

# Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 6.0 2024/09/28 5939804-00009 Date of first issue: 2020/05/26

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Phthalylsulfathiazole / Sulfamerazine 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

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

#### **GHS** label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

### **Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %

### Other hazards which do not result in classification

Important symptoms and out: : lines of the emergency assumed :

 Dust contact with the eyes can lead to mechanical irritation.
 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



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### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Kaolin	1332-58-7	>= 70 - < 80	1-26
Aluminum hydroxide	21645-51-2	>= 10 - < 20	1-17
Phthalylsulfathiazole	85-73-4	>= 10 - < 20	-
Sulfamerazine	127-79-7	>= 1 - < 10	-

### 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.

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

Get medical attention if symptoms occur.

In case of eye contact If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

> Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Protection of first-aiders

Notes to physician

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. No special precautions are necessary for first aid responders.

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

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulphur oxides



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Specific extinguishing meth-

Metal oxides

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

Wear self-contained breathing apparatus for firefighting if nec-

essarv

Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

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

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.

Advice on safe handling : Do not breathe dust.



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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.

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.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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.

### 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
Kaolin	1332-58-7	OEL-M (Respirable dust)	0.5 mg/m3	JP OEL JSOH
		OEL-M (Total dust)	2 mg/m3	JP OEL JSOH
		TWA (Res- pirable par- ticulate mat- ter)	2 mg/m3	ACGIH
Phthalylsulfathiazole	85-73-4	TWA	OEB 2 (>= 100 < 1000 μg/m3)	Internal
Aluminum hydroxide	21645-51-2	TWA (Res-	1 mg/m3	ACGIH



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		pirable par- ticulate mat- ter)	(Aluminium)	
Sulfamerazine	127-79-7	TWA	OEB 2 (>= 100 < 1000 μg/m3)	Internal

**Engineering measures** Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

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 Material

Particulates type

Chemical-resistant gloves

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection Work uniform or laboratory coat.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state fine powder

Colour White to light yellow

Odour characteristic

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) Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit



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Lower explosion limit / Lower flammability limit

No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : practically insoluble

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : Not applicable

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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.



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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**

Not classified based on available information.

### **Components:**

Kaolin:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg

Aluminum hydroxide:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Acute inhalation toxicity LC50 (Rat): > 5.09 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Remarks: Based on data from similar materials

Phthalylsulfathiazole:

LD50 (Rat, female): > 2,000 mg/kg Acute oral toxicity

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Acute dermal toxicity LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

#### Sulfamerazine:



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Acute oral toxicity : LD50 (Mouse): 25,000 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

Kaolin:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Aluminum hydroxide:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Phthalylsulfathiazole:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

Kaolin:

Species : Rabbit

Result : No eye irritation

Aluminum hydroxide:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Phthalylsulfathiazole:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.



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### Respiratory sensitisation

Not classified based on available information.

### **Components:**

### Aluminum hydroxide:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

### Aluminum hydroxide:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: positive

Remarks: Based on data from similar materials

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: equivocal

Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test

Result: positive

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 474

Result: negative

### Carcinogenicity

Not classified based on available information.

### **Components:**

### Aluminum hydroxide:

Species : Rat

Application Route : inhalation (dust/mist/fume)

Exposure time : 86 weeks



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Result : negative

Remarks : Based on data from similar materials

### Reproductive toxicity

Not classified based on available information.

#### **Components:**

### Aluminum hydroxide:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

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.

#### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### **Components:**

### Aluminum hydroxide:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 364 Days

Method : OECD Test Guideline 426

Remarks : Based on data from similar materials

Species : Rat

NOAEL : > 0.2 mg/kg

Application Route : inhalation (dust/mist/fume)

Exposure time : 12 Months

Remarks : Based on data from similar materials

### **Aspiration toxicity**

Not classified based on available information.



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### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### Components:

Aluminum hydroxide:

Toxicity to fish : LL50 (Salmo trutta (brown trout)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EL50 (Selenastrum capricornutum (green algae)): > 100 mg/l

Exposure time: 96 h

### Phthalylsulfathiazole:

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Sulfamerazine:

Toxicity to fish : LC50 (Morone saxatilis (striped bass)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 227 mg/l

Exposure time: 48 h

### Persistence and degradability

No data available

Bioaccumulative potential

**Components:** 

Phthalylsulfathiazole:

Partition coefficient: n-

: log Pow: -2

octanol/water
Sulfamerazine:

Partition coefficient: n-

: log Pow: 0.728

octanol/water

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable



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### 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

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-

ger aircraft)

Not applicable

**IMDG-Code** 

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

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

Not applicable for product as supplied.



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### **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

## 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



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### 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

### 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



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### **16. OTHER INFORMATION**

#### **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 Agen-

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH : Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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 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



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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