

Butin Anti-inflammatory Oral Paste International Animal Health Products Pty Ltd

International Animal Health Products Pty Lto
Chemwatch: 4856-98

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

Chemwatch Hazard Alert Code: 2

Issue Date: 23/12/2022 Print Date: 15/04/2024 S.GHS.AUS.EN.E

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

Product Identifier

Version No: 11.1

| Product name | Butin Anti-inflammatory Oral Paste |
|-------------------------------|------------------------------------|
| Chemical Name | Not Applicable |
| Synonyms | Butin paste |
| Chemical formula | Not Applicable |
| Other means of identification | Not Available |

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

| Relevant identified uses | Anti-inflammatory, analgesic and antipyretic oral paste for the relief of painful muscoskeletal conditions in horses. PRESCRIPTION ANIMAL REMEDY (Australia). RESTRICTED VETERINARY MEDICINE (New Zealand). Not to be used in any animal producing or intended to produce food for human consumption. |
|--------------------------|--|
|--------------------------|--|

Details of the manufacturer or supplier of the safety data sheet

| Registered company name | International Animal Health Products Pty Ltd | |
|-------------------------|---|--|
| Address | Healey Circuit Huntingwood NSW 2148 Australia | |
| Telephone | 31 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] | Acute Toxicity (Oral) Category 4, Serious Eye Damage/Eye Irritation Category 2B, Germ Cell Mutagenicity Category 2, Carcinogenicity Category 2, Reproductive Toxicity Category 2 |
| 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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Label elements

Hazard pictogram(s)





Signal word

Warning

Hazard statement(s)

| H302 | Harmful if swallowed. | |
|--------|--|--|
| H320 | Causes eye irritation. | |
| H341 | Suspected of causing genetic defects. | |
| H351 | Suspected of causing cancer. | |
| H361fd | Suspected of damaging fertility. Suspected of damaging the unborn child. | |

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

| P201 | Obtain special instructions before use. | |
|------|--|--|
| P280 | Wear protective gloves and protective clothing. | |
| P264 | P264 Wash all exposed external body areas thoroughly after handling. | |
| P270 | Do not eat, drink or smoke when using this product. | |

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. | |
| P301+P312 | IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell. | |
| P330 | Rinse mouth. | |

Precautionary statement(s) Storage

| P405 | Store locked up |
|------|-----------------|

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 |
|---|-----------|--|
| 50-33-9 | 10-30 | <u>phenylbutazone</u> |
| Not Available | balance | Ingredients determined not to be hazardous |
| Legend: 1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L * EU IOELVs available | | |

SECTION 4 First aid measures

Description of first aid measures

Eye Contact

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.

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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.

If fumes or combustion products are inhaled remove from contaminated area.

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.

► 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.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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for non-steroidal anti-inflammatories (NSAIDs)

Inhalation

Ingestion

- Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
- Patients should be managed by symptomatic and supportive care following a NSAIDs overdose.
- There are no specific antidotes.
- Emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 g/kg in children), and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose).
- Forced diuresis, alkalinisation of urine, hemodialysis, or haemoperfusion may not be useful due to high protein binding.
- ▶ For gastrointestinal haemorrhage, monitor stool guaiac and administer antacids or sucralfate.
- For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine.
- For severe allergic reactions, administer oxygen, antihistamines, epinephrine, or corticosteroids. Nephritis or nephrotic syndrome, thrombocytopenia, or haemolytic anemia may respond to glucocorticoid administration.
- For severe acidosis, administer sodium bicarbonate
- Administer as required: plasma volume expanders for severe hypotension; diazepam or other benzodiazepine for convulsions; vitamin K1 for hypoprothrombinaemia; and/or dopamine plus dobutamine intravenously to prevent or reverse early indications of renal failure.

Serious gastrointestinal toxicity, such as bleeding, ulceration, and perforation, can occur at any time, with or without warning symptoms, in patients treated chronically with NSAID therapy. Although minor upper gastrointestinal problems, such as dyspepsia, are common, usually developing early in therapy, physicians should remain alert for ulceration and bleeding in patients treated chronically with NSAIDs even in the absence of previous GI tract symptoms. In patients observed in clinical trials of several months to two years duration, symptomatic upper GI ulcers, gross bleeding or perforation appear to occur in approximately 1% of patients treated for 3 to 6 months, and in about 2% to 4% of patients treated for one year. Physicians should inform patients about the signs and/or symptoms of serious GI toxicity and what steps to take if they occur.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Except for a prior history of serious GI events and other risk factors known to be associated with peptic ulcer disease, such as alcoholism, smoking, etc., no risk factors (e.g., age, sex) have been associated with increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less well than other individuals, and most spontaneous reports of fatal GI events are in this population. Studies to date are inconclusive concerning the relative risk of various NSAIDs in causing such reactions. High doses of any NSAID probably carry a greater risk of these reactions, although controlled clinical trials showing this do not exist in most cases. In considering the use of relatively large doses (within the recommended dosage range), sufficient benefit should be anticipated to offset the potential increased risk of GI toxicity.

SECTION 5 Firefighting measures

Extinguishing media

- Water spray or fog.
- Foam.
- Dry chemical powder.
- ▶ BCF (where regulations permit).
- Carbon dioxide.

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

Advice for firefighters

Fire Fighting

- ▶ 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 courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- ▶ **DO NOT** approach containers suspected to be hot.

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| Fire/Explosion Hazard | Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use. 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) other pyrolysis products typical of burning organic material. May emit poisonous 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 | Slippery when spilt. Clean up all spills immediately. Avoid contact with skin and eyes. Wear impervious gloves and safety goggles. Trowel up/scrape up. Place spilled material in clean, dry, sealed container. Flush spill area with water. |
|--------------|--|
| Major Spills | 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. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Neutralise/decontaminate residue (see Section 13 for specific agent). Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. If contamination of drains or waterways occurs, advise emergency services. Slippery when spilt. |

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

SECTION 7 Handling and storage

Precautions for safe handling

▶ 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. • DO NOT allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. ▶ When handling, **DO NOT** eat, drink or smoke. Safe handling ▶ 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. Launder contaminated clothing before re-use. 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 are maintained. Other information Store in original containers. Keep containers securely sealed.

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

Conditions for safe storage, including any incompatibilities

Suitable container

▶ Check that containers are clearly labelled

Packaging as recommended by manufacturer.

- Storage incompatibility
- ▶ Avoid reaction with oxidising agents

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|---------------------------------------|---------------|---------------|---------------|
| Butin Anti-inflammatory Oral Paste | Not Available | Not Available | Not Available |

| Ingredient | Original IDLH | Revised IDLH |
|----------------|---------------|---------------|
| phenylbutazone | Not Available | Not Available |

Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|----------------|--|----------------------------------|
| phenylbutazone | 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. 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 |

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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.

Eye and face protection

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].

Skin protection

See Hand protection below

Hands/feet protection

- 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 | Α |
| NATURAL+NEOPRENE | A |
| NITRILE | A |

* 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

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 * | - |

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

* 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.

| up to 100 | 5000 | - | A-2 P2 |
|-----------|-------|---|-----------|
| up to 100 | 10000 | - | A-3 P2 |
| 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

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

| Appearance | Green paste with smooth texture and vanilla odour; mixes with water. Bulk density: 1.14-1.26 g/mL | | |
|--|---|---|----------------|
| Physical state | Non Slump Paste | 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) | Not Available | 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 | Miscible | 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 | Product is considered stable and 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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Information on toxicological effects

| itormation on toxicologic | al effects | | |
|---------------------------|---|--|--|
| Inhaled | There is some evidence to suggest that the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Not normally a hazard due to non-volatile nature of product | | |
| Ingestion | Accidental ingestion of the material may be damaging to the health of the individual. Non-steroidal anti-inflammatory drug (NSAID) overdose may produce nausea, vomiting, indigestion and upper abdominal pain. Other effects may include drowsiness, dizziness, confusion, disorientation, lethargy, "pins and needles", intense headache, blurred vision, ringing in the ears, muscle twitching, convulsions, stupor and coma. | | |
| Skin Contact | The material may accentuate any pre-existing dermatitis condition Open cuts, abraded or irritated skin should not be exposed to this material The material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering. | | |
| Eye | Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn). | | |
| Chronic | problems. Ample evidence from experiments exists that there Based on experience with animal studies, exposure levels which do not cause significant toxic effects to Substance accumulation, in the human body, may o occupational exposure. Prolonged use of non-steroidal analgesics damages may be diarrhoea or constipation, perforations caus Exposure to small quantities may induce hypersens dermal wheals (angioneurotic oedema), running nos thrombocytopenic purpura) may occur. | to the material may result in toxic effects to the development of the foetus, at | |
| Butin Anti-inflammatory | TOXICITY | IRRITATION | |
| Oral Paste | Not Available | Not Available | |
| | TOXICITY | IRRITATION | |
| phenylbutazone | Oral (Rat) LD50: 245 mg/kg ^[2] | Eye (rabbit): 100 mg - moderate | |

| Oral Paste | Not Available | Not Available | |
|----------------|---|---------------------------------|--|
| | TOXICITY | IRRITATION | |
| phenylbutazone | Oral (Rat) LD50: 245 mg/kg ^[2] | Eye (rabbit): 100 mg - moderate | |
| 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 | | |

PHENYLBUTAZONE

Altered sleep time, somnolence, tremor, convulsions, change in motor activity, ataxia, analgesia, elevated blood pressure, dyspnea, glomeruli and tubule changes, anuria, haematuria, leukopenia, agranulocytosis, changes in blood cell count, leukaemia, maternal effects, effects on fertility, foetoxicity, foetolethality, specific developmental abnormalities (musculoskeletal system, cardiovascular system), effects on newborn recorded. Carcinogenic by RTECS criteria.

Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a nonallergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

Accumulated studies have proved that non-steroidal anti-inflammatory drugs (NSAIDs) which block inflammation by their actions on arachidonic acid (AA) metabolism have a potential role in cancer chemotherapy and chemoprevention.

There is a general acceptance that NSAIDs induce colon cancer in humans. One suggested reason is that the balance between COX and lipoxygenase (LOX) activity determines tumorigenesis critically. Under low COX activity, arachidonic acid released from cell membranes in response to external stimuli is preferentially metabolized by LOX enzymes. The oxygenated lipids (metabolites) produced by LOXs initiate subsequent biological reactions, activate cellular signaling mechanisms through specific cell surface receptors, or are further metabolized into potent lipid mediators.

There is evidence that a 15-LOX metabolite 13S-HPODE (13S-hydroperoxyoctadecaenoic acid) generated from linoleic acid induces apoptosis in colon cancer.

Ingestion of aspirin or other NSAIDs may elicit respiratory, nasal, and gastrointestinal symptoms, as well as dermal changes in a subset of patients with asthma. The sensitivity to cyclooxygenase (COX) inhibitors has led to the hypothesis that NSAIDs may be causing upregulation of the 5-lipoxygenase pathway and its attendant products, the leukotrienes, in these patients. It has been shown increase in urinary leukotriene E 4 (LTE4) after aspirin ingestion or inhalation of lysine-aspirin in aspirin-sensitive patients with asthma. It has also been demonstrated that pharmacologic blockade at the level of the cysteinyl leukotriene receptor(s) can blunt the bronchospastic response to aspirin. Cysteinyl leukotrienes are potent bronchoconstrictors, induce mucus secretion, and increase vascular permeability. Importantly, inhibition of 5-lipoxygenase blocks not only the respiratory but also the gastrointestinal and dermal reactions to aspirin in aspirin-sensitive patients with asthma. Although these results establish the importance of 5-lipooxygenase products in mediating reactions to aspirin, the cellular source and mechanism of release of these mediators remain unclear.

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Mast cells, which are a known source of leukotrienes, are activated in the nasal response to aspirin as demonstrated by the detection of nasal tryptase after aspirin challenge. Tryptase is an enzyme specific to mast cells and is an indicator of mast cell activation. Cysteinyl leukotrienes and histamine, which can be produced by mast cells, were detected as well. The occurrence of nasal symptoms, as well as activation of mast cells, in response to aspirin was blocked by zileuton, an inhibitor of 5-lipoxygenase. This confirms that 5-lipoxygenase products are critical to the development of aspirin-induced asthma (ASA-induced) reactions in the nose. It also suggests that 5-lipoxygenase products may have a role in the activation of mast cells during this reaction.

A member or an analogue of a group of pyrazine derivatives generally regarded as safe. This is because they can be smelled at extremely low concentrations, and because they are rapidly absorbed, broken down and eliminated in humans. There is a wide margin of safety present between possible intake levels and the no-adverse-effect levels measured from chronic animal studies. These substances lack potential to cause mutations and genetic toxicity. There appears to be no evidence of reproductive or developmental effects.

Pyrazines contribute to the flavour of roasted, toasted or similarly heated foods. They arise mainly from heat-induced condensation between amino acids and sugars, but they also occur naturally in foods.

The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

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.

| 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

Toxicity

| Butin Anti-inflammatory Oral Paste | Endpoint | Test Duration (hr) | Species | Value | Source |
|---------------------------------------|--|--------------------|-------------------------------|------------------|------------------|
| | Not Available | Not Available | Not Available | Not Available | Not Available |
| phenylbutazone | Endpoint | Test Duration (hr) | Species | Value | Source |
| | NOEC(ECx) | 0.82h | Algae or other aquatic plants | >=250mg/l | 4 |
| Legend: | Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data | | | | |

DO NOT discharge into sewer or waterways.

Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|----------------|-------------------------|------------------|
| phenylbutazone | HIGH | HIGH |

Bioaccumulative potential

| Ingredient | Bioaccumulation |
|----------------|---------------------|
| phenylbutazone | LOW (LogKOW = 3.16) |

Mobility in soil

| Ingredient | Mobility |
|----------------|-----------------------|
| phenylbutazone | LOW (Log KOC = 15800) |

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal

- ▶ Containers may still present a chemical hazard/ danger when empty.
- ▶ Return to supplier for reuse/ recycling if possible.

Otherwise:

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- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.
- ▶ 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 |
|----------------|---------------|
| phenylbutazone | Not Available |

14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|----------------|---------------|
| phenylbutazone | Not Available |

SECTION 15 Regulatory information

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

phenylbutazone 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

FEI Equine Prohibited Substances List - Controlled Medication

FEI Equine Prohibited Substances List (EPSL)

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)

Additional Regulatory Information

Not Applicable

National Inventory Status

| • | |
|--|---------------------|
| National Inventory | Status |
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | Yes |
| Canada - NDSL | No (phenylbutazone) |
| China - IECSC | No (phenylbutazone) |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | Yes |
| Korea - KECI | No (phenylbutazone) |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (phenylbutazone) |

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| National Inventory | Status |
|--------------------|--|
| USA - TSCA | Yes |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | No (phenylbutazone) |
| Russia - FBEPH | No (phenylbutazone) |
| 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 | 23/12/2022 |
|---------------|------------|
| 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
- ▶ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

New Zealand HSNO Approval number: HSR100757

Veterinary Medicines (Limited Pack Size, Finished Dose) Group Std 2017

New Zealand HSNO Approval number: HSR100758

Veterinary Medicines (Non-dispersive Closed System Application) Group Std 2017