

Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Phthalylsulfathiazole / Sulfamerazine Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

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	>= 60 -<= 100



Phthalylsulfathiazole / Sulfamerazine Formulation

Version **Revision Date:** SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

Phthalylsulfathiazole	85-73-4	>= 10 -< 30
Aluminum hydroxide	21645-51-2	>= 10 -< 30
Sulfamerazine	127-79-7	< 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

the skin.

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

Contact with dust can cause mechanical irritation or drying of

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

SO.



Phthalylsulfathiazole / Sulfamerazine Formulation

Version 2.1

Revision Date: 2023/09/30

SDS Number: 5939802-00008 Date of last issue: 2023/04/04 Date of first issue: 2020/05/26

Evacuate area.

Special protective equipment

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive 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.

Keep in properly labelled containers. Conditions for safe storage

Store in accordance with the particular national regulations.



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

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	NAB (Respirable)	2 mg/m3	ID OEL		
	enough data to	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals				
		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	NAB (Respirable particulate matter)	1 mg/m3 (Aluminium)	ID OEL		
	enough data to	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals				
		TWA (Respirable particulate matter)	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



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

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.

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



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

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.

Molecular weight : No data available

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous 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 : Oxidizing agents

Hazardous decomposition : No haz

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

Eye contact

6/15



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Nu 2.1 2023/09/30 5939802

SDS Number: Date of la 5939802-00008 Date of fi

Date of last issue: 2023/04/04 Date of first issue: 2020/05/26

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 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



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

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:

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.



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

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



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

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.



Phthalylsulfathiazole / Sulfamerazine Formulation

Version 2.1

Revision Date: 2023/09/30

SDS Number: 5939802-00008

Date of last issue: 2023/04/04 Date of first issue: 2020/05/26

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Kaolin:

Toxicity to fish (Chronic tox-

icity)

: NOELR (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 30 d

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-

on coemcient.

: log Pow: -2

octanol/water
Sulfamerazine:

Partition coefficient: n-

octanol/water

log Pow: 0.728



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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

UN number Not applicable Proper shipping name Not applicable Not applicable Class Not applicable Subsidiary risk 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.



Phthalylsulfathiazole / Sulfamerazine Formulation

Version 2.1

Revision Date: 2023/09/30

SDS Number: 5939802-00008

Date of last issue: 2023/04/04 Date of first issue: 2020/05/26

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and :

control, Annex I

Not applicable

Type of hazardous materials subject to distribution and : Not applicable

control. Annex II

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 : 2023/09/30

Further information

Sources of key data used to compile the Safety Data

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/



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 2.1 2023/09/30 5939802-00008 Date of first issue: 2020/05/26

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

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

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.



Phthalylsulfathiazole / Sulfamerazine Formulation

Version 2.1

Revision Date: 2023/09/30

SDS Number: 5939802-00008

Date of last issue: 2023/04/04 Date of first issue: 2020/05/26

ID / EN