

## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

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### 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

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### 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

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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

disposal plant.

### 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

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Oils, sesame	Sesamum indicum oil	8008-74-0	$\geq 60 - < 80$ *
Phenylbutazone	3,5-Pyrazolidinedione, 4-butyl-1,2-diphenyl-	50-33-9	$\geq 10 - < 30$ *
Silicon, amorphous	Silicon dioxide	112945-52-5	$\geq 5 - < 10$ *
Ascorbic acid	No data available	50-81-7	$\geq 1 - < 5$ *

\* 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

---

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 (NO<sub>x</sub>)
- 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.
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### 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.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

Local/Total ventilation : Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.  
Advice on safe handling : Use only with adequate ventilation.  
: 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Oils, sesame	8008-74-0	TWAEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL
Phenylbutazone	50-33-9	TWA	30 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal
Silicon, amorphous	112945-52-5	TWAEV (respirable dust)	6 mg/m <sup>3</sup>	CA QC OEL
Ascorbic acid	50-81-7	TWA	5000 µg/m <sup>3</sup> (OEB 1)	Internal

**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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

---

### Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! 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.

Eye protection : Wear the following personal protective equipment:  
Safety goggles

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).

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.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : paste

Color : white

Odor : citrus

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower : No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

---

flammability limit

Vapor pressure : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

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

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

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation

Skin contact

Ingestion

Eye contact

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

---

### Acute toxicity

Harmful if swallowed.

#### Product:

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

#### Components:

##### **Oils, sesame:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### **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:

##### **Oils, sesame:**

Species : Rabbit  
Result : No skin irritation

##### **Silicon, amorphous:**

## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

---

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.

### **Components:**

#### **Oils, sesame:**

Species : Rabbit  
Result : No eye irritation

#### **Phenylbutazone:**

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

#### **Silicon, amorphous:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

### **Ascorbic acid:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### **Components:**

#### **Oils, sesame:**

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Result : negative



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

---

### Ascorbic acid:

Test Type : Maurer optimisation test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Oils, sesame:

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

#### 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

Test Type: Chromosomal aberration  
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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

---

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

---

### 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.

## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

---

### 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 :  $\geq 8,100$  mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks

### Aspiration toxicity

Not classified based on available information.

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## 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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version 5.0      Revision Date: 07/06/2024      SDS Number: 666668-00023      Date of last issue: 04/06/2024  
Date of first issue: 05/12/2016

---

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:

#### Oils, sesame:

Biodegradability : Result: Readily biodegradable.

#### Ascorbic acid:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 5 d  
Method: OECD Test Guideline 302

### Bioaccumulative potential

#### Components:

#### Phenylbutazone:

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

#### Ascorbic acid:

Partition coefficient: n-octanol/water : log Pow: -1.85

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

---

### 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

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

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

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## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

CA QC OEL	:	Québec. Regulation respecting occupational health and safe-
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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

ty, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants

CA QC OEL / TWAEV : Time-weighted average exposure value

AIIC - 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; KECI - 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 Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 07/06/2024  
Date format : mm/dd/yyyy

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	666668-00023	Date of first issue: 05/12/2016

---

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.

CA / Z8