SAFETY DATA SHEET
according to the Hazardous Products Regulations

Phenylbutazone Formulation

SECTION 1. IDENTIFICATION

Product name : Phenylbutazone Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Acute toxicity (Oral) : Category 4
Eye irritation : Category 2A

GHS label elements
Hazard pictograms : ⚠️

Signal Word : Warning
Hazard Statements : H302 Harmful if swallowed.
H319 Causes serious eye irritation.

Precautionary Statements : Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear eye protection and face protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
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 attention.

Disposal:
P501 Dispose of contents and container to an approved waste
Other hazards
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Common Name/Synonym</td>
</tr>
<tr>
<td>Phenylbutazone</td>
<td>3,5-Pyrazolidinedione, 4-butyl-1,2-diphenyl-50-33-9</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>Silicon dioxide 112945-52-5</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>No data available 50-81-7</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact:
Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed:
If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:
Harmful if swallowed.
Causes serious eye irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

Protection of first-aiders:
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES
Suitable extinguishing media: Water spray
                      Alcohol-resistant foam
                      Carbon dioxide (CO2)
                      Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
                        Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
                        Use water spray to cool unopened containers.
                        Remove undamaged containers from fire area if it is safe to do so.
                        Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus.
                        Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
                        Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment.
                        Prevent further leakage or spillage if safe to do so.
                        Retain and dispose of contaminated wash water.
                        Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.
                        Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
                        Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
                        Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
                        Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion.
                        Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling: Do not breathe dust. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylbutazone</td>
<td>50-33-9</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>TWA (Respirable)</td>
<td>1.5 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total)</td>
<td>4 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAERV (respirable dust)</td>
<td>6 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>50-81-7</td>
<td>TWA</td>
<td>5000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection:
Material

Remarks

Eye protection

Skin and body protection

Hygiene measures

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Color

Odor

Odor Threshold

pH

Melting point/freezing point

Initial boiling point and boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

Flammability (liquids)

Upper explosion limit / Upper flammability limit

Lower explosion limit / Lower flammability limit
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not classified as a reactivity hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous rea-</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>ctions</td>
<td></td>
</tr>
</tbody>
</table>

**Conditions to avoid**
- Heat, flames and sparks.
- Avoid dust formation.

**Incompatible materials**
- Oxidizing agents

**Hazardous decomposition products**
- No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**
- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**
Harmful if swallowed.
Phenylbutazone Formulation

Product:
Acute oral toxicity: Acute toxicity estimate: 1,225 mg/kg
Method: Calculation method

Components:
Phenylbutazone:
Acute oral toxicity: LD50 (Rat): 245 mg/kg
LD50 (Mouse): 238 mg/kg
LD50 (Dog): 332 mg/kg

Silicon, amorphous:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg
Remarks: Based on data from similar materials

Ascorbic acid:
Acute oral toxicity: LD50 (Rat): 11,900 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
Silicon, amorphous:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Ascorbic acid:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.
# Phenylbutazone Formulation

## Components:

### Phenylbutazone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

### Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 405</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Ascorbic acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 405</td>
<td></td>
</tr>
</tbody>
</table>

## Respiratory or skin sensitization

### Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

## Components:

### Ascorbic acid:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maurer optimisation test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity

Not classified based on available information.

## Components:

### Phenylbutazone:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>positive</td>
</tr>
<tr>
<td>Test Type: In vitro sister chromatid exchange assay in mammalian cells</td>
<td>negative</td>
</tr>
<tr>
<td>Test Type: Chromosomal aberration</td>
<td>negative</td>
</tr>
</tbody>
</table>
Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Ingestion
  Result: negative

- Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

- Test Type: Micronucleus test
  Species: Mouse
  Application Route: Ingestion
  Result: positive

Germ cell mutagenicity - Assessment:
Weight of evidence does not support classification as a germ cell mutagen.

**Silicon, amorphous:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials

Genotoxicity in vivo:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Rat
  Application Route: Ingestion
  Result: negative
  Remarks: Based on data from similar materials

**Ascorbic acid:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

- Test Type: Chromosome aberration test in vitro
  Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Ingestion
  Result: negative

Carcinogenicity:
Not classified based on available information.
Components:

Phenylbutazone:
Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : positive

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Result : positive

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Silicon, amorphous:
Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative
Remarks : Based on data from similar materials

Ascorbic acid:
Species : Mouse
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Reproductive toxicity
Not classified based on available information.

Components:

Phenylbutazone:
Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Embryo-fetal toxicity.: NOAEL: 42 mg/kg body weight
Result: negative

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Ingestion
Result: negative

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Ingestion
Embryo-fetal toxicity.: NOAEL: 60 mg/kg body weight
Result: negative
Silicon, amorphous:
Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Ascorbic acid:
Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Phenylbutazone:
Species: Rat
NOAEL: 50 mg/kg
LOAEL: 100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Target Organs: Kidney
Remarks: Significant toxicity observed in testing

Species: Mouse
NOAEL: 150 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks

Silicon, amorphous:
Species: Rat
NOAEL: 1.3 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Ascorbic acid:
Species: Rat, male
NOAEL: >= 8,100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Phenylbutazone:

Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

Silicon, amorphous:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Ascorbic acid:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to microorganisms: EC50: 140 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8
**Persistence and degradability**

**Components:**

**Ascorbic acid:**

**Bioaccumulative potential**

**Components:**

**Phenylbutazone:**
Partition coefficient: n-octanol/water: log Pow: 3.16

**Ascorbic acid:**
Partition coefficient: n-octanol/water: log Pow: -1.85

**Mobility in soil**
No data available

**Other adverse effects**
No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**Domestic regulation**
SAFETY DATA SHEET
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TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tempera-
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Phenylbutazone Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>3.2</td>
<td>09/30/2023</td>
<td>666668-00021</td>
<td>04/04/2023</td>
<td>05/12/2016</td>
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Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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CA / Z8