Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 10.03.2023 Version number 3.00 (replaces version 2.00) Revision: 10.03.2023

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

· **Product identifier**

· **Trade name:** **Phenylbutazone, API**

· **Article number:** 2511
· **CAS Number:**
50-33-9
· **EC number:**
200-029-0
· **Registration number** The substance is exempt from REACH-registration.
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
· **Uses advised against** No relevant information available.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY

· **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
· **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Acute Tox. 3	H301 Toxic if swallowed.
Acute Tox. 4	H312 Harmful in contact with skin.
Acute Tox. 4	H332 Harmful if inhaled.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
Resp. Sens. 1	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1	H317 May cause an allergic skin reaction.
Carc. 2	H351 Suspected of causing cancer.
STOT SE 3	H335 May cause respiratory irritation.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.

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· **Hazard pictograms**

GHS06

GHS08

· **Signal word** Danger
· **Hazard statements**

H301	Toxic if swallowed.
H312+H332	Harmful in contact with skin or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H335	May cause respiratory irritation.

· **Precautionary statements**

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321	Specific treatment (see on this label).
P330	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.
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Determination of endocrine-disrupting properties** Not applicable.

3 Composition/information on ingredients

· **Substances**
· **CAS No. Description**
CAS: 50-33-9 phenylbutazone
· **Identification number(s)**
· **EC number:** 200-029-0

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4 First aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** Do not induce vomiting; call for medical help immediately.
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
All regular extinguishing media can be used.
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.
· **Advice for firefighters**
· **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.
· **Additional information**
Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Avoid contact with the substance.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Take up dry. Clean up with water.
Dispose contaminated material as waste according to item 13.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Precautions for safe handling**
Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.
· **Information about fire - and explosion protection:** Avoid dust formation when handling larger quantities.

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· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Keep container tightly sealed.
· **Storage class:** TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:** Not required.
· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Appropriate engineering controls** No further data; see item 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
· **Respiratory protection:**
Dust protection mask.
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
· **Hand protection** Protective gloves
· **Material of gloves**
Rubber gloves
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye/face protection** Tightly sealed goggles
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**

· **Physical state**	Solid
· **Colour:**	White
· **Odour:**	Nearly odourless
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	104–107 °C

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· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Product is not flammable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **pH**	Not applicable.
· **Viscosity:**	
· **Kinematic viscosity**	Not applicable.
· **Dynamic:**	Not applicable.
· **Solubility**	
· **water at 22 °C:**	0.7 g/l
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Particle characteristics**	Not determined
· **Other information**	
· **Appearance:**	
· **Form:**	Solid
· **Important information on protection of health and environment, and on safety.**	
· **Auto-ignition temperature:**	Not determined.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	
· **Evaporation rate**	Not applicable.
· **Information with regard to physical hazard classes**	
· **Explosives**	Void Void
· **Flammable gases**	Void Void
· **Aerosols**	Void Void
· **Oxidising gases**	Void Void
· **Gases under pressure**	Void Void
· **Flammable liquids**	Void Void
· **Flammable solids**	Void Void

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· **Self-reactive substances and mixtures**	Void Void
· **Pyrophoric liquids**	Void Void
· **Pyrophoric solids**	Void Void
· **Self-heating substances and mixtures**	Void Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void Void
· **Oxidising liquids**	Void Void
· **Oxidising solids**	Void Void
· **Organic peroxides**	Void Void
· **Corrosive to metals**	Void Void
· **Desensitised explosives**	Void Void

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:**
Carbon monoxide
Carbon dioxide
Nitrogen oxides

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity**
Toxic if swallowed.
Harmful in contact with skin or if inhaled.
· **LD/LC50 values relevant for classification:**
Oral LD50 245 mg/kg (rat)
· **Skin corrosion/irritation** Causes skin irritation.
· **Serious eye damage/irritation** Causes serious eye irritation.
· **Respiratory or skin sensitisation**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.

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· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Suspected of causing cancer.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** May cause respiratory irritation.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.
· **Information on other hazards**
· **Endocrine disrupting properties**
On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Endocrine disrupting properties**
Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.
The product does not contain substances with endocrine disrupting properties.
· **Other adverse effects**
· **Additional ecological information:**
· **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to local regulations.

14 Transport information

· **UN number or ID number**
· **ADR, IMDG, IATA** UN2811

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· **UN proper shipping name**	
· **ADR**	2811 TOXIC SOLID, ORGANIC, N.O.S. (phenylbutazone)
· **IMDG**	TOXIC SOLID, ORGANIC, N.O.S. (phenylbutazone)
· **IATA**	Toxic solid, organic, n.o.s. (phenylbutazone)
· **Transport hazard class(es)**	
· **ADR, IMDG, IATA**	
· **Class**	6.1 Toxic substances.
· **Label**	6.1
· **Packing group**	
· **ADR, IMDG, IATA**	III
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Toxic substances.
· **Hazard identification number (Kemler code):**	60
· **EMS Number:**	F-A,S-A
· **Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	5 kg
· **Transport category**	2
· **Tunnel restriction code**	E
· **IMDG**	
· **Limited quantities (LQ)**	5 kg
· **UN "Model Regulation":**	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (PHENYLBUTAZONE), 6.1, III

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Not listed
· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
Substance is not listed.

· **National regulations:**
· **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**
TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.
· **Reasons for alterations** This version replaces all old versions.
· **Version number of previous version:** 2.00

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· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Carc. 2: Carcinogenicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3