SAFETY DATA SHEET

1. Identification

Product identifier Phenylbutazone
Other means of identification

Chemical name 3,5-Pyrazolidinedione, 4-butyl-1,2-diphenyl-

Manufacturer/Importer/Supplier/Distributor information

Manufacturer
- Company name Total Pharmacy Supply
- Address 3400 Avenue E East
- Arlington
- TX
- 76040
- US
- Telephone (800) 878-2822
- Website www.totalpharmacysupply.com

Emergency phone number
- CHEMTREC within US & Canada 1-800-424-9300
- CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.
Health hazards
- Acute toxicity, oral Category 3
- Serious eye damage/eye irritation Category 2A
- Reproductive toxicity Category 2
- Specific target organ toxicity, repeated exposure Category 1 (cardiovascular system, gastrointestinal tract)

OSHA hazard(s) Not classified.

Label elements

Signal word Danger
Hazard statement Toxic if swallowed. Causes serious eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs (cardiovascular system, gastrointestinal tract) through prolonged or repeated exposure.

Precautionary statement

Prevention
Wash thoroughly after handling. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

Response
If swallowed: Immediately call a poison center/doctor. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.

Storage
Store locked up.
Disposal
Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Material name: Phenylbutazone
SDS-379TPS Issue date: 03-27-2017
4. First-aid measures

**Inhalation**
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed**
Cardiovascular effects. Gastrointestinal disturbances. Irritation of eyes and mucous membranes.

**Indication of immediate medical attention and special treatment needed**
Treatment of nonsteroidal anti-inflammatory drug (NSAID) overdose should be symptomatic and supportive and may include the following: Induce vomiting (DO NOT use syrup of ipecac) or perform gastric lavage. Administer activated charcoal as a slurry. For gastrointestinal hemorrhage, 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 hemolytic 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 hypoprothrombinemia; and/or dopamine plus dobutamine intravenously to prevent or reverse early indications of renal failure. Forced diuresis, alkalization or urine, and hemoperfusion may not be useful. (Poisindex) (USP DI)

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire-fighting equipment/instructions**
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

**Precautions for safe handling**
As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
8. Exposure controls/personal protection

Exposure limit values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylbutazone (CAS 50-33-9)</td>
<td>TWA</td>
<td>0.5 mg/m³</td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

9. Physical and chemical properties

Appearance

White to off-white crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless or slight odor.

Odor threshold

Not available.

pH

6.3 (2.8% solution)

Melting point/freezing point

219.2 - 224.6 °F (104 - 107 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

30 %

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

< 0.0000001 kPa at 25 °C

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Very slightly soluble.

Partition coefficient (n-octanol/water)

5
3.16

Auto-ignition temperature 788 °F (420 °C) (BAM, fluidized dust)
Viscosity Not available.

Other information
Chemical family Pyrazole derivative.
Molecular formula C19-H20-N2-O2
Molecular weight 308.37
Solubility (other) Freely soluble in acetone, in ether, and in benzene; soluble in alcohol, in chloroform, and in ethyl acetate.

10. Stability and reactivity
Reactivity No reactivity hazards known.
Chemical stability Material is stable under normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid None known.
Hazardous decomposition products NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
Ingestion Toxic if swallowed.
Inhalation Due to lack of data the classification is not possible.
Skin contact Due to lack of data the classification is not possible.
Eye contact Causes serious eye irritation.
Cross sensitivity Persons sensitive to aspirin or any of the other nonsteroidal anti-inflammatory agents may be sensitive to this material also. This material may cause bronchoconstriction or anaphylaxis in aspirin-sensitive asthmatics.
Acute toxicity Toxic if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
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<tbody>
<tr>
<td>Phenylbutazone (CAS 50-33-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Mouse</td>
<td>238 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>245 mg/kg</td>
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</tbody>
</table>

Skin corrosion/irritation Due to lack of data the classification is not possible.
Serious eye damage/eye irritation Causes serious eye irritation.

Local effects
100 mg Irritancy test (Draize) Result: Irritant. Species: Rabbit Organ: Eye.
Respiratory sensitization Due to lack of data the classification is not possible.
Skin sensitization Due to lack of data the classification is not possible.
Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity
Chromosomal aberrations in Chinese hamster ovary cells Result: Positive (with activation).
Chromosomal aberrations in bone marrow cells Result: Negative.
**Mutagenicity**
- Mouse dominant lethal test
  - Result: Negative.
- S. typhimurium Ames assay
  - Result: Negative.
- Sister chromatid exchange in Chinese hamster ovary cells
  - Result: Negative.

**Carcinogenicity**
Based on available data, the classification criteria are not met. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

- 0 - 100 mg/kg Carcinogenicity study
  - Result: Small number of renal tubular cell adenomas/carcinomas. Female rats had 2 rare transitional cell carcinomas at highest dose.
  - Species: Rat
  - Test Duration: 103 weeks

- 0 - 300 mg/kg Carcinogenicity study
  - Result: Increased incidence of hepatocellular adenomas/carcinomas in males.
  - Species: Mouse
  - Test Duration: 103 weeks

**Reproductive toxicity**
Suspected of damaging fertility or the unborn child. Therapeutic use of nonsteroidal anti-inflammatory agents (NSAIDs) during the second half of pregnancy is associated with adverse effects in the fetus such as premature closure of the ductus arteriosus, which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that NSAIDs administered during late pregnancy can cause prolonged gestation, difficult labor, delayed birth, and decreased pup survival rates.

- 50 mg/kg/day Reproductivity study
  - Result: No evidence of birth defects.
  - Species: Rabbit

- >= 42 mg/kg/day Reproductivity study
  - Result: No evidence of birth defects.
  - Species: Rat

**Specific target organ toxicity - single exposure**
Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**
Causes damage to organs (cardiovascular system, gastrointestinal tract) through prolonged or repeated exposure.

**Aspiration hazard**
Based on available data, the classification criteria are not met.

**Ecotoxicity**
No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability**
No data is available on the degradability of this product.

**Bioaccumulative potential**
Not available.

**Mobility in soil**
Not available.

**Other adverse effects**
Not available.

**Disposal considerations**
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations**
Not available.

**Hazardous waste code**
Not available.

**Waste from residues / unused products**
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**Transport information**
- **DOT**
  - UN number: UN2811
  - UN proper shipping name: Toxic solid, organic, n.o.s. (Phenylbutazone)
  - Transport hazard class(es): 6.1
  - Subsidiary class(es): Not available.
15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
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<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
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<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<td>New Zealand Inventory</td>
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<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
16. Other information, including date of preparation or last revision

Issue date 03-27-2017