SAFETY DATA SHEET

Phthalylsulfathiazole / Sulfamerazine Formulation

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SECTION 1. IDENTIFICATION

Product name : Phthalylsulfathiazole / Sulfamerazine Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

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

Not a hazardous substance or mixture.

Additional Labeling

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.

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.
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 (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 products	:	Carbon oxides Nitrogen oxides (NOx) Sulfur 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 fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec-	:	Follow safe handling advice (see section 7) and personal

tive equipment and emergency procedures : 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.

Conditions for safe storage : Keep in properly labeled 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

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis

Kaolin	1332-58-7	CMP (Respirable fraction)	2 mg/m³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		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 (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 : 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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : fine powder

Color	:	White to light yellow
Odor	:	characteristic
Odor 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
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 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

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 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

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

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

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

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:

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 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 synthesis 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 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

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

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-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.

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.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

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

SECTION 16. OTHER INFORMATION

Further information

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
AR OEL / CMP	:	TLV (Threshold Limit Value)

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 Recom-

mendations 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.

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