

# Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 5939808-00008
 Date of first issue: 26.05.2020

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Phthalylsulfathiazole / Sulfamerazine Formulation

### Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

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

### **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.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	
Kaolin	1332-58-7	>= 70 -< 90	



## Phthalylsulfathiazole / Sulfamerazine Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 5939808-00008 Date of first issue: 26.05.2020

Phthalylsulfathiazole	85-73-4	>= 10 -< 20
Aluminum hydroxide	21645-51-2	>= 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.

Wash with water and soap. In case of skin contact

Get medical attention if symptoms occur.

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

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 Metal oxides Silicon oxides

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



# Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: 2.1 30.09.2023 5939808-00008

Date of last issue: 04.04.2023 Date of first issue: 26.05.2020

Evacuate area.

Special protective equipment

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

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

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

Advice on safe handling

Use only with adequate ventilation.

Do not breathe dust.

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.

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.



# Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 5939808-00008
 Date of first issue: 26.05.2020

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
Kaolin	1332-58-7	PEL (long term) (Res- pirable dust)	2 mg/m3	SG OEL
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH
Phthalylsulfathiazole	85-73-4	TWA	OEB 2 (>= 100 < 1000 μg/m3)	Internal
Aluminum hydroxide	21645-51-2	TWA (Res- pirable par- ticulate mat- ter)	1 mg/m3 (Aluminium)	ACGIH
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

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

Hygiene measures

: Work uniform or laboratory coat.

: If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing place.



# Phthalylsulfathiazole / Sulfamerazine Formulation

Version Rev 2.1 30.0

Revision Date: 30.09.2023

SDS Number: 5939808-00008

Date of last issue: 04.04.2023 Date of first issue: 26.05.2020

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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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, han-

dling 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



## Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 5939808-00008 Date of first issue: 26.05.2020

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.

Molecular weight No data available

Particle size No data available

## 10. STABILITY AND REACTIVITY

Not classified as a reactivity hazard. Reactivity 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.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents 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

Remarks: Based on data from similar materials

Acute inhalation toxicity LC50 (Rat): > 2.07 mg/l

Exposure time: 4 h



# Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 5939808-00008
 Date of first issue: 26.05.2020

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion 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

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 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

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

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



# Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 5939808-00008
 Date of first issue: 26.05.2020

Phthalylsulfathiazole:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Aluminum hydroxide:

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

Remarks : Based on data from similar materials

Phthalylsulfathiazole:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

**Aluminum hydroxide:** 

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



# Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 5939808-00008 Date of first issue: 26.05.2020

#### 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 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



# Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 5939808-00008
 Date of first issue: 26.05.2020

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.

#### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### **Components:**

Kaolin:

Toxicity to fish (Chronic tox- : NOELR (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

icity) Exposure time: 30 d



# Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: 30.09.2023

SDS Number: 5939808-00008

Date of last issue: 04.04.2023 Date of first issue: 26.05.2020

Phthalylsulfathiazole:

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

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

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-

octanol/water

log Pow: 0.728

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.



# Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 5939808-00008 Date of first issue: 26.05.2020

Dispose of in accordance with local regulations.

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

**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** 

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

Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

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



# Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 2.1
 30.09.2023
 5939808-00008
 Date of first issue: 26.05.2020

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials)

Regulations

Not applicable

: Not applicable

## 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 Agen-

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health (General Provisions)

Regulations - First Schedule Permissible Exposure Limits of

Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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



# Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.1 30.09.2023 5939808-00008 Date of first issue: 26.05.2020

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

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.

SG / EN