

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Phenylbutazone Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification


Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Acute toxicity (Oral) : Category 4

Serious eye damage/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.

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

P280 Wear eye protection/ face protection.

Response:

P301 + P317 + P330 IF SWALLOWED: Get medical help.
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 + P317 If eye irritation persists: Get medical help.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 20 %

Other hazards which do not result in classification

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|----------------|---------|-----------------------|
| Phenylbutazone | 50-33-9 | $\geq 20 - < 30$ |
| Ascorbic acid | 50-81-7 | $\geq 1 - < 5$ |

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 : Harmful if swallowed.
Causes serious eye irritation.

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

delayed 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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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_x)

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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- 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.
- Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|----------------|---------|-------------------------------|--|----------|
| Phenylbutazone | 50-33-9 | TWA | 30 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 300 µg/100 cm ² | Internal |
| Ascorbic acid | 50-81-7 | TWA | 5000 µg/m ³ (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
- Hand protection

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

| | | |
|--------------------------|---|---|
| Material | : | Chemical-resistant gloves |
| Remarks | : | Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|---|
| Appearance | : | paste |
| Colour | : | white |
| Odour | : | citrus |
| Odour 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 flammability limit | : | No data available |

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

Vapour pressure : No data available

Relative vapour density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

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

Auto-ignition 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 size : No data available

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

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

Ascorbic acid:

Acute oral toxicity : LD50 (Rat): 11,900 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Ascorbic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Phenylbutazone:

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

Ascorbic acid:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Ascorbic acid:

Test Type : Maurer optimisation test
Exposure routes : Skin contact

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

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.

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)

SAFETY DATA SHEET

according to the Globally Harmonized System



Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

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

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 foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Embryo-foetal toxicity: NOAEL: 42 mg/kg body weight
Result: negative

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight
Result: negative

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

Ascorbic acid:

Effects on foetal development : Test Type: Embryo-foetal 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.

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

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Phenylbutazone:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

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:

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

Mobility in soil

No data available

Other adverse effects

No data available

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Phenylbutazone Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 673820-00019 Date of last issue: 04.04.2023
Date of first issue: 12.05.2016

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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 30.09.2023

Further information

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

Date format : dd.mm.yyyy

Full text of other abbreviations

AllC - 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 Con-

SAFETY DATA SHEET

according to the Globally Harmonized System



Phenylbutazone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.2 | 30.09.2023 | 673820-00019 | Date of first issue: 12.05.2016 |

centration 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

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.

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