SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Phenylbutazone Formulation

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

1.1 Product identifier
Trade name : Phenylbutazone Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATA STEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 4 : H302: Harmful if swallowed.
Eye irritation, Category 2 : H319: Causes serious eye irritation.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Exclamation Mark]</td>
</tr>
</tbody>
</table>

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/face protection.

Response:
Hazardous components which must be listed on the label:
Phenylbutazone

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 20 %

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylbutazone</td>
<td>50-33-9</td>
<td>200-029-0</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3; H301 Eye Irrit. 2; H319</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td></td>
<td></td>
<td></td>
<td>231-545-4</td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
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).

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.

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

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>2.4 mg/m³ (Silica)</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA) (inhaled dust)</td>
<td>6 mg/m³ (Silica)</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>0.1 mg/m³</td>
<td>2004/37/EC</td>
</tr>
</tbody>
</table>

Further information: Carcinogens or mutagens

<table>
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<tr>
<th>Components</th>
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Phenylbutazone Formulation

Version 3.0  Revision Date: 09.04.2021  SDS Number: 673819-00015  Date of last issue: 10.10.2020  Date of first issue: 12.05.2016

8.2 Exposure controls

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
Eye protection: Wear the following personal protective equipment:
Safety goggles
Equipment should conform to I.S. EN 166

Hand protection
Material: Chemical-resistant gloves
Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer.
Wash hands before breaks and at the end of workday.

Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: paste
Colour: white
Odour: citrus
Odour Threshold: No data available

Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available

Flammability (solid, gas): May form explosive dust-air mixture during processing, han-
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Flash point : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature Decomposition temperature : No data available
pH : No data available
Viscosity Viscosity, kinematic : No data available
Solubility(ies) Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Vapour pressure : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.
Phenylbutazone Formulation

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure:
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity:
Harmful if swallowed.

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

### 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

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

**Components:**

- **Phenylbutazone:**
  - **Species:** Rabbit
  - **Result:** Irritation to eyes, reversing within 21 days

- **Silicon, amorphous:**
  - **Species:** Rabbit
  - **Method:** OECD Test Guideline 405
  - **Result:** No eye irritation
  - **Remarks:** Based on data from similar materials

### Respiratory or skin sensitisation

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

- **Phenylbutazone:**
  - **Genotoxicity in vitro:**
    - **Test Type:** Bacterial reverse mutation assay (AMES)
      - **Result:** negative
    - **Test Type:** Chromosome aberration test in vitro
      - **Result:** positive
    - **Test Type:** In vitro sister chromatid exchange assay in mammalian cells
      - **Result:** negative
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

**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
Phenylbutazone Formulation

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

Reproductive toxicity
Not classified based on available information.

Components:

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

Silicon, amorphous:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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
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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

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

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: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
aquatic invertebrates

Toxicity to algae/aquatic plants:

- **Exposure time:** 24 h
- **Method:** OECD Test Guideline 202
- **Remarks:** Based on data from similar materials

- **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

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

**Components:**

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

**Product:**

- **Assessment:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

**Product:**

- **Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods
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Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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.

SECTION 14: Transport information

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements

- H301: Toxic if swallowed.
- H319: Causes serious eye irritation.

Full text of other abbreviations

- Acute Tox.: Acute toxicity
- Eye Irrit.: Eye irritation
- 2004/37/EC: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
- IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- 2004/37/EC / TWA: Long term exposure limit
- IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
 Phenylbutazone Formulation

Version 3.0  Revision Date: 09.04.2021  SDS Number: 673819-00015  Date of last issue: 10.10.2020

Classification of the mixture:
- Acute Tox. 4: H302  Calculation method
- Eye Irrit. 2: H319  Calculation method

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification procedure:
- Acute Tox. 4: Calculation method
- Eye Irrit. 2: Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

IE / EN