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: EHSDATASTEWARD@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)
   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/ face protection.
   Response:
Phenylbutazone Formulation

**Version** 4.0  **SDS Number:** 673819-00016  **Date of last issue:** 09.04.2021

**Revision Date:** 27.08.2021  **Date of first issue:** 12.05.2016

P301 + P312 + P330  IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P337 + P313  If eye irritation persists: Get medical advice/ attention.

**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>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>Acute Tox. 3; H301 Eye Irrit. 2; H319</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute toxicity estimate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute oral toxicity: 245 mg/kg</td>
<td></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 prod-: Carbon oxides
5.3 Advice for firefighters

Special protective equipment for firefighters:
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.
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) (inhalable dust)</td>
<td>6 mg/m³ (Silica)</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>
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: |
| Hand protection | Safety goggles |
| Remarks | Equipment should conform to I.S. EN 166 |

| Material | Chemical-resistant gloves |
| 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, handling or other means. |
| Flammability (liquids) | No data available |
## Phenylbutazone Formulation

**Version 4.0**  
**Revision Date:** 27.08.2021  
**SDS Number:** 673819-00016  
**Date of last issue:** 09.04.2021  
**Date of first issue:** 12.05.2016

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: $n$-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explosives</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity
Not classified as a reactivity hazard.

#### 10.2 Chemical stability
Stable under normal conditions.

#### 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
Acute toxicity estimate: 245 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Phenylbutazone:

Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
**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>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>27.08.2021</td>
<td>673819-00016</td>
<td>09.04.2021</td>
<td>12.05.2016</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td>Chromosome aberration test in vitro</td>
<td>positive</td>
</tr>
<tr>
<td></td>
<td>In vitro sister chromatid exchange assay in mammalian cells</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td>Chromosomal aberration</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td>Rodent dominant lethal test (germ cell) (in vivo)</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Phenylbutazone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
</tbody>
</table>
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

Reproductive toxicity
Not classified based on available information.

Components:

Phenylbutazone:

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Embryo-foetal toxicity: NOAEL: 42 mg/kg body weight</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight</td>
</tr>
</tbody>
</table>

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Phenylbutazone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>150 mg/kg</td>
</tr>
</tbody>
</table>
Phenylbutazone Formulation

Application Route : Ingestion
Exposure time : 13 Weeks

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

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

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**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**

<table>
<thead>
<tr>
<th>Product</th>
<th>: 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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminated packaging</td>
<td>: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.</td>
</tr>
</tbody>
</table>

**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 : Not applicable
the market and use of certain dangerous substances, preparations and articles (Annex XVII)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

REACH - List of substances subject to authorisation (Annex XIV)


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

IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concen-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Version 4.0  Revision Date: 27.08.2021  SDS Number: 673819-00016  Date of last issue: 09.04.2021  Date of first issue: 12.05.2016

<table>
<thead>
<tr>
<th>Classification of the mixture</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4 H302</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Irrit. 2 H319</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

Further information:


Classification of the mixture:

Acute Tox. 4 H302
Eye Irrit. 2 H319

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