

Section 1 - Identification of The Material and Supplier

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Chemical nature: Phenylbutazone in a suitable medium.
Trade Name: **Butalone Granules Analgesic and Anti-inflammatory**
APVMA Code: 35620
Product Use: To treat musculoskeletal disorders and other conditions where NSAIDs are indicated.
Creation Date: **March, 2017**
This version issued: **March, 2017** and is valid for 5 years from this date.
Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification**Statement of Hazardous Nature**

This product is classified as: Xn, Harmful. Xi, Irritating. Hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

UN Number: None allocated

**GHS Signal word: WARNING**

Acute Toxicity Oral Category 4
Skin Irritation Category 2
Eye irritation Category 2B
Specific Target Organ Toxicity - Single Exposure Category 3

HAZARD STATEMENT:

H302: Harmful if swallowed.
H315: Causes skin irritation.
H320: Causes eye irritation.
H335: May cause respiratory irritation.

PREVENTION

P102: Keep out of reach of children.
P261: Avoid breathing dusts.
P262: Do not get in eyes, on skin, or on clothing.
P270: Do not eat, drink or smoke when using this product.
P271: Use only outdoors or in a well ventilated area.
P281: Use personal protective equipment as required.

RESPONSE

P312: Call a POISON CENTRE or doctor if you feel unwell.
P362: Take off contaminated clothing and wash before reuse.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313: If skin irritation occurs: Get medical advice.
P337+P313: If eye irritation persists: Get medical advice.
P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

STORAGE

P402: Store in a dry place.

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P410: Protect from sunlight.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Emergency Overview

Physical Description & Colour: White granules.

Odour: Non specific odour.

Major Health Hazards: irritating to eyes, respiratory system and skin, irritating to respiratory system and skin, harmful if swallowed. This is a physiologically active product and so contact should be minimised, especially if the user is taking a form of medication, as interactions can sometimes give unexpected and undesired results.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc, %	TWA (mg/m ³)	STEL (mg/m ³)
Phenylbutazone	50-33-9	>60 *	not set	not set
Other non hazardous ingredients	secret	to 100	not set	not set

* Each sachet contains 1 gram Phenylbutazone.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Inhalation: If irritation occurs, contact a Poisons Information Centre, or call a doctor. Remove source of contamination or move victim to fresh air. If breathing is difficult, oxygen may be beneficial if administered by trained personnel, preferably on a doctor's advice. In severe cases, symptoms of pulmonary oedema can be delayed up to 48 hours after exposure.

Skin Contact: Quickly and gently brush away excess particles. Wash gently and thoroughly with warm water (use non-abrasive soap if necessary) for 10-20 minutes or until product is removed. Under running water, remove contaminated clothing, shoes and leather goods (e.g. watchbands and belts) and completely decontaminate them before reuse or discard. If irritation persists, repeat flushing and seek medical attention.

Eye Contact: Quickly and gently brush particles from eyes. Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 15 minutes or until the product is removed, while holding the eyelid(s) open. Take care not to rinse contaminated water into the unaffected eye or onto the face. Obtain medical attention immediately. Take special care if exposed person is wearing contact lenses.

Ingestion: If swallowed, do NOT induce vomiting. Wash mouth with water and contact a Poisons Information Centre, or call a doctor.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: No data

Upper Flammability Limit: No data.

Lower Flammability Limit: No data.

Autoignition temperature: No data.

Flammability Class: No data.

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Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, clean up, rinsing to sewer and put empty container in garbage. Although no special protective clothing is normally necessary because of occasional minor contact with this product, it is good practice to wear impermeable gloves when handling chemical products. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits

TWA (mg/m³)

STEL (mg/m³)

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: This product should only be used in a well ventilated area. If natural ventilation is inadequate, use of a fan is suggested.

Eye Protection: Protective glasses or goggles should be worn when this product is being used. Failure to protect your eyes may cause them harm. Emergency eye wash facilities are also recommended in an area close to where this product is being used.

Skin Protection: Prevent skin contact by wearing impervious gloves, clothes and, preferably, apron. Make sure that all skin areas are covered. See below for suitable material types.

Protective Material Types: We suggest that protective clothing be made from the following materials: cotton, rubber, PVC.

Respirator: If there is a significant chance that dusts are likely to build up in the area where this product is being used, we recommend that you use a suitable dust mask.

Eyebaths or eyewash stations and safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

Section 9 - Physical and Chemical Properties:

Physical Description & colour:	White granules.
Odour:	Non specific odour.
Boiling Point:	No specific data. Expected to decompose before boiling.
Freezing/Melting Point:	No specific data. Solid at normal temperatures.
Volatiles:	No data.
Vapour Pressure:	No data.
Vapour Density:	Not applicable.
Specific Gravity:	No data.
Water Solubility:	No data.
pH:	No data.
Volatility:	No data.
Odour Threshold:	No data.
Evaporation Rate:	Not applicable.
Coeff Oil/water Distribution:	No data
Viscosity:	Not applicable.
Autoignition temp:	No data.

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Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: strong acids, strong bases, oxidising agents.

Fire Decomposition: Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

Ingredient

Risk Phrases

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

Compounding effects: Phenylbutazone may cross the placenta and be excreted in breast milk.

Potential Health Effects

Handling of the formulated product is not expected to cause any adverse affects. The following data pertains particularly to the active and any hazardous ingredients in the formulation, rather than this specific formulation.

Inhalation:

Short Term Exposure: This product is an inhalation irritant. Symptoms may include headache, irritation of nose and throat and increased secretion of mucous in the nose and throat. Other symptoms may also become evident, but they should disappear after exposure has ceased if treatment is prompt.

Long Term Exposure: The data available suggests that repeated or prolonged exposure can induce extreme immune system responses in the form of chest pain due to constriction of the airwaves, hives, deep skin weals, running nose and blurred vision.

Skin Contact:

Short Term Exposure: This product is a skin irritant. Symptoms may include itchiness and reddening of contacted skin. Other symptoms may also become evident, but if treated promptly, all should disappear once exposure has ceased.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: This product is an eye irritant. Symptoms may include stinging and reddening of eyes and watering which may become copious. Other symptoms may also become evident. If exposure is brief, symptoms should disappear once exposure has ceased. However, lengthy exposure or delayed treatment may cause permanent damage.

Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. Available data shows that this product is harmful, but symptoms are not available. However, this product may be irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.

Long Term Exposure: Chronic ingestion is unlikely however the data available suggests that signs as described above could be anticipated. Leukaemia has been reported in patients receiving Phenylbutazone.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA.

NTP: No significant ingredient is classified as carcinogenic by NTP.

IARC: No significant ingredient is classified as carcinogenic by IARC.

Leukaemia has been reported in patients receiving Phenylbutazone although the relationship is not clear.

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Section 12 - Ecological Information

Insufficient data to be sure of status.

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Phenylbutazone, is mentioned in the SUSMP.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (Feb 2016)

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