Sulfamethoxazole / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	28.09.2024	6289825-00013	Date of first issue: 25.08.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfamethoxazole / Trimethoprim Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Sub-category 1A

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements :
H303 May be harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P203 Obtain, read and follow all safety instructions before use.
P260 Do not breathe mist or vapours.
P264 Wash hands thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P330 + P331 + P316 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get emergency medical help immediately.
P302 + P361 + P354 + P316 IF ON SKIN: Take off immediately all contaminated clothing. Immediately rinse with water for several minutes. Get emergency medical help immediately.
P304 + P340 + P316 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get emergency medical help immediately.
P305 + P354 + P338 + P316 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get emergency medical help immediately.
P318 IF exposed or concerned, get medical advice.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Corrosive to the respiratory tract.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sulfamethoxazole	723-46-6	>= 30 - < 50
Trimethoprim	738-70-5	>= 5 - < 10
Sodium hydroxide	1310-73-2	>= 5 - < 10

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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
If swallowed	:	If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	May be harmful if swallowed. Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Causes severe burns. Causes digestive tract burns. Corrosive to respiratory system.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	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	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NOx) Sulphur oxides Metal 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	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. 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. Prevent spreading over a wide area (e.g. by containment or oil barriers). 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	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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.

7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing.

Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Explosives

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sulfamethoxazole	723-46-6	TWA	OEB 2 (>= 100 < 1000 µg/m3)	Internal
Trimethoprim	738-70-5	TWA	400 µg/m3 (OEB 2)	Internal
Sodium hydroxide	1310-73-2	CEIL	2 mg/m3	IN OEL
		C	2 mg/m3	ACGIH

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	9.5 - 12.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1.179 g/cm³

Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	Not applicable

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents Acids
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

May be harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 3,531 mg/kg
Method: Calculation method

Components:

Sulfamethoxazole:

Acute oral toxicity : LD50 (Mouse): 2,300 mg/kg

Trimethoprim:

Acute oral toxicity	:	LD50 (Rat): 1,500 - 5,300 mg/kg LD50 (Mouse): 1,910 - 7,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 400 - 500 mg/kg Application Route: Intraperitoneal LD50 (Dog): 90 mg/kg Application Route: Intravenous LD50 (Mouse): 132 mg/kg Application Route: Intravenous

Sodium hydroxide:

Acute inhalation toxicity	:	Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation

Causes severe burns.

Components:

Sulfamethoxazole:

Species	:	Rabbit
Result	:	No skin irritation

Sodium hydroxide:

Result	:	Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Sodium hydroxide:

Result	:	Irreversible effects on the eye
Remarks	:	Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Sulfamethoxazole:

Test Type	:	Magnusson-Kligman-Test
Exposure routes	:	Skin contact
Species	:	Guinea pig

Result	:	negative

Trimethoprim:

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

Sodium hydroxide:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Sulfamethoxazole:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Humans Result: negative

Trimethoprim:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosomal aberration Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Rat Result: negative Test Type: Chromosomal aberration Species: Humans Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Sulfamethoxazole:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	26 weeks
Result	:	negative

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Trimethoprim:

Effects on fertility	:	Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 70 mg/kg body weight Result: No effects on fertility
Effects on foetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 70 mg/kg body weight Result: Effects on newborn Remarks: Maternal toxicity observed. Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 70 mg/kg body weight Result: Embryotoxic effects. Remarks: Maternal toxicity observed. Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 15 mg/kg body weight Result: Embryotoxic effects., Teratogenic effects Test Type: Development Species: Hamster Application Route: Oral Developmental Toxicity: LOAEL: 1.7 mg/kg body weight Result: Embryotoxic effects., No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects., No teratogenic effects

Reproductive toxicity - Assessment	:	Suspected of damaging the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Bone marrow) through prolonged or repeated exposure.

Components:

Trimethoprim:

Target Organs	:	Bone marrow
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Trimethoprim:

Species	:	Rat
NOAEL	:	100 mg/kg
LOAEL	:	300 mg/kg
Application Route	:	Oral
Exposure time	:	6 Months
Target Organs	:	Bone marrow, Liver, Pituitary gland, Thyroid

Species	:	Rat
LOAEL	:	300 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Target Organs	:	Bone marrow

Species	:	Dog
NOAEL	:	2.5 mg/kg
LOAEL	:	45 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Target Organs	:	Blood, Thyroid

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Trimethoprim:

Ingestion	:	Target Organs: Bone marrow Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Sulfamethoxazole:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 562.5 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0268 mg/l Exposure time: 96 h NOEC (Synechococcus leopoliensis (blue-green algae)): 0.0059 mg/l Exposure time: 96 h
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to microorganisms	:	NOEC (activated sludge): 3.76 mg/l Method: OECD Test Guideline 301D
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.533 mg/l Exposure time: 21 d Species: Danio rerio (zebra fish)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0.01 mg/l Exposure time: 30 d Species: Daphnia magna (Water flea)
M-Factor (Chronic aquatic toxicity)	:	10

Trimethoprim:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna Straus): 92 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l Exposure time: 72 h NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l Exposure time: 72 h

		EC50 (Anabaena flos-aquae): 253 mg/l Exposure time: 72 h EC10 (Anabaena flos-aquae): 26 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC10: 16.7 mg/l Exposure time: 3 hrs Test Type: Respiration inhibition Method: OECD Test Guideline 209 EC50: > 1,000 mg/l Exposure time: 3 hrs Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.157 mg/l Exposure time: 21 d Species: Zebrafish
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 6 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

Persistence and degradability

Components:

Sulfamethoxazole:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: OECD Test Guideline 301D

Trimethoprim:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 4 % Exposure time: 28 d Method: OECD Test Guideline 301D Result: Not inherently biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: OECD Test Guideline 302B

Bioaccumulative potential

Components:

Sulfamethoxazole:

Bioaccumulation	:	Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): < 120

Partition coefficient: n-octanol/water	:	log Pow: 0.89

Trimethoprim:

Partition coefficient: n-octanol/water	:	log Pow: 0.91

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 1824
Proper shipping name	:	SODIUM HYDROXIDE SOLUTION
Class	:	8
Packing group	:	II
Labels	:	8
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	UN 1824
Proper shipping name	:	Sodium hydroxide solution
Class	:	8
Packing group	:	II
Labels	:	Corrosive
Packing instruction (cargo aircraft)	:	855
Packing instruction (passenger aircraft)	:	851

IMDG-Code

UN number	:	UN 1824
Proper shipping name	:	SODIUM HYDROXIDE SOLUTION (Sulfamethoxazole)
Class	:	8
Packing group	:	II
Labels	:	8
EmS Code	:	F-A, S-B

Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

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

DSL : not determined

AICS : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 28.09.2024

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/

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
IN OEL : India. Permissible levels of certain chemical substances in work environment.

ACGIH / C : Ceiling limit
IN OEL / CEIL : ceiling 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.

IN / EN