

## Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	1681366-00018	Date of first issue: 17.05.2017

#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

: Sulfadoxine / Trimethoprim Formulation Product name

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				
Decommended use of the		cial and realizations on use				

#### Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS	Classification
-----	----------------

Serious eye damage/eye irritation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure	:	Category 1 (Bone marrow)

#### **GHS** label elements

Hazard pictograms :	
Signal Word :	Danger
Hazard Statements :	H318 Causes serious eye damage. H361d Suspected of damaging the unborn child. H372 Causes damage to organs (Bone marrow) through pro- longed or repeated exposure.
Precautionary Statements :	<ul> <li>Prevention:</li> <li>P201 Obtain special instructions before use.</li> <li>P202 Do not handle until all safety precautions have been read and understood.</li> <li>P260 Do not breathe mist or vapors.</li> <li>P264 Wash skin thoroughly after handling.</li> <li>P270 Do not eat, drink or smoke when using this product.</li> <li>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</li> </ul>
	<b>Response:</b> P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with



>= 1 -< 5

>= 2 -< 3

# Sulfadoxine / Trimethoprim Formulation

Version 5.1	Revision Date: 30.09.2023	SDS Number: 1681366-00018		ssue: 04.04.2023 ssue: 17.05.2017			
		and easy to de CENTER or d	o. Continue rinsing octor/ physician.	ove contact lenses, if present g. Immediately call a POISON cerned: Get medical advice/			
		<b>Storage:</b> P405 Store lo	cked up.				
		<b>Disposal:</b> P501 Dispose posal plant.	P501 Dispose of contents/ container to an approved waste dis-				
Othe	r hazards						
None	e known.						
SECTION	3. COMPOSITION/IN	FORMATION ON IN	GREDIENTS				
Subs	tance / Mixture	: Mixture					
Com	ponents						
Cher	nical name		CAS-No.	Concentration (% w/w)			
1,3-D	)ioxan-5-ol		4740-78-7	>= 30 -< 50			
1,3-D	ioxolan-4-ylmethanol		5464-28-8	>= 30 -< 50			
Sulfa	doxine		2447-57-6	>= 10 -< 20			

#### **SECTION 4. FIRST AID MEASURES**

Trimethoprim

Sodium hydroxide

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.
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. Get medical attention immediately.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	

738-70-5

1310-73-2



Versio 5.1	on	Revision Date: 30.09.2023	-	9S Number: 81366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017	
Ρ	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).		
N	Notes to physician		:	Treat symptomatically and supportively.		
SECT	ION 5.	FIRE-FIGHTING MEA	ASU	IRES		
S	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical		
	Insuita nedia	ble extinguishing	:	None known.		
	Specific hazards during fire fighting		:	Exposure to comb	oustion products may be a hazard to health.	
H		ous combustion prod-	:	Carbon oxides Metal oxides		
	pecific ds	extinguishing meth-	:	<ul> <li>Use extinguishing measures that are appropriate to local cumstances and the surrounding environment.</li> <li>Use water spray to cool unopened containers.</li> <li>Remove undamaged containers from fire area if it is safe so.</li> <li>Evacuate area.</li> </ul>		
	•	protective equipment ighters	t : In the event of fire, wear self-contained breathing apparatus Use personal protective equipment.			
SECT	SECTION 6. ACCIDENTAL RELE			EMEASURES		
tiv	ve equ	al precautions, protec- ipment and emer- rrocedures	:	Follow safe handl	ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).	

Environmental precautions	<ul> <li>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.</li> </ul>
Methods and materials for containment and cleaning up	<ul> <li>Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.</li> <li>Clean up remaining materials from spill with suitable absorbent.</li> <li>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.</li> <li>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</li> </ul>



# Sulfadoxine / Trimethoprim Formulation

Version 5.1	Revision Date: 30.09.2023	SDS Number: 1681366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017						
SECTION									
SECTION	SECTION 7. HANDLING AND STORAGE								
Tech	nnical measures		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.						
Loca	al/Total ventilation	: Use only with	adequate ventilation.						
Local/Total ventilation Advice on safe handling		Do not swalk Do not get in Avoid prolon Wash skin th Handle in ac practice, bas assessment Keep contair Do not eat, d Take care to	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						
Hygi	ene measures	<ul> <li>environment.</li> <li>If exposure to chemical is likely during typical use, provide flushing systems and safety showers close to the working place.</li> <li>When using do not eat, drink or smoke.</li> <li>Wash contaminated clothing before re-use.</li> <li>The effective operation of a facility should include review engineering controls, proper personal protective equipme appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and th use of administrative controls.</li> </ul>							
Con	ditions for safe storage								
Mate	erials to avoid	<ul> <li>Do not store with the following product types:</li> <li>Strong oxidizing agents</li> <li>Self-reactive substances and mixtures</li> <li>Organic peroxides</li> <li>Explosives</li> <li>Gases</li> </ul>							

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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	VLE-P	2 mg/m <sup>3</sup>	NOM-010- STPS-2014
		С	2 mg/m <sup>3</sup>	ACGIH



# Sulfadoxine / Trimethoprim Formulation

Version 5.1	Revision Date: 30.09.2023		issue: 04.04.2023 issue: 17.05.2017	
Engi	neering measures	<ul> <li>Use appropriate engineering controls and manufacturin technologies to control airborne concentrations (e.g., dr less quick connections).</li> <li>All engineering controls should be implemented by facil design and operated in accordance with GMP principles protect products, workers, and the environment.</li> <li>Containment technologies suitable for controlling comp- are required to control at source and to prevent migratio the compound to uncontrolled areas (e.g., open-face containment devices).</li> <li>Minimize open handling.</li> </ul>		
Pers	onal protective equipr	nt		
Fi	iratory protection Iter type I protection	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type		
М	aterial	Chemical-resistant gloves		
	emarks protection	<ul> <li>Consider double gloving.</li> <li>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</li> </ul>		
Skin	and body protection	aerosols. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.		

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	light brown, yellow
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	9.3 - 10.0
Melting point/freezing point	:	Not applicable
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available



# Sulfadoxine / Trimethoprim Formulation

Ver 5.1	sion	Revision Date: 30.09.2023	-	S Number: 1366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	
	Relative	e vapor density	:	No data available	
	Relative	e density	:	No data available	
	Density		:	1.210 - 1.250 g/c	M <sup>3</sup>
	Solubilit Wate	ty(ies) er solubility	:	No data available	
		n coefficient: n-	:	No data available	
	octanol/ Autoign	ition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosit Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
	Molecul	lar weight	:	Not applicable	
	Particle	size	:	Not applicable	

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac-	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
tions		5 5 5
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents Acids
Hazardous decomposition products	:	No hazardous decomposition products are known.



Version 5.1	Revision Date: 30.09.2023		OS Number: 81366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017
SECTION	11. TOXICOLOGICAL I	NF	ORMATION	
Inhal Skin Inges	contact	of	exposure	
	<b>e toxicity</b> classified based on availa	ble	information.	
Prod Acute	<u>uct:</u> e oral toxicity	:	Acute toxicity e Method: Calcul	stimate: > 5,000 mg/kg ation method
<u>Com</u>	ponents:			
	<b>Dioxan-5-ol:</b> e oral toxicity	:	LD50 (Rat): > 5	5,000 mg/kg
Acute	e dermal toxicity	:	LD50 (Rat): > 2 Remarks: Base	2,000 mg/kg ed on data from similar materials
1,3-D	)ioxolan-4-ylmethanol:			
Acute	e oral toxicity	:	LD50 (Rat): > 5	5,000 mg/kg
Acute	e dermal toxicity	:	LD50 (Rat): > 2 Remarks: Base	2,000 mg/kg ed on data from similar materials
Sulfa	idoxine:			
Acute	e oral toxicity	:	LD50 (Mouse):	5,200 mg/kg
Trim	ethoprim:			
Acute	e oral toxicity	:	LD50 (Rat): 1,5	600 - 5,300 mg/kg
			LD50 (Mouse):	1,910 - 7,000 mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Rat): 40 Application Rot	0 - 500 mg/kg ute: Intraperitoneal
			LD50 (Dog): 90 Application Ro	) mg/kg ute: Intravenous
			LD50 (Mouse): Application Ro	132 mg/kg ute: Intravenous
	um hydroxide:		A	
Acute	e inhalation toxicity	:	Assessment: C	orrosive to the respiratory tract.



Skin corrosion/irritation								
Not classified based on avail	Not classified based on available information.							
Product:								
Result	: No skin irritation							
Components:								
1,3-Dioxan-5-ol:								
Species	: Rabbit							
Method	: OECD Test Guid	Jeline 404						
Result	: No skin irritation							
Remarks	: Based on data fr	om similar materials						
1,3-Dioxolan-4-ylmethanol:								
Species	: Rabbit							
Method	: OECD Test Guid	Jeline 404						
Result	: No skin irritation							
Remarks	: Based on data from similar materials							
Sulfadoxine:								
Species	: Rabbit							
Method	: OECD Test Guid	deline 404						
Result	: irritating							
Sodium hydroxide:								
Result	: Corrosive after 3	B minutes or less of exposure						
Serious eye damage/eye ir	ritation							
Causes serious eye damage								
Components:								
1,3-Dioxan-5-ol:								
Species	: Rabbit							
Result	: Irritation to eyes,	, reversing within 21 days						
Method	: OECD Test Guid	deline 405						
Remarks	: Based on data fr	om similar materials						
1,3-Dioxolan-4-ylmethanol:								
Species	: Rabbit							
Result		, reversing within 21 days						
Method	: OECD Test Guid							
Remarks	: Based on data fr	rom similar materials						
Sulfadoxine:								
Result	: irritating							
	, and a second sec							



Sodium hydroxide:ResultRemarksRespiratory or skin sensitizatSkin sensitizationNot classified based on availalRespiratory sensitizationNot classified based on availalComponents:1,3-Dioxan-5-ol:Test TypeRoutes of exposureSpeciesMethodResultRemarks1,3-Dioxolan-4-ylmethanol:Test TypeRoutes of exposureSpeciesMethodResultRemarksTest TypeRoutes of exposureSpeciesMethodResultRemarksTimethoprim:Test TypeRoutes of exposureSpeciesMethodResultRemarksTimethoprim:Test TypeRoutes of exposureSpeciesResultTest TypeRoutes of exposureSpeciesResultTest TypeRoutes of exposureSpeciesResultTest TypeRoutes of exposureSpeciesResultSodium hydroxide:Test Type	: Base tion ble inform ble inform : Max : Skin : OEC : nega : Base : Max : Skin : Guir : OEC : nega	ation. mization Test contact ea pig D Test Guideline 406 tive d on data from similar materials mization Test contact ea pig D Test Guideline 406	
Skin sensitization         Not classified based on available         Respiratory sensitization         Not classified based on available         Components:         1,3-Dioxan-5-ol:         Test Type         Routes of exposure         Species         Method         Result         Remarks         1,3-Dioxolan-4-ylmethanol:         Test Type         Routes of exposure         Species         Method         Result         Remarks         1,3-Dioxolan-4-ylmethanol:         Test Type         Routes of exposure         Species         Method         Result         Remarks         Trimethoprim:         Test Type         Routes of exposure         Species         Method         Result         Remarks         Trimethoprim:         Test Type         Routes of exposure         Species         Result         Sodium hydroxide:         Test Type	ole inforr ole inforr : Max : Skin : Guir : DEC : nega : Baso : Max : Skin : Guir : OEC : nega	ation. mization Test contact ea pig D Test Guideline 406 tive d on data from similar materials mization Test contact ea pig D Test Guideline 406 tive	
Not classified based on availableRespiratory sensitizationNot classified based on availableComponents:1,3-Dioxan-5-ol:Test TypeRoutes of exposureSpeciesMethodResultRemarks1,3-Dioxolan-4-ylmethanol:Test TypeRoutes of exposureSpeciesMethodResultRemarks1,3-Dioxolan-4-ylmethanol:Test TypeRoutes of exposureSpeciesMethodResultRemarksTrimethoprim:Test TypeRoutes of exposureSpeciesResultTest TypeRoutes of exposureSpeciesResultTest TypeRoutes of exposureSpeciesResultSodium hydroxide:Test Type	<ul> <li>Image: Max</li> <li>Max</li> <li>Skin</li> <li>Guir</li> <li>Base</li> <li>Kin</li> <li>Guir</li> <li>OEC</li> <li>nega</li> </ul>	ation. mization Test contact ea pig D Test Guideline 406 tive d on data from similar materials mization Test contact ea pig D Test Guideline 406 tive	
Not classified based on available Components: 1,3-Dioxan-5-ol: Test Type Routes of exposure Species Method Result Remarks 1,3-Dioxolan-4-ylmethanol: Test Type Routes of exposure Species Method Result Remarks Trimethoprim: Test Type Routes of exposure Species Result Remarks Crimethoprim: Test Type Routes of exposure Species Result Test Type Routes of exposure Species Result Test Type Routes of exposure Species Result Test Type Routes of exposure Species Result	: Max : Skin : Guir : OEC : nega : Baso : Max : Skin : Guir : OEC : nega	nization Test contact ea pig D Test Guideline 406 tive d on data from similar materials nization Test contact ea pig D Test Guideline 406 tive	
Components:1,3-Dioxan-5-ol:Test TypeRoutes of exposureSpeciesMethodResultRemarks1,3-Dioxolan-4-ylmethanol:Test TypeRoutes of exposureSpeciesMethodResultResultRemarksTrimethoprim:Test TypeRoutes of exposureSpeciesMethodResultRemarksTrimethoprim:Test TypeRoutes of exposureSpeciesResultTest TypeRoutes of exposureSpeciesResultTest TypeRoutes of exposureSpeciesResultSodium hydroxide:Test Type	: Max : Skin : Guir : OEC : nega : Baso : Max : Skin : Guir : OEC : nega	nization Test contact ea pig D Test Guideline 406 tive d on data from similar materials nization Test contact ea pig D Test Guideline 406 tive	
<ul> <li><b>1,3-Dioxan-5-ol:</b> <ul> <li>Test Type</li> <li>Routes of exposure</li> <li>Species</li> <li>Method</li> <li>Result</li> <li>Remarks</li> </ul> </li> <li><b>1,3-Dioxolan-4-ylmethanol:</b> <ul> <li>Test Type</li> <li>Routes of exposure</li> <li>Species</li> <li>Method</li> <li>Result</li> <li>Remarks</li> </ul> </li> <li><b>Trimethoprim:</b> <ul> <li>Test Type</li> <li>Routes of exposure</li> <li>Species</li> <li>Rethod</li> <li>Result</li> <li>Remarks</li> </ul> </li> <li><b>Sodium hydroxide:</b> <ul> <li>Test Type</li> </ul> </li> </ul>	: Skin : Guir : OEC : nega : Base : Base : Max : Skin : Guir : OEC : nega	contact ea pig D Test Guideline 406 tive d on data from similar materials nization Test contact ea pig D Test Guideline 406 tive	
Test Type Routes of exposure Species Method Result Remarks <b>1,3-Dioxolan-4-ylmethanol:</b> Test Type Routes of exposure Species Method Result Remarks <b>Trimethoprim:</b> Test Type Routes of exposure Species Result <b>Sodium hydroxide:</b> Test Type	: Skin : Guir : OEC : nega : Base : Base : Max : Skin : Guir : OEC : nega	contact ea pig D Test Guideline 406 tive d on data from similar materials nization Test contact ea pig D Test Guideline 406 tive	
Test Type Routes of exposure Species Method Result Remarks <b>Trimethoprim:</b> Test Type Routes of exposure Species Result <b>Sodium hydroxide:</b> Test Type	: Skin : Guir : OEC : nega	contact ea pig D Test Guideline 406 tive	
Test Type Routes of exposure Species Result <b>Sodium hydroxide:</b> Test Type			
Test Type	: Derr : Guir	nization Test al ea pig skin sensitizer.	
Routes of exposure Result		an repeat insult patch test (HRIPT contact tive	)
Germ cell mutagenicity Not classified based on availal	la inform	ation	
Components:		auun.	
1,3-Dioxan-5-ol:			
Genotoxicity in vitro		Type: Bacterial reverse mutation a It: negative	assay (AMES)
		Type: In vitro mammalian cell gen lt: negative	e mutation tes
		9 / 18	



/ersion 5.1	Revision Date: 30.09.2023	SDS Number:Date of last issue1681366-00018Date of first issue	
Geno	toxicity in vivo	: Test Type: Mammalian erythrocyte cytogenetic assay) Species: Mouse Result: negative Remarks: Based on data from simi	
	ioxolan-4-ylmethand toxicity in vitro	: Test Type: Bacterial reverse mutat Result: negative Test Type: In vitro mammalian cell	
Geno	toxicity in vivo	Result: negative Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Result: negative	
	ethoprim: toxicity in vitro	: Test Type: Bacterial reverse mutat Result: negative	ion assay (AMES)
		Test Type: Chromosomal aberratic Result: negative Test Type: In vitro mammalian cell Result: negative	
		Test Type: DNA damage and repa thesis in mammalian cells (in vitro) Result: negative	ir, unscheduled DNA syn-
Geno	toxicity in vivo	: Test Type: Micronucleus test Species: Rat Result: negative	
		Test Type: Chromosomal aberratic Species: Humans Result: negative	n
	nogenicity lassified based on ava	ble information.	
-	oductive toxicity ected of damaging the	nborn child.	
<u>Com</u>	oonents:		
	ethoprim: is on fertility	: Test Type: Fertility Species: Rat Application Route: Oral	



Versi 5.1	ion	Revision Date: 30.09.2023		9S Number: 81366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017
				Fertility: NOAEL: <sup>*</sup> Result: No effects	70 mg/kg body weight on fertility.
	Effects	on fetal development	:	Result: Effects on	: Oral oxicity: LOAEL: 70 mg/kg body weight
				Result: Embryotox	: Oral pxicity: LOAEL: 70 mg/kg body weight
				•	
	Reprod sessme		:	Suspected of dam	naging the unborn child.
		single exposure ssified based on availa	ble	information.	
	Compo	onents:			
	Sulfade Assess		:	May cause respira	atory irritation.
		epeated exposure damage to organs (Be	one	marrow) through p	rolonged or repeated exposure.
	Compo	onents:			
		n <b>oprim:</b> Organs ment	:	Bone marrow Causes damage t exposure.	o organs through prolonged or repeated



Version 5.1	Revision Date: 30.09.2023	SDS Number: 1681366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017
	peated dose toxicity		
Co	mponents:		
	methoprim:		
NO LO Apr Exr	ecies AEL AEL Dication Route Dosure time get Organs	: Rat : 100 mg/kg : 300 mg/kg : Oral : 6 Months : Bone marrow, L	iver, Pituitary gland, Thyroid
LÖ Apr Exr	ecies AEL Dication Route Dosure time get Organs	: Rat : 300 mg/kg : Oral : 3 Months : Bone marrow	
NO LO Apr Exr	ecies AEL AEL Dication Route Dosure time get Organs	: Dog : 2.5 mg/kg : 45 mg/kg : Oral : 3 Months : Blood, Thyroid	
Asi	piration toxicity		
	classified based on ava	ilable information.	
Ex	perience with human ex	xposure	
Co	mponents:		
Sul	fadoxine:		
Ing	estion		Blood most common side effects are:, Nausea, ache, anemia, Rash, Stevens-Johnson syn-
Tri	methoprim:		
Ing	estion		Bone marrow ominal pain, Nausea, Vomiting, skin rash, lache, mental depression, confusion
SECTIO	N 12. ECOLOGICAL IN	FORMATION	
Eco	otoxicity		
<u>Co</u>	mponents:		

1,3-Dioxan-5-ol:

Toxicity to fish	: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
	Exposure time: 96 h
	Remarks: Based on data from similar materials



Vers 5.1	sion	Revision Date: 30.09.2023		9S Number: 81366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017
		/ to daphnia and other invertebrates	:	EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials	
	Toxicity plants	∕ to algae/aquatic	:	mg/l Exposure time: 72	hneriella subcapitata (green algae)): > 100 : h on data from similar materials
				mg/l Exposure time: 72	irchneriella subcapitata (green algae)): > 1 h on data from similar materials
	Toxicity	/ to microorganisms	:	EC10: > 1,000 mg Exposure time: 3 l Method: OECD Te Remarks: Based o	า
	<b>1,3-Dic</b> Toxicity	<b>xolan-4-ylmethanol:</b> / to fish	:	Exposure time: 96	s promelas (fathead minnow)): > 100 mg/l 5 h on data from similar materials
		to daphnia and other invertebrates	:	Exposure time: 48	agna (Water flea)): > 100 mg/l h on data from similar materials
	Toxicity plants	/ to algae/aquatic	:	mg/l Exposure time: 72	hneriella subcapitata (green algae)): > 100 : h on data from similar materials
				mg/l Exposure time: 72	irchneriella subcapitata (green algae)): > 1 : h on data from similar materials
	Toxicity	/ to microorganisms	:	EC10: > 1,000 mg Exposure time: 3 l Method: OECD Te Remarks: Based o	n
	Sulfad	oxine <sup>.</sup>			
	Toxicity		:	Exposure time: 96	s promelas (fathead minnow)): > 100 mg/l i h on data from similar materials
		<i>r</i> to daphnia and other invertebrates	:	Exposure time: 48	agna (Water flea)): > 100 mg/l h on data from similar materials
	Toxicity	/ to algae/aquatic	:	EC50 (Anabaena	flos-aquae (cyanobacterium)): 17 mg/l



Version 5.1	Revision Date: 30.09.2023		9S Number: 81366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017
plant	plants		Exposure time: 72 Method: OECD To Remarks: Based of	
			Exposure time: 72 Method: OECD Te	
			EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials	
			mg/l Exposure time: 72 Method: OECD To	
			Exposure time: 7 Method: ISO 8692	
	city to daphnia and other tic invertebrates (Chron- cicity)	:	Exposure time: 21	nagna (Water flea)): 6.2 mg/l l d on data from similar materials
Toxid	Toxicity to microorganisms		EC50: > 1,000 mg Exposure time: 3 Test Type: Respir Remarks: Based of	h
			NOEC: 1,000 mg/ Exposure time: 3 Test Type: Respir Remarks: Based of	h
Trim	ethoprim:			
	sity to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): 100 mg/l S h
	city to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna Straus (Water flea)): 92 mg/l 3 h
Toxic plant	city to algae/aquatic s	:	EC50 (Pseudokiro mg/l Exposure time: 72	chneriella subcapitata (microalgae)): 80.3 2 h
			NOEC (Pseudokir mg/l Exposure time: 72	rchneriella subcapitata (green algae)): 16 2 h



Version 5.1	Revision Date: 30.09.2023		DS Number: 81366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017
			EC50 (Anabaena Exposure time: 72	flos-aquae): 253 mg/l 2 h
			EC10 (Anabaena Exposure time: 72	flos-aquae): 26 mg/l 2 h
Toxicit icity)	ty to fish (Chronic tox-	:	NOEC (Zebrafish Exposure time: 2 <sup>-</sup>	
	ty to daphnia and other c invertebrates (Chron-	:	NOEC (Daphnia i Exposure time: 2 <sup>-</sup>	magna (Water flea)): 6 mg/l 1 d
	y to microorganisms	:	Exposure time: 3 Test Type: Respire	
			EC50: > 1,000 m Exposure time: 3 Test Type: Respir Method: OECD T	hrs
Persis	stence and degradabili	ity		
<u>Comp</u>	onents:			
-	<b>oxan-5-ol:</b> gradability	:	Result: Inherently Remarks: Based	v biodegradable. on data from similar materials
	<b>oxolan-4-ylmethanol:</b> gradability	:	Result: Inherently Remarks: Based	v biodegradable. on data from similar materials
	<b>loxine:</b> gradability	:	Result: Not readil Biodegradation: Exposure time: 28 Remarks: Based	5%
	<b>thoprim:</b> gradability	:	Result: Not readil Biodegradation: Exposure time: 28 Method: OECD T	4 %
			Biodegradation: Exposure time: 28	



# Sulfadoxine / Trimethoprim Formulation

Version 5.1	Revision Date: 30.09.2023	SDS Number: 1681366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017	
Bioa	ccumulative potentia	al		
Com	ponents:			
1,3-D	oioxan-5-ol:			
	ion coefficient: n- nol/water	: log Pow: -0.65		
Trime	ethoprim:			
	ion coefficient: n- nol/water	: log Pow: 0.91		
Mobi	lity in soil			
No da	ata available			
Othe	r adverse effects			
No da	ata available			

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 w	aste
	handling site for recycling or disposal.	
	If not otherwise specified: Dispose of as unused pro-	duct.

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

<b>UNRTDG</b> UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Sulfadoxine, Trimethoprim)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3082
Proper shipping name	÷	Environmentally hazardous substance, liquid, n.o.s.
1 11 3		(Sulfadoxine, Trimethoprim)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passen- ger aircraft)	:	964
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3082



Version 5.1	Revision Date: 30.09.2023	-	DS Number: 81366-00018	Date of last issue: 04.04.2023 Date of first issue: 17.05.2017		
Prope	Proper shipping name		ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Sulfadoxine, Trimethoprim)			
Label EmS	ng group s	:	9 III 9 F-A, S-F yes			
	Transport in bulk according Not applicable for product as s			OL 73/78 and the IBC Code		
Dome	estic regulation					
UN ni	002-SCT umber er shipping name	:	UN 3082 ENVIRONMENT/ N.O.S. (Sulfadoxine, Tri	ALLY HAZARDOUS SUBSTANCE, LIQUID,		
Class Packi Label	ng group	::	9 III 9	neurophin)		
-	ial precautions for us					
				r informational purposes only, and solely ial as it is described within this Safety Data		

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.

#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for 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

#### **SECTION 16. OTHER INFORMATION**

Revision Date Date format		30.09.2023 dd.mm.yyyy
Full text of other abbreviat	ions	
ACGIH NOM-010-STPS-2014		USA. ACGIH Threshold Limit Values (TLV) Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con-



#### Sulfadoxine / Trimethoprim Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	1681366-00018	Date of first issue: 17.05.2017

ACGIH / C : Ceiling limit NOM-010-STPS-2014 / VLE- : Ceiling value P

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 Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8