according to GB/T 16483 and GB/T 17519



# Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	1681358-00021	Date of first issue: 2017/05/17

### **1. PRODUCT AND COMPANY IDENTIFICATION**

Product name	:	Sulfadoxine / Trimethoprim Formulation		
Manufacturer or supplier's de Company	etai :	i <b>ls</b> MSD		
Address	:	No. 485 Jing Tai Road Pu Tuo District - Shanghai - China 200331		
Telephone	:	+1-908-740-4000		
Emergency telephone number	:	86-571-87268110		
E-mail address	:	EHSDATASTEWARD@msd.com		
Recommended use of the chemical and restrictions on use				
Recommended use Restrictions on use	:	Veterinary product Not applicable		

### 2. HAZARDS IDENTIFICATION

#### **Emergency Overview**

Appearance Colour Odour	:	liquid light brown, yellow No data available			
, ,	Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.				
GHS Classification Serious eye damage/eye irri- tation	:	Category 1			
Reproductive toxicity	:	Category 2			
Specific target organ toxicity - repeated exposure	:	Category 2			
Short-term (acute) aquatic hazard	:	Category 2			
Long-term (chronic) aquatic hazard	:	Category 2			

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	<b>bel elements</b> pictograms		
Signal	word	: Danger	✓ ✓
Hazard	statements	H361d Suspec H373 May cau peated exposi	serious eye damage. cted of damaging the unborn child. use damage to organs through prolonged or re- ure. aquatic life with long lasting effects.
Frecau	tionary statements	P202 Do not h and understoc P260 Do not b P273 Avoid re	preathe mist or vapours. lease to the environment. otective gloves/ protective clothing/ eye protec
		water for seve and easy to do CENTER/ doc	IF exposed or concerned: Get medical advice/
		<b>Storage:</b> P405 Store loo	cked up.
		Disposal:	of contents/ container to an approved waste

Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

#### **Environmental hazards**

Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

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#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

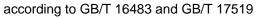
Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7	>= 30 -< 50
1,3-Dioxolan-4-ylmethanol	5464-28-8	>= 30 -< 50
Sulfadoxine	2447-57-6	>= 10 -< 20
Trimethoprim	738-70-5	>= 3 -< 10
Sodium hydroxide	1310-73-2	>= 2 -< 3

### 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately.
If inhaled In case of skin contact	:	When symptoms persist or in all cases of doubt seek medical advice. If inhaled, remove to fresh air. Get medical attention.
in case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. 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.
If swallowed	:	Get medical attention immediately. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
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	:	None known.



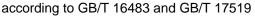


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me	dia			
	ecific hazards during fire- tting	:	Exposure to comb	pustion products may be a hazard to health.
Ha: uct	zardous combustion prod- s	:	Carbon oxides Metal oxides	
Spe ods	ecific extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	ecial protective equipment firefighters	:		e, wear self-contained breathing apparatus. ective equipment.
6. ACCI	DENTAL RELEASE MEA	SUF	RES	
tive	rsonal precautions, protec- e equipment and emer- ncy procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
Env	vironmental precautions	:	Prevent spreading barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages
-	thods and materials for tainment and cleaning up	:	For large spills, pu ment to keep mat be pumped, store Clean up remainin bent. Local or national u posal of this mate employed in the c mine which regula Sections 13 and 1	a absorbent material. Tovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. In materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements.

## 7. HANDLING AND STORAGE

### Handling





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Technical measures			: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.				
	Total ventilation e on safe handling	<ul> <li>Use only with adequate</li> <li>Do not breathe mist of Do not swallow.</li> <li>Do not get in eyes.</li> <li>Avoid prolonged or rep Wash skin thoroughly Handle in accordance practice, based on the sessment</li> <li>Keep container tightly Do not eat, drink or small</li> </ul>		st or vapours. r repeated contact with skin. ghly after handling. nce with good industrial hygiene and safety the results of the workplace exposure as-			
Avoida	ance of contact		kidizing agents bids				
Stora	ge						
	tions for safe storage	St Ke St	ore locked up. eep tightly close ore in accordan	ce with the particular national regulations.			
Mater	ials to avoid		o not store with rong oxidizing a	the following product types: agents			
Packa	aging material	: Ur	nsuitable materi	al: None known.			

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Sulfadoxine	2447-57-6	TWA	30 µg/m3 (OEB 3)	Internal
		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal
Trimethoprim	738-70-5	TWA	400 µg/m3 (OEB 2)	Internal
Sodium hydroxide	1310-73-2	MAC	2 mg/m3	CN OEL
		С	2 mg/m3	ACGIH

Engineering measures

 Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con-

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tainment devices). Minimize open handling.

Personal protective equipme	ent	
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
Eye/face 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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hand protection		C C
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Hygiene measures	:	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	:	liquid
Colour	:	light brown, yellow
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	9.3 - 10.0
Melting point/freezing point	:	Not applicable
Initial boiling point and boiling	:	No data available

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	range				
	Flash p	point		No data available	
		ation rate		No data available	
			•		5
		ability (solid, gas)	:	Not applicable	
	Flamm	ability (liquids)	•	No data available	
		explosion limit / Upper bility limit	:	No data available	9
		explosion limit / Lower bility limit	:	No data available	9
	Vapour	pressure	:	No data available	)
	Relativ	e vapour density	:	No data available	9
	Relativ	e density	:	No data available	9
	Density	/	:	1.210 - 1.250 g/c	m <sup>3</sup>
	Solubili Wat	ity(ies) er solubility	:	No data available	9
		n coefficient: n-	:	No data available	9
	octanol Auto-ig	/water nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	)
	Explosi	ve properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	Not applicable	
	Particle Particle	e characteristics e size	:	Not applicable	

## **10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.



according to GB/T 16483 and GB/T 17519

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Incom	itions to avoid apatible materials rdous decomposition cts	:	None known. Oxidizing agents Acids No hazardous de	ecomposition products are known.
1. TOXIC	OLOGICAL INFORMAT	101	1	
Expos	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity			
	assified based on availa	ble	information.	
Produ Acute	oral toxicity	:	Acute toxicity esti Method: Calculati	mate: > 5,000 mg/kg on method
Comp	oonents:			
	ioxan-5-ol:			
Acute	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
Acute	dermal toxicity	:	LD50 (Rat): > 2,0 Remarks: Based	00 mg/kg on data from similar materials
1,3-D	ioxolan-4-ylmethanol:			
Acute	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
Acute	dermal toxicity	:	LD50 (Rat): > 2,0 Remarks: Based	00 mg/kg on data from similar materials
Sulfa	doxine:			
Acute	oral toxicity	:	LD50 (Mouse): 5,	200 mg/kg
II Trime	ethoprim:			
	oral toxicity	:	LD50 (Rat): 1,500	) - 5,300 mg/kg
			LD50 (Mouse): 1,	910 - 7,000 mg/kg
	toxicity (other routes of histration)	:	LD50 (Rat): 400 - Application Route	
			LD50 (Dog): 90 m Application Route	

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			LD50 (Mouse): 1 Application Route	
Sod	ium hydroxide:			
	te inhalation toxicity	:	Assessment: Cor	rosive to the respiratory tract.
_	n corrosion/irritation classified based on avai	lable	information.	
Pro	duct:			
Res		:	No skin irritation	
<u>Con</u>	nponents:			
	Dioxan-5-ol:			
Spe		:	Rabbit	
Met Res		:	OECD Test Guid No skin irritation	eline 404
	narks	:		om similar materials
1,3-	Dioxolan-4-ylmethanol	:		
Spe	cies	:	Rabbit	
Met	hod	:	OECD Test Guid	eline 404
Res		:	No skin irritation	
Ren	harks	:	Based on data fro	om similar materials
	adoxine:			
Spe	cies	:	Rabbit	
Met Res	nod	:	OECD Test Guid irritating	eline 404
I Kes		•	Innating	
	ium hydroxide:			
Res	ult	:	Corrosive after 3	minutes or less of exposure
Seri	ous eye damage/eye ir	ritati	on	
	ses serious eye damage			
<u>Con</u>	nponents:			
1,3-	Dioxan-5-ol:			
Spe	cies	:	Rabbit	
Res		:	Irritation to eyes,	reversing within 21 days
Met		:	OECD Test Guid	eline 405
Rem	narks	:	Based on data fro	om similar materials

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### 1,3-Dioxolan-4-ylmethanol:

Species Result Method Remarks	:	Rabbit Irritation to eyes, reversing within 21 days OECD Test Guideline 405 Based on data from similar materials
Sulfadoxine:		

Result
Result
rtooun

: irritating

### 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:**

#### 1,3-Dioxan-5-ol:

:	Maximisation Test
:	Skin contact
:	Guinea pig
:	OECD Test Guideline 406
:	negative
:	Based on data from similar materials
	:

# 1,3-Dioxolan-4-ylmethanol:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Test Type Exposure routes Species Method Result Remarks	: Based on data from similar materials

#### Trimethoprim:

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

### Sodium hydroxide:

Test	Туре

: Human repeat insult patch test (HRIPT)

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ersion 0	Revision Date: 2024/09/28	SDS Numbe 1681358-00	
Expos Resul	sure routes t	: Skin cor : negative	
	cell mutagenicity assified based on ava	ailable information	on.
<u>Comp</u>	oonents:		
1,3-Di	ioxan-5-ol:		
Geno	toxicity in vitro	: Test Typ Result: r	be: Bacterial reverse mutation assay (AMES) negative
		Test Typ Result: r	pe: In vitro mammalian cell gene mutation test negative
Geno	toxicity in vivo	cytogen Species Result: r	
1,3-Di	ioxolan-4-ylmethano	ol:	
Geno	toxicity in vitro	: Test Typ Result: r	be: Bacterial reverse mutation assay (AMES) negative
		Test Typ Result: r	pe: In vitro mammalian cell gene mutation test negative
Geno	toxicity in vivo		
Trime	ethoprim:		
Geno	toxicity in vitro	: Test Typ Result: r	be: Bacterial reverse mutation assay (AMES) negative
		Test Typ Result: r	be: Chromosomal aberration negative
		Test Typ Result: r	pe: In vitro mammalian cell gene mutation test negative
			be: DNA damage and repair, unscheduled DNA syn- mammalian cells (in vitro) negative
Geno	toxicity in vivo	: Test Typ Species Result: r	

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Not c	<b>inogenicity</b> lassified based on avai	lable	Species: Human Result: negative	
-	oductive toxicity ected of damaging the	unbo	rn child.	
Com	ponents:			
	ethoprim:			
Effec	ts on fertility	:	Test Type: Ferti Species: Rat Application Rou Fertility: NOAEL Result: No effect	te: Oral .: 70 mg/kg body weight
Effec ment	ts on foetal develop-	:	Result: Effects	te: Oral Toxicity: LOAEL: 70 mg/kg body weight
			Result: Embryo	te: Oral Toxicity: LOAEL: 70 mg/kg body weight
				er

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Repro		: Suspected of damaging the unborn child.	
	<b>- single exposure</b> lassified based on ava	able information	
	ponents:		
Sulfa Asses	doxine: ssment	: May cause respiratory irritation.	
May o	F - repeated exposure cause damage to orga conents:	s through prolonged or repeated exposure.	
Trime Targe	ethoprim: et Organs ssment	<ul> <li>Bone marrow</li> <li>Causes damage to organs through prolonged or reexposure.</li> </ul>	speate
-	ated dose toxicity ponents:		
Trime Speci NOAE LOAE Applie Expos	ethoprim: es	: Rat : 100 mg/kg : 300 mg/kg : Oral : 6 Months : Bone marrow, Liver, Pituitary gland, Thyroid	
Expo		: Rat : 300 mg/kg : Oral : 3 Months : Bone marrow	
Expo	ΞL	<ul> <li>Dog</li> <li>2.5 mg/kg</li> <li>45 mg/kg</li> <li>Oral</li> <li>3 Months</li> <li>Blood, Thyroid</li> </ul>	

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### Experience with human exposure

## Components:

## Sulfadoxine:

Ingestion	:	Target Organs: Blood Symptoms: The most common side effects are:, Nausea, Vomiting, Headache, anemia, Rash, Stevens-Johnson syn- drome
Trimethoprim:		
Ingestion	:	Target Organs: Bone marrow Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

#### **12. ECOLOGICAL INFORMATION**

## Ecotoxicity

### Components:

#### 1,3-Dioxan-5-ol:

1,5-DIOXall-5-01.		
Toxicity to fish	:	LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
		Exposure time: 72 h Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials
1,3-Dioxolan-4-ylmethanol:		

ije Diekelan i Jimemanen		
Toxicity to fish	:	LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
	:	EL50 (Daphnia magna (Water flea)): > 100 mg/l

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aquat	ic invertebrates		Exposure time: 48 Remarks: Based	3 h on data from similar materials	
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 72	hneriella subcapitata (green algae)): > 10 2 h on data from similar materials	
			mg/l Exposure time: 72	tirchneriella subcapitata (green algae)): > 2 h on data from similar materials	
Toxici	ty to microorganisms	:	EC10: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials		
Sulfa	doxine:				
Toxici	ty to fish	:	Exposure time: 96	s promelas (fathead minnow)): > 100 mg/l S h on data from similar materials	
	ty to daphnia and other ic invertebrates	:	Exposure time: 48	agna (Water flea)): > 100 mg/l 3 h on data from similar materials	
Toxici plants	ty to algae/aquatic	:	Exposure time: 72 Method: OECD T		
			Exposure time: 72 Method: OECD T		
			mg/l Exposure time: 72 Method: OECD T		
			mg/l Exposure time: 72 Method: OECD T		
			EC50 (Microcystis Exposure time: 7	s aeruginosa (blue-green algae)): 0.135 m d	

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icity) Toxicit aquati ic toxic M-Fac toxicity	tor (Chronic aquatic	: :	1 NOEC (Daphnia Exposure time: 2 Remarks: Based 1 EC50: > 1,000 m Exposure time: 3 Test Type: Respi Remarks: Based NOEC: 1,000 mg Exposure time: 3 Test Type: Respi	on data from similar materials magna (Water flea)): 6.2 mg/l 1 d on data from similar materials g/l h ration inhibition on data from similar materials /l
	<b>thoprim:</b> ty to fish	:	LC50 (Pimephale Exposure time: 9	s promelas (fathead minnow)): 100 mg/l 5 h
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia n Exposure time: 4	
Toxicit plants	ty to algae/aquatic	:	mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 16
			Exposure time: 7	
			EC10 (Anabaena Exposure time: 7	flos-aquae): 26 mg/l 2 h
Toxicit icity)	ty to fish (Chronic tox-	:	NOEC (Zebrafish Exposure time: 2	
aquati ic toxic	c invertebrates (Chron-	:	NOEC (Daphnia Exposure time: 2 EC10: 16.7 mg/l Exposure time: 3 Test Type: Respi	hrs

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П			Method: OECD T	est Guideline 209
			EC50: > 1,000 m Exposure time: 3 Test Type: Respi Method: OECD T	hrs
Persis	stence and degradabi	lity		
<u>Comp</u>	onents:			
1,3-Di	oxan-5-ol:			
Biode	gradability	:	Result: Inherently Remarks: Based	v biodegradable. on data from similar materials
1,3-Di	oxolan-4-ylmethanol:			
Biode	gradability	:	,	v biodegradable. on data from similar materials
Sulfac	doxine:			
Biode	gradability	:	Biodegradation: Exposure time: 2	5 %
Trime	thoprim:			
	gradability	:	Result: Not readil Biodegradation: Exposure time: 2 Method: OECD T	4 %
			Biodegradation: Exposure time: 2	
Bioac	cumulative potential			
Comp	onents:			
1,3-Di	oxan-5-ol:			
	on coefficient: n-	:	log Pow: -0.65	
	<b>thoprim:</b> on coefficient: n- ol/water	:	log Pow: 0.91	

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	i <b>lity in soil</b> ata available		
	<b>r adverse effects</b> ata available		
13. DISPO	DSAL CONSIDERATION	IS	
Wast	osal methods e from residues aminated packaging	Dispose of in : Empty contai dling site for	se of waste into sewer. accordance with local regulations. ners should be taken to an approved waste han- recycling or disposal.
14 TD AN			se specified: Dispose of as unused product.
14. IRAN	SPORT INFORMATION		
Inter	national Regulations		
	<b>TDG</b> umber er shipping name	N.O.S.	ENTALLY HAZARDOUS SUBSTANCE, LIQUID,
Labe	ing group	: 9 : III : 9 : yes	, Trimethoprim)
UN/II	- <b>DGR</b> D No. er shipping name		ally hazardous substance, liquid, n.o.s. , Trimethoprim)
Labe	ing group Is ing instruction (cargo	: 9 : III : Miscellaneou : 964	S
Pack ger a	ing instruction (passen- ircraft)	: 964	
<b>IMDC</b> UN n	onmentally hazardous <b>3-Code</b> umber er shipping name	: yes : UN 3082 : ENVIRONME N.O.S.	ENTALLY HAZARDOUS SUBSTANCE, LIQUID,
Labe EmS	ing group	(Sulfadoxine, 9 III 9 F-A, S-F yes	Trimethoprim)

according to GB/T 16483 and GB/T 17519



# Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
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### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

GB 6944/12268	
UN number :	UN 3082
Proper shipping name :	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
	N.O.S.
	(Sulfadoxine, Trimethoprim)
Class : Packing group : Labels :	9
Packing group :	III
Labels :	9
Marine pollutant :	no

#### 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

## National regulatory information

Law on the Prevention and Control of Occupational Diseases

#### **Regulations on Safety Management of Hazardous Chemicals**

Regulations on Salety Management of Hazardous C	inclineals
Catalogue of Hazardous Chemicals	: This product is not listed in the cata- logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de- termination.
Identification of Major Hazard Installations for Hazardou 18218)	is Chemicals (GB : Not listed
Hazardous Chemicals for Priority Management under SAWS	: Not listed
Regulations on Labour Protection in Workplaces wi	here Toxic Substances are Used
Catalogue of Highly Toxic Chemicals	: Not listed
Regulation of Environmental Management on the Fi and Export of Toxic Chemicals	rst Import of Chemicals and the Import
China Severely Restricted Toxic Chemicals for Import and Export	: Not listed
Regulation on the Administration of Precursor Cher	nicals
Catalogue and Classification of Productor Chamicals	· Not listed

Catalogue and Classification of Precursor Chemicals : Not listed

according to GB/T 16483 and GB/T 17519



# Sulfadoxine / Trimethoprim Formulation

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#### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

#### 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	:	2024/09/28
Further information		
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

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

Date format	:	yyyy/mm/dd	
Full text of other abbreviations			
ACGIH CN OEL	:	USA. ACGIH Threshold Limit Values (TLV) Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.	
ACGIH / C CN OEL / MAC	:	Ceiling limit Maximum allowable concentration	

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



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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

#### Disclaimer

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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