

# Phenylbutazone Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 16.1 2024/09/28 666677-00025 Date of first issue: 2016/05/12

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Phenylbutazone Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Acute toxicity (Oral) : Category 4

Serious eye damage/eye irri-

tation

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/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON



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CENTER/ 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 advice/ at-

tention.

# 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

lines of the emergency as-

sumed

Important symptoms and out : Contact with dust can cause mechanical irritation or drying of

the skin.

May form explosive dust-air mixture during processing, han-

dling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Phenylbutazone	50-33-9	>= 20 - < 30	9-1154
Ascorbic acid	50-81-7	>= 1 - < 10	5-62

#### 4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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.

: Wash with water and soap. In case of skin contact

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.



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Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

Harmful if swallowed.
 Causes serious eve irritation.

delayed

Causes serious eye imitation.

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 prod- :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec-:

tive equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces



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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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 7. HANDLING AND STORAGE

Handling

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. Do not breathe dust.

Advice on safe handling

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 as-

sessment

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.

Avoidance of contact

Oxidizing agents 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.

Storage

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

Packaging material Unsuitable material: None known.



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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Phenylbutazone	50-33-9	TWA	30 μg/m3 (OEB 3)	Internal
		Wipe limit	300 μg/100 cm <sup>2</sup>	Internal
Ascorbic acid	50-81-7	TWA	5000 μg/m3 (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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

Particulates type

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).

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : paste



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Colour white

Odour citrus

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point Not applicable

Decomposition temperature No data available

pΗ No data available

No data available Evaporation rate

No data available Auto-ignition temperature

Viscosity

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure No data available

Density and / or relative density

Density No data available

Relative vapour density No data available

Explosive properties Not explosive



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

Molecular weight : No data available

Particle characteristics

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 reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

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:** 

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



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#### 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

Result : No eye irritation

Method : OECD Test Guideline 405

### 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 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



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Test Type: In vitro sister chromatid exchange assay in mam-

malian 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) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Phenylbutazone:

Species : Rat Application Route : Ingestion



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Exposure time : 103 weeks Result : positive

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Result : positive

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

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 develop-

ment

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

Ascorbic acid:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

**Application Route: Ingestion** 

Result: negative

STOT - single exposure

Not classified based on available information.



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#### 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 : >= 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

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



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#### 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

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

# 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

### **International Regulations**

**UNRTDG** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable



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Environmentally hazardous : no

**IATA-DGR** 

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable Class : Not applicable : Not applicable Subsidiary risk : Not applicable Packing group Labels : Not applicable **EmS Code** Not applicable Marine pollutant Not applicable

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

Refer to section 15 for specific national regulation.

### Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

# **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

### **Industrial Safety and Health Law**

# **Harmful Substances Prohibited from Manufacture**

Not applicable

# **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable



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Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

**Substances Subject to be Notified Names** 

Not applicable

**Substances Subject to be Indicated Names** 

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning** 

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

**Poisonous and Deleterious Substances Control Law** 

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

**High Pressure Gas Safety Act** 

Not applicable

**Explosive Control Law** 

Not applicable

**Vessel Safety Law** 

Not regulated as a dangerous good

**Aviation Law** 

Not regulated as a dangerous good



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#### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act** 

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **16. OTHER INFORMATION**

#### **Further information**

Sources of key data used to compile the Safety Data

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Date format : yyyy/mm/dd

# Full text of other abbreviations

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



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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; TECI - 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.

JP / EN