

Phenylbutazone

Safety Data Sheet

258393

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 06/03/2012 Revision date 08/11/2019
 Supersedes 01/03/2017

Version: 3.1

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

1.1. Product identifier

Product form : Substance
 Substance name : Phenylbutazone
 IUPAC name : 4-Butyl-1,2-diphenylpyrazolidine-3,5-dione
 EC-No. : 200-029-0
 CAS-No. : 50-33-9
 Product code : 258393
 Formula : C₁₉H₂₀N₂O₂
 Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - The Netherlands
 T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

| Organisation/Company | Address | Comment |
|---|---------------------------------|---------|
| Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust | Avonley Road SE14 5ER London | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 3 H301
 Skin corrosion/irritation, Category 2 H315

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Serious eye damage/eye irritation, Category 2 H319
Respiratory sensitisation, Category 1B H334
Skin sensitisation, category 1B H317
Carcinogenicity, Category 2 H351

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP) :



GHS06



GHS08

Signal word (CLP) :

Danger

Hazard statements (CLP) :

H301 - Toxic if swallowed.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H351 - Suspected of causing cancer.

Precautionary statements (CLP) :

P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|----------------|---|----------|--|
| Phenylbutazone | (CAS-No.) 50-33-9 (EC-No.) 200-029-0 | 99 - 101 | Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1B, H334 Skin Sens. 1B, H317 Carc. 2, H351 |

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- | | |
|---------------------------------------|--|
| First-aid measures after inhalation | : Remove victim to fresh air Obtain medical attention if breathing difficulty persists. |
| First-aid measures after skin contact | : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse Seek medical attention if ill effect or irritation develops. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water Seek medical advice. |
| First-aid measures after ingestion | : Rinse mouth. Seek medical attention immediately. |

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- | | |
|--------------------------------|--|
| Suitable extinguishing media | : Carbon dioxide Dry powder Foam Water spray. |
| Unsuitable extinguishing media | : Do not use a heavy water stream. |

5.2. Special hazards arising from the substance or mixture

- | | |
|--|--|
| Fire hazard | : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides. |
| Explosion hazard | : Product is not explosive. |
| Hazardous decomposition products in case of fire | : Nitrogen oxides Carbon oxides (CO, CO ₂). |

5.3. Advice for firefighters

- | | |
|--------------------------------|---|
| Firefighting instructions | : Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not enter fire area without proper protective equipment, including respiratory protection. |

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak if safe to do so.

Methods for cleaning up : Take up liquid spill into absorbent material. Hose down area with water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from sunlight.
Store away from heat.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Handle in accordance with good industrial hygiene and safety practice.

Hand protection:

| Type | Material | Permeation | Thickness (mm) | Standard |
|--------|----------------------|-------------------|----------------|------------|
| Gloves | Nitrile rubber (NBR) | 6 (> 480 minutes) | 0,11 | EN ISO 374 |

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Chemical resistant apron. Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|--|
| Physical state | : Solid |
| Appearance | : Crystalline powder. |
| Molecular mass | : 308.4 g/mol |
| Colour | : White. |
| Odour | : odourless. |
| Odour threshold | : No data available |
| pH | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : 104 - 107 °C |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : No data available |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : Poorly soluble in water Soluble in dilute solutions of alkali hydroxides. Water: 0.7 g/l |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : No data available |
| Oxidising properties | : No data available |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

Direct sunlight.

10.5. Incompatible materials

Strong oxidizers

Strong acids

Bases.

10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Toxic if swallowed.

| Phenylbutazone (50-33-9) | |
|--------------------------|-----------|
| LD50 oral rat | 245 mg/kg |

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.

Germ cell mutagenicity : Not classified

Carcinogenicity : Suspected of causing cancer.

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

IARC group : 2A

SECTION 12: Ecological information**12.1. Toxicity**

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

| Phenylbutazone (50-33-9) | |
|-------------------------------|---|
| Persistence and degradability | Biodegradability in water: no data available. |

12.3. Bioaccumulative potential

| Phenylbutazone (50-33-9) | |
|---------------------------|------------------------------------|
| Bioaccumulative potential | No bioaccumulation data available. |

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects



No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Avoid release to the environment.
 Product/Packaging disposal : Dispose in a safe manner in accordance with local/national recommendations
 recommendations regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

| ADR | IATA |
|--|---|
| 14.1. UN number | |
| 2811 | 2811 |
| 14.2. UN proper shipping name | |
| TOXIC SOLID, ORGANIC, N.O.S. | Toxic solid, organic, n.o.s. |
| 14.3. Transport hazard class(es) | |
| 6.1 | 6.1 |
|  |  |
| 14.4. Packing group | |
| III | III |
| 14.5. Environmental hazards | |
| Dangerous for the environment : No | Dangerous for the environment : No |
| No supplementary information available | |

14.6. Special precautions for user**. Overland transport**

Classification code (ADR) : T2
 Special provisions (ADR) : 274, 614
 Limited quantities (ADR) : 5kg
 Excepted quantities (ADR) : E1
 Packing instructions (ADR) : P002, IBC08, LP02, R001
 Special packing provisions (ADR) : B3
 Mixed packing provisions (ADR) : MP10

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Portable tank and bulk container : T1
instructions (ADR)

Portable tank and bulk container : TP33
special provisions (ADR)

Tank code (ADR) : SGAH, L4BH

Tank special provisions (ADR) : TU15, TE19

Vehicle for tank carriage : AT


Transport category (ADR) : 2

Special provisions for carriage - Bulk (ADR) : VC1, VC2, AP7

Special provisions for carriage - Loading, unloading and handling (ADR) : CV13, CV28

Special provisions for carriage - Operation (ADR) : S9

Hazard identification number (Kemler No.) : 60

Orange plates : 

Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

PCA Excepted quantities (IATA) : E1

PCA Limited quantities (IATA) : Y645

PCA limited quantity max net quantity (IATA) : 10kg

PCA packing instructions (IATA) : 670

PCA max net quantity (IATA) : 100kg

CAO packing instructions (IATA) : 677

CAO max net quantity (IATA) : 200kg

Special provisions (IATA) : A3, A5

ERG code (IATA) : 6L

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Phenylbutazone is not on the REACH Candidate List

Phenylbutazone is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

| | | | |
|-----|---|----------|--|
| 1.2 | Main use category | Added | |
| 1.4 | Emergency telephone | Modified | Added additional information |
| 2 | Classification (DSD/DPD) | Removed | Obsolete |
| 2.1 | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Modified | |
| 2.2 | Precautionary statements (CLP) | Removed | |
| 4.1 | First-aid measures after ingestion | Removed | |
| 6.1 | Protective equipment | Removed | |
| 6.3 | Methods for cleaning up | Added | |
| 7.2 | Maximum storage period | Removed | |
| 8.2 | Hand protection | Modified | Specified material, thickness, et cetera of gloves |

Abbreviations and acronyms:

| | |
|-------|---|
| SDS | Safety Data Sheet |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| IMDG | International Maritime Dangerous Goods |
| IATA | International Air Transport Association |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |

Data sources : Supplier.

Full text of H- and EUH-statements:

| | |
|---------------------|--|
| Acute Tox. 3 (Oral) | Acute toxicity (oral), Category 3 |
| Carc. 2 | Carcinogenicity, Category 2 |
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Resp. Sens. 1B | Respiratory sensitisation, Category 1B |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| Skin Sens. 1B | Skin sensitisation, category 1B |
| H301 | Toxic if swallowed. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H351 | Suspected of causing cancer. |

SDS EU (REACH Annex II) duchefa nieuwe logo

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.