Material Safety Data Sheet

Butalone Granules Analgesic and Anti-inflammatory

Classified as hazardous according to the criteria of NOHSC

SECTION I Identification of the Material and Supplier
Product Name: Butalone Granules Analgesic and Anti-inflammatory
Recommended Use: To treat musculoskeletal disorders and other conditions where NSAIDs are indicated.
Supplier Details: Apex Laboratories Pty. Ltd.
ACN Number: 000 397 240
Street: 61 Chivers Road
Suburb: Somersby
State: NSW
Country: Australia
Post Code: 2250
Phone: +61 2 4372 1661 (Business hours – 8.30am – 5.00pm)
Fax: +61 2 4372 1668 (fax)
Website: http://www.apexlabs.com.au
Emergency contact: As above or Poisons Information Centre 131126 (Australia)

SECTION II Hazard Identification
Classification: Classified as hazardous according to the criteria of NOHSC
Risk Phrases: R22 Harmful if swallowed
R36/37/38 Irritating to eyes, respiratory system and skin.
Safety Phrases: None allocated
ADG Class: None allocated
Hazchem Code: None allocated
Poisons Schedule: S4

SECTION III Composition

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS No</th>
<th>Proportion</th>
<th>TWA mg/m3</th>
<th>STEL mg/m3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylbutazone</td>
<td>50-33-9</td>
<td>&gt;60% to 100%</td>
<td>10</td>
<td>not set</td>
</tr>
<tr>
<td>Other non hazardous ingredients</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

The 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 over an entire working lifetime. The TWA exposure standard set by Worksafe Australia for dusts not otherwise specified is 10mg/m³. The STEL (Short Term Exposure Limit) is an exposure value that should not be exceeded for more than 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL.

SECTION IV First Aid Measures
Ingestion: If swallowed rinse mouth out with water, give water to drink and seek medical advice. Induce vomiting.
Eye: Irrigate with copious quantities of lukewarm water for 10 minutes and seek medical advice.
Skin: Wash well with soap and water and if concerned seek medical advice.
Inhalation: Generally not required. If concerned move to fresh air and seek medical advice.

SECTION V Fire Fighting Measures
Extinguishing Media: Dry agent, water fog, mist or spray, carbon dioxide. As appropriate for surrounding material.
Combustion Hazards
- No known toxic hazards.

Precautions for Firefighters
- Wear self contained breathing apparatus and protective clothing.

Hazchem Code
- None allocated

SECTION VI Accidental Release Measures

Emergency Procedures
- Spillage of formulated product from marketed packaging is unlikely to ever be serious, however, in the event of a major spill, protect drains and water courses from contamination.

Materials and Methods
- Wear protective clothing (overalls, goggles, gloves and boots) and prevent further spillage. Shovel spillage into labelled containers and dispose after consulting appropriate authorities.

SECTION VII Handling and Storage

Precautions
- Always use good occupational work practices and observe recommendations on the label. Keep exposure to this product to a minimum. Prohibit eating, drinking and smoking in storage and handling areas. Wash hands after handling and remove contaminated clothing and any protective equipment before entering eating areas.

Conditions
- Store product in original containers as per label instruction (below 30°C or room temperature).

SECTION VIII Exposure Controls and Personal Protection

National Exposure Standards
- No exposure standard has been allocated for this mixture or any significant ingredient within this mixture.

Biological Limit Values
- No biological limit has been allocated for this mixture.

Engineering Controls
- No specific engineering controls are required for this mixture.

Personal Protective Equipment

Eye
- Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands after handling and prior to touching eye and in particular handling contact lenses.

Skin
- Skin protection is not normally necessary, however it is good practice to avoid contact with chemicals by wearing suitable gloves when handling.

Respiratory
- Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to build up then use of a suitable dust mask would be appropriate.

SECTION IX Physical and Chemical Properties

Appearance
- White granules.

Odour
- Non specific odour.

pH
- No data available.

Vapour pressure
- No data available.

Boiling point/range
- No data available.

Freezing/Melting point
- No data available.

Solubility
- No data available.

Specific gravity/density
- No data available.

Flash Points
- No data available.

Flammable limits (in air)
- No data available.

Ignition temperature
- No data available.
Chemical stability
This mixture is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

Conditions to avoid
No specific conditions to avoid other than extreme heat.

Incompatible materials
No data available.

Decomposition products
No known decomposition products.

Hazardous reactions
No data available.

SECTION XI Toxicological Information
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.

Acute Health Effects
Ingestion
Eye
The data available suggests that eye contact may result in a transient irritation and associated blinking and pain.

Skin
The data available suggests that skin contact may result in mild discomfort.

Inhalation
The data available suggests that inhalation of the dust may be discomfor ting to the upper respiratory tract. Pre-existing respiratory disease may be exacerbated by inhalation of the dusts.

Chronic Health Effects
Ingestion
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.

Eye
The data available suggests that repeated or prolonged exposure may lead to conjunctivitis.

Skin
The data available suggests that repeated or prolonged contact may be discomfor ting to the skin.

Inhalation
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.

Advice to Doctor
Treatment for any adverse effects should be symptomatic. Following overdose the stomach should be emptied by emesis or lavage with sodium bicarbonate solution.

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

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

SECTION XII Ecological Information
Ecotoxicity
No data available.

Persistence and Degradability
No data available.

Mobility
No data available.

SECTION XIII Disposal Considerations
Disposal Methods
Empty containers may be recycled or sent to a commercial waste disposal site. Unused product should be suitable for landfill however contact the relevant local Waste Disposal Authority.

Special Precautions
Do not dispose into sewers or waterways.
### SECTION XIV Transport Information

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN Number</td>
<td>None allocated.</td>
</tr>
<tr>
<td>UN Shipping Name</td>
<td>None allocated.</td>
</tr>
<tr>
<td>ADG Class</td>
<td>None allocated</td>
</tr>
<tr>
<td>Packing Group</td>
<td>None allocated</td>
</tr>
<tr>
<td>Special Precautions</td>
<td>None allocated</td>
</tr>
<tr>
<td>Hazchem Code</td>
<td>None allocated</td>
</tr>
</tbody>
</table>

### SECTION XV Regulatory Information

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poisons Schedule</td>
<td>S4</td>
</tr>
</tbody>
</table>

### SECTION XVI Other Information

**Date**

This MSDS has been reviewed and updated as required in May 2009.

**Key to Abbreviations**

- NOHSC: National Occupational Health and Safety Commission
- ADG Class: Australian Dangerous Goods Class
- CAS Number: Chemical Abstracts Service Number
- TWA: Time Weighted Average
- STEL: Short Term Exposure Limit
- UN: United Nations

**Disclaimer**

This Material Safety Data Sheet has been developed according to WORKSAFE Australia, NOHSC Guidelines.

Hazard Classifications have been determined in consultation with the Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. However, to the best of our knowledge, the finished product is unlikely to cause harm to humans handling, administering and dispensing as per label instructions.

The data, information and recommendations herein are represented in good faith and are believed to be correct as of the date hereof.

The purpose of this Material Safety Data Sheet is to describe products in terms of their safety requirements.

Apex Laboratories Pty Ltd make no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers (“the product”).

The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability prior to use of the product.

The physical data shown herein are typical values based on material tested. These values should not be construed as guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots hereof.

Due care should be taken to make sure that the use or disposal of this product and/or its packaging is in compliance with relevant Federal, State and Local Government Regulations.