

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## PHENYLBUTAZONUM

EN

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name:	Phenylbutazone Phenylbutazonum Fenylbutazon Phénylbutazone Phenylbutazon
N° CAS:	50-33-9
N° EC:	200-029-0

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Acute toxicity (category 3)	H301
Acute toxicity (category 4)	H312
Skin irritation (category 2)	H315
Skin sensitization (category 1)	H317
Eye irritation (category 2A)	H319
Acute toxicity (category 4)	H332
Respiratory sensitization (category 1)	H334
Specific target organ toxicity, single exposure (category 3)	H335
Carcinogenicity	H351
Reproductive toxicity (category 2)	H361

#### 2.2 Label elements

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### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s):

Danger

Hazard statements:

H301	Toxic if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H361	Suspected of damaging fertility or the unborn child <state specific effect if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash ... thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.
P285	Not applicable.
P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
P302 + P352	IF ON SKIN: Wash with plenty of water/...
P304 + P312	IF INHALED: Call a POISON CENTER/doctor/... if you feel unwell.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P304 + P341	Not applicable.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER/doctor/... if you feel unwell.
P321	Specific treatment (see ... on this label).
P322	Not applicable.
P330	Rinse mouth.
P332 + P313	If skin irritation occurs: Get medical advice/attention.

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P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...
P362	Take off contaminated clothing.
P363	Wash contaminated clothing before reuse.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to...
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Phenylbutazone
IUPAC name:	4-butyl-1,2-diphenylpyrazolidine-3,5-dione
Synonyms:	Not applicable.
N° CAS:	50-33-9
N° EC:	200-029-0
Molecular Formula:	C <sub>19</sub> H <sub>20</sub> N <sub>2</sub> O <sub>2</sub>
Content:	99.0 % to 101.0 % (dried substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Not applicable.
After inhalation:	Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.
After skin contact:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist.
After ingestion:	Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

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Self-protection of the first aider: Not applicable.

### 4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation: Not available.

Symptoms/effects after skin contact: Not available.

Symptoms/effects after eye contact: Not available.

Symptoms/effects after ingestion: Symptoms may include dizziness, headache, nausea and loss of coordination.

### 4.3 Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Water spray. Carbon dioxide. Dry powder.

Unsuitable extinguishing media: Not available.

### 5.2 Special hazards arising from the substance/mixture

Fire hazard: See Heading 2.2.

### 5.3 Advice for firefighters

Surrounding fires: Use extinguishing media appropriate for surrounding fire.

Protection against fire: Not available.

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

General precautions: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spay.

Personal precautions: spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

#### For emergency responders

General precautions: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spay.

Personal precautions: spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

### 6.2 Environmental precautions

Not available.

### 6.3 Methods and material for containment and cleaning up

Ensure waste is collected and contained. Clean thoroughly.

### 6.4 Reference to other sections

Not available.

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### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Material should be handled with caution. Avoid any direct contact with the product.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in well closed container. Protected from light.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Not available.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Not available.

#### 8.2 Exposure controls

##### Appropriate engineering control

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter.

##### Individual protection measures

Eye/face protection:	Chemical goggles or safety glasses.
Skin protection:	Wear suitable protective clothing.
Hand protection:	Wear suitable gloves resistant to chemical penetration.
Respiratory protection:	Wear approved mask. In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards:	Not determined.

##### Environmental exposure control

Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	104-107 °C

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Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Practically insoluble in water, sparingly soluble in alcohol. It dissolves in alkaline solutions.
Solubility in water:	Insoluble.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Stable under normal condition.

### 10.2 Chemical stability

Not available.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

None under normal use. See Heading 7.

### 10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

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Acute toxicity:	LD <sub>50</sub> oral-rat: 245 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Ecology-general: Hazardous waste. Use suitable disposal containers.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Regional legislation (waste): Dispose in a safe manner in accordance with local/national regulations.

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Product/Packaging disposal recommendations: Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : 2811

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : TOXIC SOLID, ORGANIC, N.O.S.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : 6.1



##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : III

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Dangerous to the environment: No  
Marine pollutant: No

##### 14.6 Special precautions for user

###### Overland transport

- Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Phenylbutazone)
- UN No.: 2811
- ADR Class: 6.1
- ADR Packing group: III
- Labeling ADR:



###### Transport by sea

- Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Phenylbutazone)
- UN No.: 2811
- IMDG Class: 6.1
- IMDG Packing group: III
- IMDG-Label:



###### Air transport

- Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Phenylbutazone)
- UN No.: 2811



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- IATA – Class or division: 6.1

- IATA Packing group: III

- IATA-Label:



### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

### 14.8 Additional transport information

Not available.

## SECTION 15: REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

### 15.2 Chemical safety assessment

Not available.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

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### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

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