

Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 28.09.2024 5939805-00008 Date of first issue: 26.05.2020

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Phthalylsulfathiazole / Sulfamerazine Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 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

SECTION 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.

Other hazards

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Kaolin	1332-58-7	>= 70 -< 90	
Phthalylsulfathiazole	85-73-4	>= 10 -< 20	
Aluminum hydroxide	21645-51-2	>= 10 -< 20	
Sulfamerazine	127-79-7	>= 5 -< 10	

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.



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 28.09.2024 5939805-00008 Date of first issue: 26.05.2020 2.2

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 eves can lead to mechanical irritation. No special precautions are necessary for first aid responders.

Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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)

Sulfur oxides Metal 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

Evacuate area.

Special protective equipment

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec: : tive equipment and emer-

gency 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.



Phthalylsulfathiazole / Sulfamerazine Formulation

Date of last issue: 30.09.2023 Version **Revision Date:** SDS Number: 28.09.2024 5939805-00008 Date of first issue: 26.05.2020 2.2

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. Use only with adequate ventilation.

Local/Total 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.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

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.

Conditions for safe storage Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Do not store with the following product types: Materials to avoid

Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters



Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 2.2
 28.09.2024
 5939805-00008
 Date of first issue: 26.05.2020

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Kaolin	1332-58-7	VLE-PPT (Respirable fraction)	2 mg/m³	NOM-010- STPS-2014
		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	VLE-PPT (Respirable fraction)	1 mg/m³ (Aluminum)	NOM-010- STPS-2014
		TWA (Respirable particulate matter)	1 mg/m³ (Aluminum)	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

exposure assessment demonstrates exposures outside the

recommended 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : fine powder

Color : White to light yellow

Odor : characteristic

Odor Threshold : No data available



Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 2.2
 28.09.2024
 5939805-00008
 Date of first issue: 26.05.2020

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

Vapor pressure : Not applicable

Relative vapor 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

Autoignition 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 characteristics

Particle size : No data available



Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 2.2
 28.09.2024
 5939805-00008
 Date of first issue: 26.05.2020

SECTION 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,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 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

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



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 28.09.2024 5939805-00008 Date of first issue: 26.05.2020

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

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

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



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 28.09.2024 5939805-00008 Date of first issue: 26.05.2020

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Aluminum hydroxide:

Test Type : Maximization Test
Routes of exposure : 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.



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 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 2.2
 28.09.2024
 5939805-00008
 Date of first issue: 26.05.2020

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 fetal development : Test Type: Embryo-fetal 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



Phthalylsulfathiazole / Sulfamerazine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 28.09.2024 5939805-00008 Date of first issue: 26.05.2020

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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



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 Version
 Revision Date:
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 Date of last issue: 30.09.2023

 2.2
 28.09.2024
 5939805-00008
 Date of first issue: 26.05.2020

Other adverse effects

No data available

SECTION 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

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

Not applicable

producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined



Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 2.2
 28.09.2024
 5939805-00008
 Date of first issue: 26.05.2020

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

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

Sources of key data used to compile the Material Safety

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

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



Phthalylsulfathiazole / Sulfamerazine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 2.2
 28.09.2024
 5939805-00008
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