 495.6)
trimethoprim	LOW (Log KOC = 905)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- ▶ Reduction
- Reuse
- Recycling
- ▶ Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

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- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- ▶ Where in doubt contact the responsible authority.
- Recycle wherever possible or consult manufacturer for recycling options.
- Consult State Land Waste Authority for disposal.
- Bury or incinerate residue at an approved site.
- ▶ Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
sulfamethazine	Not Available
trimethoprim	Not Available
bromhexine hydrochloride	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
sulfamethazine	Not Available
trimethoprim	Not Available
bromhexine hydrochloride	Not Available

SECTION 15 Regulatory information

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

sulfamethazine is found on the following regulatory lists

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

trimethoprim is found on the following regulatory lists

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

Australian Inventory of Industrial Chemicals (AIIC)

bromhexine hydrochloride is found on the following regulatory lists

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 2

Australian Inventory of Industrial Chemicals (AIIC)

Additional Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (bromhexine hydrochloride)

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National Inventory	Status
Canada - NDSL	No (sulfamethazine; trimethoprim; bromhexine hydrochloride)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (trimethoprim)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	No (bromhexine hydrochloride)
USA - TSCA	No (trimethoprim; bromhexine hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	No (trimethoprim)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	10/03/2023
Initial Date	27/08/2013

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

- ▶ PC TWA: Permissible Concentration-Time Weighted Average
- ▶ PC STEL: Permissible Concentration-Short Term Exposure Limit
- ▶ IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- ▶ STEL: Short Term Exposure Limit
- ▶ TEEL: Temporary Emergency Exposure Limit。
- ▶ IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- ▶ NOAEL: No Observed Adverse Effect Level
- ▶ LOAEL: Lowest Observed Adverse Effect Level
- ▶ TLV: Threshold Limit Value
- ▶ LOD: Limit Of Detection
- ▶ OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- ▶ BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- ▶ AIIC: Australian Inventory of Industrial Chemicals
- ▶ DSL: Domestic Substances List
- ▶ NDSL: Non-Domestic Substances List
- ▶ IECSC: Inventory of Existing Chemical Substance in China
- ▶ EINECS: European INventory of Existing Commercial chemical Substances
- ▶ ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ▶ ENCS: Existing and New Chemical Substances Inventory
- ► KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- ▶ TSCA: Toxic Substances Control Act
- ▶ TCSI: Taiwan Chemical Substance Inventory
- ▶ INSQ: Inventario Nacional de Sustancias Químicas
- ▶ NCI: National Chemical Inventory

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▶ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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