

# Phthalylsulfathiazole / Sulfamerazine Formulation

Version 2.0      Revision Date: 04.04.2023      SDS Number: 5939807-00007      Date of last issue: 01.10.2022  
Date of first issue: 26.05.2020

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## Section 1: Identification

Product name : Phthalylsulfathiazole / Sulfamerazine Formulation

### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

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

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## Section 2: Hazard identification

### GHS Classification

Not a hazardous substance or mixture.

### 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

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.

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## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Kaolin	1332-58-7	>= 70 -< 90
Aluminum hydroxide	21645-51-2	>= 10 -< 20
Phthalylsulfathiazole	85-73-4	>= 10 -< 20

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Sulfamerazine	127-79-7	>= 1 -< 10
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## Section 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 : 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 : Contact with dust can cause mechanical irritation or drying of the skin.  
 Dust contact with the eyes can lead to mechanical irritation.
- Protection of first-aiders : No special precautions are necessary for first aid responders.
- Notes to physician : Treat symptomatically and supportively.

## Section 5: Fire-fighting measures

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 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 products : Carbon oxides  
 Nitrogen oxides (NO<sub>x</sub>)  
 Sulphur oxides  
 Metal oxides  
 Silicon oxides
- 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 : Wear self-contained breathing apparatus for firefighting if necessary.  
 Use personal protective equipment.

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## Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures : 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.

## Section 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.  
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.  
Take care to prevent spills, waste and minimize release to the environment.
- 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.

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- 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

## Section 8: Exposure controls/personal protection

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Kaolin	1332-58-7	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		WES-TWA (Respirable dust)	2 mg/m <sup>3</sup>	NZ OEL
		TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH
Phthalylsulfathiazole	85-73-4	TWA	OEB 2 (>= 100 < 1000 µg/m <sup>3</sup> )	Internal
Aluminum hydroxide	21645-51-2	TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminium)	ACGIH
Sulfamerazine	127-79-7	TWA	OEB 2 (>= 100 < 1000 µg/m <sup>3</sup> )	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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection  
 Material : 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.

## Section 9: Physical and chemical properties

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Appearance	:	fine powder
Colour	:	White to light yellow
Odour	:	characteristic
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	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	practically insoluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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Molecular weight : No data available

Particle size : No data available

## Section 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.

## Section 11: Toxicological information

Exposure routes : 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  
 Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 2.07 mg/l  
 Exposure time: 4 h  
 Test atmosphere: dust/mist  
 Assessment: The substance or mixture has no acute inhalation toxicity  
 Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg  
 Assessment: The substance or mixture has no acute dermal toxicity  
 Remarks: Based on data from similar materials

#### 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 toxicity

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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 inhalation toxicity  
Remarks: Based on data from similar materials

**Phthalylsulfathiazole:**

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity

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:**

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  
Remarks : Based on data from similar materials

**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

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||Remarks : Based on data from similar materials

## 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.

### 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

## Chronic toxicity

### 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 synthesis in mammalian cells (in vitro)  
Result: equivocal  
Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test  
Result: positive



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Genotoxicity in vivo : Remarks: Based on data from similar materials  
: 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  
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 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:**

#### **Aluminum hydroxide:**

Species : Rat  
NOAEL : > 100 mg/kg

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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.

## Section 12: Ecological information

### Ecotoxicity

#### Components:

##### **Kaolin:**

Toxicity to fish (Chronic toxicity)	:	NOELR (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 30 d
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##### **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

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## Bioaccumulative potential

### Components:

#### Phthalylsulfathiazole:

|| Partition coefficient: n-octanol/water : log Pow: -2

#### Sulfamerazine:

|| Partition coefficient: n-octanol/water : log Pow: 0.728

#### Mobility in soil

No data available

#### Other adverse effects

No data available

## Section 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 handling site for recycling or disposal.  
 If not otherwise specified: Dispose of as unused product.

## Section 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

#### 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 aircraft) : Not applicable  
 Packing instruction (passenger aircraft) : Not applicable

#### IMDG-Code

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable

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Subsidiary risk : Not applicable  
Packing group : Not applicable  
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

#### NZS 5433

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

### Special precautions for user

Not applicable

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## Section 15: Regulatory information

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

#### HSNO Approval Number

Not applicable

#### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined  
DSL : not determined  
IECSC : not determined

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## Section 16: Other information

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### 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/>

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

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### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average  
 NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIIC - 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; 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.

# SAFETY DATA SHEET



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